61–63. RADIOACTIVE MATERIALS (TITLE A).

(Statutory Authority: § 13–7–40 et seq., as amended, of the 1976 Code, namely the Atomic Energy and Radiation Control Act)

Editor's Note

Unless noted otherwise, the following constitutes the history for 61–63, 1.1 through 11.29.

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Table of Contents

PART I General Provisions

RHA	
1.1	Scope
1.2	Definitions
1.3	Units of Radiation Dose
1.4	Units of Radioactivity
1.5	Records
1.6	Inspections
1.7	Tests and Surveys
1.8	Impounding
1.9	Exemptions from Licensing
1.10	Exemptions from Requirements of these Regulations
1.11	Additional Requirements
1.12	Violations
1.13	Communications
1.14	Annual Fees
1.15	Financial Assurances and Recordkeeping for Decommissioning
1.16	Schedule A
1.17	[Appendix A] Criteria Relating to Use of Financial Tests and Parent Company Guarantees for Providing Reasonable Assurance of Funds for Decommissioning
1.18	[Appendix B] Criteria Relating to Use of Financial Tests and Self Guarantees for Providing Reasonable Assurance of Funds for Decommissioning

PART II Licensing of Radioactive Materials

RHA	
2.1	Purpose and Scope
2.2	Types of Licenses
2.3	General Licenses—Source Material
2.4	General Licenses—Radioactive Material Other Than Source Material
2.5	Filing of Application for Specific Licenses
2.6	General Requirements for the Issuance of Specific Licenses
2.7	Special Requirements for Issuance of Certain Specific Licenses for Radioactive Materials
2.8	Special Requirements for Specific License of Broad Scope
2.9	Issuance of Specific Licenses
2.10	Specific Terms and Conditions of Licenses

2.11 Expiration and Termination of Licenses and Decommissioning of Sites and Separate Buildings or Outdoor Areas
2.12 Renewal of Specific Licenses
2.13 Amendment of Licenses at Request of Licensee
2.14 Department Action on Applications to Renew or Amend
2.15 Inalienability of Licenses
2.16 Persons Possessing a License for Source, Byproduct, or Special Nuclear Material in Quantities not Sufficient to Form a Critical Mass on Effective Date of These Regulations
2.17 Persons Possessing Radioactive Material Other Than Agreement Material on Effective Date of These Regulations
2.18 Transfer of Material
2.19 Modification, Revocation, and Termination of Licenses
2.20 Exemptions
2.21 Reciprocal Recognition of Licenses
2.22 Transportation of Radioactive Materials
2.23 Schedule A. Generally Licensed Equipment when Manufactured in Accordance with the Specifications Contained in a Specific License
2.24 Schedule B. Exempt Quantities
2.25 Schedule C. Exempt Concentrations
2.26 Schedule D. Groups of Medical Uses of Radioactive Material
2.27 Requirements for License to Manufacture and Distribute Industrial Products Containing Depleted Uranium for Mass-Volume Applications
2.28 Requirements for Specific License to Manufacture, Assemble, Repair, or Distribute Commodities, Products, or Devices which Contain Naturally Occurring or Accelerator-Produced Radioactive Material (NARM)
2.29 Registration of Sealed Sources and Devices Containing Sealed Sources
2.30 Emergency Plan for Large Quantity Users
2.31 Schedule E. Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release
2.32 Reporting Requirements

PART III Standards for Protection Against Radiation

RHA
3.1 Purpose and Scope
3.2 Definitions
3.3 Units of Radiation Dose
3.4 Radiation Protection Programs
3.5 Occupational Dose Limits for Adults
3.6 Compliance with Requirements for Summation of External and Internal Doses
3.7 Determination of External Dose From Airborne Radioactive Material
3.8 Determination of Internal Exposure
3.9 [Reserved]
3.10 Planned Special Exposures
3.11 Occupational Dose Limits for Minors
3.12 Dose to an Embryo/Fetus
3.13 Dose Limits for Individual Members of the Public.
3.14 Compliance with Dose Limits for Individual Members of the Public
3.15 [Reserved]
3.16 Surveys and Monitoring
3.17 Conditions Requiring Individual Monitoring of External and Internal Occupational Dose
3.18 Control of Exposure from External Sources in Restricted Areas
3.19 Respiratory Protection and Controls to Restrict Internal Exposure in Restricted Areas
3.20 Storage and Control of Licensed Material
3.21 Caution Signs
3.22 Posting Requirements
3.23 Exceptions to Posting Requirements
3.24 Labeling Containers
3.25 Exemptions to Labeling Requirements

3.26 Procedures for Receiving and Opening Packages
3.27 Waste Disposal —General Requirements
3.28 Method for Obtaining Approval of Proposed Disposal Procedures
3.29 Disposal by Release into Sanitary Sewerage
3.30 Treatment or Disposal by Incineration
3.31 Disposal of Specific Wastes
3.32 Transfer for Disposal and Manifests
3.33 Compliance with Environmental and Health Protection Regulations
3.34 Records—General Provisions
3.35 Records of Radiation Protection Programs
3.36 Records of Surveys
3.37 Determination of Prior Occupational Dose
3.38 Records of Planned Special Exposures
3.39 Records of Individual Monitoring Results
3.40 Records of Dose to Individual Members of the Public
3.41 Records of Waste Disposal
3.42 Vacating Premises
3.43 Form of Records
3.44 Reports of Theft or Loss of Licensed Material
3.45 Notification of Incidents
3.46 Reports of Exposures, Radiation Levels, and Concentrations of Radioactive Material Exceeding the Limits
3.47 Reports of Planned Special Exposures
3.48 Reports to Individuals of Exceeding Dose Limits
3.49 Reports of Individual Monitoring
3.50 Application for Exemptions
3.51 Additional Requirements
3.52 [Appendix A] Protection Factors for Respirators
3.53 [Appendix B] Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage
3.54 [Appendix C] Quantities of Licensed Material Requiring Labeling
3.55 [Appendix D] Requirements for Low-Level-Waste Transfer for Disposal at Land Disposal Facilities and Manifests
3.56 [Appendix E] Classifications and Characteristics of Low-Level Radioactive Waste
3.57 [Appendix F] Radiological Criteria for License Termination

PART IV Use of Radionuclides in the Health Professions

SUBPART A General Information

RHA
4.1 Purpose and Scope
4.2 Definitions
4.3 Maintenance of Records
4.4 Provisions for the Protection of Human Research Subjects
4.5 FDA, Other Federal, and State Requirements
4.6 License Required
4.7 Application for License, Amendment, or Renewal
4.8 License Amendments
4.9 Notifications
4.10 Exemptions Regarding "Type A" Specific Licenses of Broad Scope
4.11 License Issuance
4.12 Specific Exemptions

SUBPART B General Administrative Requirements

RHA
4.13 Authority and Responsibilities for the Radiation Protection Program
4.14 Radiation Protection Program Changes
4.15 Supervision
4.16 [Reserved]

4.17 Written Directives
4.18 Procedures for Administrations Requiring a Written Directive
4.19 Suppliers for Sealed Sources or Devices for Medical Use
4.20 Training for Radiation Safety Officers and Associate Radiation Safety Officer
4.21 Training for an Authorized Medical Physicist
4.22 Training for an Authorized Nuclear Pharmacist
4.23 Training for Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized Medical Physicist, Authorized User, Nuclear Pharmacist, and Authorized Nuclear Pharmacist
4.24 Recentness of Training

SUBPART C General Technical Requirements

RHA
4.25 Possession, Use, and Calibration of Instruments Used to Measure the Activity of Unsealed Radioactive Material
4.26 Calibration of Survey Instruments
4.27 Determination of Dosages of Unsealed Radioactive Material for Medical Use
4.28 Authorization for Calibration, Transmission, and Reference Sources
4.29 Requirements for Possession of Sealed Sources and Brachytherapy Sources
4.30 Labeling of Vials and Syringes
4.31 Surveys of Ambient Radiation Exposure Rate
4.32 Release of Individuals Containing Unsealed Radioactive Material or Implants Containing Radioactive Material
4.33 Provision of Mobile Medical Services
4.34 Decay-in-Storage

SUBPART D Unsealed Radioactive Material—Written Directive Not Required

RHA
4.35 Use of Unsealed Radioactive Material for Uptake, Dilution, and Excretion Studies for Which a Written Directive is not Required
4.36 Training for Uptake, Dilution, and Excretion Studies
4.37 Use of Unsealed Radioactive Material for Imaging and Localization Studies for Which a Written Directive is not Required
4.38 Permissible Molybdenum-99, Strontium-82, and Strontium-85 Concentrations
4.39 Training for Imaging and Localization Studies

SUBPART E Unsealed Radioactive Material—Written Directive Required

RHA
4.40 Use of Unsealed Radioactive Material for Which a Written Directive is Required
4.41 Safety Instruction
4.42 Safety Precautions
4.43 Training for Use of Unsealed Radioactive Material for Which a Written Directive is Required
4.44 Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities Less Than or Equal to 1.22 Gigabecquerels (33 Millicuries)
4.45 Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities Greater Than 1.22 Gigabecquerels (33 Millicuries)

SUBPART F Manual Brachytherapy

RHA
4.46 Use of Sources for Manual Brachytherapy
4.47 Surveys After Source Implant and Removal
4.48 Brachytherapy Sources Accountability
4.49 Safety Instruction

4.50 Safety Precautions
4.51 Calibration Measurements of Brachytherapy Sources
4.52 Strontium-90 Sources for Ophthalmic Treatments
4.53 Therapy-Related Computer Systems
4.54 Training for Use of Manual Brachytherapy Sources
4.55 Training for Ophthalmic Use of Strontium-90

SUBPART G Sealed Sources for Diagnosis

RHA
4.56 Use of Sealed Sources and Medical Devices for Diagnosis
4.57 Training for Use of Sealed Sources for Diagnosis

SUBPART H Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

RHA
4.58 Use of a Sealed Source in a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit
4.59 Surveys of Patients and Human Research Subjects Treated With a Remote Afterloader Unit
4.60 Installation, Maintenance, Adjustment, and Repair
4.61 Safety Procedures and Instructions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units
4.62 Safety Precautions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units
4.63 Dosimetry Equipment
4.64 Full Calibration Measurements on Teletherapy Units
4.65 Full Calibration Measurements on Remote Afterloader Units
4.66 Full Calibration Measurements on Gamma Stereotactic Radiosurgery Units
4.67 Periodic Spot-Checks for Teletherapy Units
4.68 Periodic Spot-Checks for Remote Afterloader Units
4.69 Periodic Spot-Checks for Gamma Stereotactic Radiosurgery Units
4.70 Additional Technical Requirements for Mobile Remote Afterloader Units
4.71 Radiation Surveys
4.72 Full-inspection Servicing for Teletherapy and Gamma Stereotactic Radiosurgery Units
4.73 Therapy-Related Computer Systems
4.74 Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

SUBPART J Training and Experience Requirements

RHA
4.75 Radiation Safety Officer
4.76 Training for Update, Dilution, and Excretion Studies
4.77 Training For Imaging and Localization Studies
4.78 Training For Therapeutic Use of Unsealed Radioactive Material
4.79 Training For Treatment of Hyperthyroidism
4.80 Training For Treatment of Thyroid Carcinoma
4.81 Training for Use of Brachytherapy Sources
4.82 Training for Ophthalmic Use of Strontium-90
4.83 Training for Use of Sealed Sources for Diagnosis
4.84 Training for Use of Therapeutic Medical Devices
4.85 Training for Authorized Medical Physicist
4.86 Training For an Authorized Nuclear Pharmacist
4.87 Training For Experienced Nuclear Pharmacists

SUBPART K Other Medical Uses of Radioactive Material or Radiation From Radioactive Material

RHA

4.88 Other Medical Uses of Radioactive Material or Radiation From Radioactive Material

SUBPART L Records

RHA
4.89 Records of Authority and Responsibilities for Radiation Protection Programs
4.90 Records of Radiation Protection Program Changes
4.91 Records of Written Directives
4.92 Records For Procedures For Administrations Requiring a Written Directive
4.93 Records of Calibrations of Instruments Used to Measure the Activity of Unsealed Radioactive Material
4.94 Records of Radiation Survey Instrument Calibrations
4.95 Records of Dosages of Unsealed Radioactive Material For Medical Use
4.96 Records of Leaks Tests and Inventory of sealed Sources and Brachytherapy Sources
4.97 Records of Surveys For Ambient Radiation Exposure Rate
4.98 Records of the Release of Individuals Containing Unsealed Radioactive Material or Implants Containing Radioactive Material
4.99 Records of Mobile Medical Services
4.100 Records of Decay-in-Storage
4.101 Records of Molybdenum-99 Concentrations
4.102 Records of Safety Instruction
4.103 Records of Surveys After Source Implant and Removal
4.104 Records of Brachytherapy Source Accountability
4.105 Records of Calibration Measurements of Brachytherapy Sources
4.106 Records of Decay of Strontium-90 Sources for Ophthalmic Treatments
4.107 Records of Installation, Maintenance, Adjustment, and Repair of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic and Radiosurgery Units
4.108 Records of Safety Procedures
4.109 Records of Dosimetry Equipment Used with Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units
4.110 Records of Teletherapy, Remote Afterloader, and Gamma Stereotactic Radiosurgery Full Calibrations
4.111 Records of Periodic Spot-Checks for Teletherapy Units
4.112 Records of Periodic Spot-Checks for Remote Afterloader Units
4.113 Records of Periodic Spot-Checks for Gamma Stereotactic Radiosurgery Units
4.114 Records of Additional Technical Requirements for Mobile Remote Afterloader Units
4.115 Records of Surveys of Therapeutic Treatment Units
4.116 Records of Full-inspection Servicing for Teletherapy and Gamma Stereotactic Radiosurgery Units

SUBPART M Reports

RHA
4.117 Report and Notification of a Medical Event
4.118 Report and Notification of a Dose to an Embryo/Fetus or a Nursing Child
4.119 Report of a Leaking Source
4.120 Report and Notification for an Eluate Exceeding Permissible Molybdenum-99, Strontium-82, and Strontium-85 Concentrations

PART V Special Requirements for Industrial Radiographic Operations

RHA
5.1 Purpose
5.2 Scope
5.3 Definitions
5.4 Issuance of Specific Licenses for use of Sealed Sources in Radiography

5.5 Limits on External Radiation Levels from Storage Containers and Source Changers
5.6 Performance and Locking Requirements for Radiography Equipment
5.7 Labeling, Storage, and Transportation
5.8 Radiation Survey Instruments
5.9 Leak Testing, Repair, Tagging, Opening, Modification and Replacement of Sealed Sources
5.10 Quarterly Inventory and Receipt/Transfer Records
5.11 Utilization Logs
5.12 Training
5.13 Operating and Emergency Procedures
5.14 Personnel Monitoring Control
5.15 Surveillance
5.16 Posting
5.17 Radiation Surveys and Survey Records
5.18 Supervision of Radiographer's Assistant
5.19 Inspection and Maintenance of Radiographic Exposure Devices, Transport and Storage Containers, Associated Equipment, Source Changers and Survey Instruments
5.20 Permanent Radiographic Installation
5.21 Conducting Industrial Radiographic Operations
5.22 Radiation Safety Officer for Industrial Radiography
5.23 Form of Records
5.24 Location of Documents and Records
5.25 Reporting Requirements
5.26 Appendix A. Radiographer Certification

PART VI Notices, Instructions, and Reports to Workers; Inspections

RHA
6.1 Purpose and Scope
6.2 Definitions
6.3 Posting of Notices to Workers
6.4 Instructions to Workers
6.5 Notification and Reports to Individuals
6.6 Presence of Representatives of Licensees and Workers During Inspections
6.7 Consultation with Workers During Inspections
6.8 Bequests by Workers for Inspections
6.9 Inspections not Warranted; Informal Review
6.10 Employee Protection
6.11 Discrimination Prohibited

PART VII Licensing Requirements for Land Disposal of Radioactive Waste

RHA
7.1 Purpose and Scope
7.2 Definitions
7.3 License Required
7.4 Content of Application
7.5 General Information
7.6 Specific Technical Information
7.7 Technical Analyses
7.8 Institutional Information
7.9 Financial Information
7.10 Requirements for Issuance of a License
7.11 Conditions of Licenses
7.12 Application for Renewal or Closure
7.13 Contents of Application for Site Closure and Stabilization
7.14 Postclosure Observation and Maintenance
7.15 Transfer of License
7.16 Termination of License
7.17 General Requirements
7.18 Protection of General Population from Releases of Radioactivity

7.19 Protection of Individuals from Inadvertent Intrusion
7.20 Protection of Individuals During Operations
7.21 Stability of the Disposal Site After Closure
7.22 Disposal Site Suitability Requirements for Land Disposal
7.23 Disposal Site Design for Near-Surface Disposal
7.24 Near-Surface Disposal Facility Operation and Disposal Site Closure
7.25 Environmental Monitoring
7.26 Alternative Requirements for Design and Operations
7.27 Institutional Requirements
7.28 Alternative Requirements for Waste Classification and Characteristics
7.29 Applicant Qualifications and Assurances
7.30 Funding for Disposal Site Closure and Stabilization
7.31 Financial Assurances for Institutional Controls
7.32 Maintenance of Records, Reports, and Transfers
7.33 Tests on Land Disposal Facilities
7.34 Department Inspections of Land Disposal Facilities

PART VIII Special Requirements for Well Logging Operations

RHA
8.1 Purpose
8.2 Scope
8.3 Definitions
8.4 Specific Licenses for Well Logging
8.5 Agreement with Well Owner or Operator
8.6 Labeling of Well Logging Device
8.7 Storage of Well Logging Devices
8.8 Transportation of Well Logging Devices
8.9 Radiation Survey Instruments
8.10 Leak Testing of Sealed Sources
8.11 Physical Inventory
8.12 Utilization Logs
8.13 Criteria for Sealed Source Design and Integrity
8.14 Inspection, Maintenance, and Opening of Source or Source Holder
8.15 Subsurface Tracer Studies
8.16 Radioactive Markers
8.17 Uranium Sinker Bars
8.18 Use of Sealed Sources in a Well Without Surface Casings
8.19 Training Requirements for Well Logging Personnel
8.20 Operating and Emergency Procedures
8.21 Personnel Monitoring
8.22 Radiation Surveys
8.23 Contamination Control
8.24 Surveillance of Operations
8.25 Documents and Records Required at Field Stations
8.26 Documents and Records Required at Temporary Jobsites
8.27 Notification of Incidents and Lost Sources; Abandonment Procedures for Irretrievable Sources

PART IX Licensing of Naturally Occurring Radioactive Material (NORM)

RHA
9.1 Purpose and Scope
9.2 Definitions
9.3 Exemptions
9.4 Radiation Survey Instruments
9.5 General License
9.6 Transfer of Waste for Disposal
9.7 Specific License

PART X Licensing Requirements for Interim Storage of Radioactive Waste

RHA

10.1 Purpose and Scope
10.2 Definitions
10.3 License Required
10.4 Content of Application
10.5 General Information
10.6 Specific Technical Information
10.7 Technical Analysis
10.8 Financial Information
10.9 Requirements for Issuance of a License
10.10 Conditions of Licenses
10.11 Application for renewal or termination
10.12 Contents of Application for Termination of the License
10.13 Protection of Individuals during operations
10.14 Environmental Monitoring
10.15 Applicant Qualifications and Assurances
10.16 Institutional Requirements
10.17 Maintenance of Records and Reports
10.18 Tests on Storage Facilities
10.19 Department Inspections of Storage Facilities

PART XI Licensing and Radiation Safety Requirements for Irradiators

RHA
11.1 Purpose and Scope
11.2 Definitions
11.3 Specific Licenses for Irradiators
11.4 [Reserved]
11.5 Applications for Exemptions
11.6 Request for Written Statements
11.7 Performance Criteria for Sealed Sources
11.8 Access Control
11.9 Shielding
11.10 Fire Protection
11.11 Radiation Monitors
11.12 Control of Source Movement
11.13 Irradiator Pools
11.14 Source Rack Protection
11.15 Power Failures
11.16 Design Requirements
11.17 Construction Monitoring and Acceptance Testing
11.18 Training
11.19 Operating and Emergency Procedures
11.20 Personnel Monitoring
11.21 Radiation Surveys
11.22 Detection of Leaking Sources
11.23 Inspection and Maintenance
11.24 Pool Water Purity
11.25 Attendance During Operation
11.26 Entering and Leaving the Radiation Room
11.27 Irradiation of Explosives or Flammable Materials
11.28 Records and Retention Records
11.29 Reports

PART I
General Provisions

RHA 1.1. Scope.

Except as otherwise specifically provided, these regulations apply to all persons who receive, possess, use, transfer or acquire any radioactive material; provided, however, that nothing in these regulations shall apply to any person to the extent such person is subject to regulation by the United States Nuclear Regulatory Commission. Nothing in Part III of these regulations shall be interpreted as

limiting the intentional exposure of patients to radiation for the purpose of diagnostic or therapy by persons licensed to practice one or more of the health professions within the authority granted to them by statute or regulation. These regulations shall become effective January 1, 1994.

RHA 1.2. Definitions.

As used in these regulations:

1.2.1 "Accelerator-produced material" means any material made radioactive by a particle accelerator.

1.2.2 "Act" means Act No. 223, Atomic Energy and Radiation Control Act enacted by the 1967 Session South Carolina Legislature. (Section 13-7-40 et. seq, 1976 S.C. Code of Law [as amended]).

1.2.3 "Agreement State" means any State with which the United States Nuclear Regulatory Commission has entered into an effective agreement under Section 274b. of the Atomic Energy Act of 1954, as amended (73 Stat. 689).

1.2.4 "Airborne radioactive material" means any radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors or gases.

1.2.5 "Airborne radioactivity area" means a room, enclosure, or area in which airborne radioactive materials, composed wholly or partly of licensed material, exist in concentrations—

i) In excess of the derived air concentrations (DACs) specified in Appendix B, RHA 3.53, or

ii) To such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6 percent of the annual limit on intake (ALI) or 12 DAC-hours.

1.2.6 "Byproduct material" means:

(1) Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material;

(2) The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition;

(3)(i) Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or

(ii) Any material that

(A) Has been made radioactive by use of a particle accelerator; and

(B) Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and

(4) Any discrete source of naturally occurring radioactive material, other than source material, that

(i) The Nuclear Regulatory Commission, (NRC) in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and

(ii) Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.

1.2.7 "Calendar quarter" means not less than 12 consecutive weeks nor more than 14 consecutive weeks. The first calendar quarter of each year shall begin in January; and subsequent calendar quarters shall be such that no day is included in more than one calendar quarter or omitted from inclusion within a calendar quarter. No licensee shall change the method observed by him of determining calendar quarters except at the beginning of a calendar year.

1.2.8 "Department" means the South Carolina Department of Health and Environmental Control.

1.2.9 "Depleted Uranium" means the source material uranium in which the isotope Uranium-235 is less than 0.711 weight percent of the total uranium present. Depleted uranium does not include special nuclear material.

1.2.10 "Discrete source" means a radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical, or research activities.

1.2.11 "Dosimetry processor" means an individual or an organization that processes and evaluates personnel monitoring equipment in order to determine the radiation dose delivered to the equipment.

1.2.12 "High Radiation Area" means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving a dose equivalent in excess of 0.1 rem (1 mSv) in 1 hour at 30 centimeters from the radiation source or 30 centimeters from any surface that the radiation penetrates.

1.2.13 "Human Use" means the intentional internal or external administration of radiation or radioactive material to any individual.

1.2.14 "Individual" means any human being.

1.2.15 "License" except where otherwise specified, means either a general license or specific license issued pursuant to these regulations as further defined in Part II of these regulations.

1.2.16 "Licensing State" means any State with regulations equivalent to the Suggested State Regulations for Control of Radiation.

1.2.17 "NARM" means any naturally occurring or accelerator produced radioactive material. It does not include byproduct, source, or special nuclear material.

1.2.18 "Natural radioactivity" means radioactivity of naturally occurring nuclides.

1.2.19 "Occupational dose" means exposure of an individual to radiation (i) in a restricted area; or (ii) in the course of employment in which the individual's duties involve exposure to radiation; provided that occupational dose shall not be deemed to include any exposure of an individual to radiation for the purpose of medical diagnosis or medical therapy of such individual.

1.2.20 "Particle accelerator" means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 megaelectron volt. For purposes of this definition, "accelerator" is an equivalent term.

1.2.21 "Person" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group agency, political subdivision of this State, any other state or political subdivision or agency thereof, and any legal successor, representative, agent or agency of the foregoing, other than United States Nuclear Regulatory Commission, and other than Federal Government Agencies licensed by the United States Nuclear Regulatory Commission.

1.2.22 "Personnel monitoring equipment" means devices designed to be carried or worn by an individual for the purpose of measuring the dose which an individual receives (e.g. film badges, film rings, pocket chambers, pocket dosimeters, thermoluminescent dosimeters, etc.).

1.2.23 "Pharmacist" means an individual licensed by the State of South Carolina to compound and dispense drugs, prescriptions and poisons.

1.2.24 "Physician" means an individual licensed by the State of South Carolina to dispense drugs in the practice of medicine.

1.2.25 "Principal activities" means activities authorized by the license which are essential to achieving the purpose(s) for which the license was issued or amended. Storage during which no licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.

1.2.26 "Radiation" means gamma rays, X-rays, alpha and beta particles, high-speed electrons, neutrons, and other nuclear particles; but not sound or radio waves, or visible, infrared, or ultraviolet light.

1.2.27 "Radiation Area" means any area, accessible to individuals, in which there exists ionizing radiation at such levels that the whole body could receive a dose equivalent in excess of 5 millirem in 1 hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates.

1.2.28 "Radiation safety officer" means any person directly responsible for protection against radiation.

1.2.29 "Radioactive material" means any material, solid, liquid, or gas, which emits radiation spontaneously.

1.2.30 "Research and development" means (i) theoretical analysis, exploration, or experimentation or (ii) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental purposes, including the experimental production and testing of models, devices, equipment, materials, and processes. "Research and development" as used in these regulations, does not include the internal or external administration of radiation or radioactive materials to human beings.

1.2.31 "Restricted area" means any area to which access is controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials. "Restricted area" shall not include any areas used for residential quarters, although a separate room or rooms in a residential building may be set apart as a restricted area.

1.2.32 "Sealed source" means radioactive material that is permanently bonded or fixed in a capsule or matrix designed to prevent release and dispersal of the radioactive material under the most severe conditions which are likely to be encountered in normal use and handling.

1.2.33 "Source material" means: (1) uranium or thorium, or any combination thereof, in any physical or chemical form or (2) ores that contain by weight one-twentieth of one percent (0.05 percent) or more of (i) uranium, (ii) thorium, or (iii) any combination thereof. Source material does not include special nuclear material.

1.2.34 "Source of radiation" means any radioactive material, or any device or equipment emitting or capable of producing radiation.

1.2.35 "Special nuclear material in quantities not sufficient to form a critical mass" means uranium enriched in the isotope U-235 in quantities not exceeding 350 grams of contained U-235; Uranium-233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams; or any combination of them in accordance with the following formula: for each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all of the kinds of special nuclear material in combination shall not exceed "1" (i.e., unity). For example, the following quantities in combination would not exceed the limitation and are within the formula, as follows:

$$[175 \text{ (grams contained U-235)}]/350 + [50(\text{grams U-233})]/200 + [50 \text{ (grams Pu)}]/200 = 1$$

1.2.36 "Storage container" means a device in which sealed sources are transported or stored.

1.2.37 "Survey" means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of sources of radiation. When appropriate, such evaluation includes a physical survey of the location of materials and/or equipment and measurements of levels of radiation or concentrations of radioactive material present.

1.2.38 "Unrefined and unprocessed ore" means ore in its natural form prior to any processing such as grinding, roasting, beneficiating, or refining. Processing does not include sieving or encapsulation of ore or preparation of samples for laboratory analysis.

1.2.39 "Unrestricted area" means any area access to which is not controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials, and any area used for residential quarters.

1.2.40 "These regulations" means Parts I, II, III, IV, V, VI, VII, VIII, IX, X, and XI of Regulation 61-63.

1.2.41 "Whole body" means the entire body, or a major portion thereof, or the head and trunk, or the active blood forming organs, or the lens of the eyes or the gonads. Whole body does not refer to the skin of the whole body.

1.2.42 Definitions of certain other words and phrases as used in these regulations are set forth in other sections.

HISTORY: Amended by State Register Volume 38, Issue No. 10, Doc. No. 4462, eff October 24, 2014.

RHA 1.3. Units of Radiation Dose.

1.3.1 "Dose" means the quantity of radiation absorbed, per unit of mass, by the body or by any portion of the body. When these regulations specify a dose during a period of time, the dose means the total quantity of radiation absorbed, per unit of mass, by the body or by any portion of the body during such period of time. Several different units of dose are in current use. Definitions of units as used in these regulations are set forth in the following paragraphs: 1.3.2 and 1.3.3.

1.3.2 The "rad" is a measure of the dose of any radiation to body tissues in terms of the energy absorbed per unit mass of the tissue. One rad is the dose corresponding to the absorption of 100 ergs per gram of tissue. (One millirad [mrad] = 0.001 rad.)

1.3.3 The "rem" is a measure of the dose of any radiation to body tissue in terms of its estimated biological effect relative to a dose of one roentgen (R) of x-rays. (One millirem [mrem] = 0.001 rem.) The relation of the rem to other dose units depends on the biological effect under consideration and upon the conditions of irradiation. For the purpose of these regulations, any of the following is considered to be equivalent to a dose of one rem:

1.3.3.1 A dose of 1 R due to x or gamma radiation;

1.3.3.2 A dose of 1 rad due to x, gamma, or beta radiation;

1.3.3.3 A dose of 0.1 rad due to neutrons or high energy protons;

1.3.3.4 A dose of 0.05 rad due to particles heavier than protons and with sufficient energy to reach the lens of the eye.

If it is more convenient to measure the neutron flux, or equivalent, than to determine the neutron dose in rads, as provided in sub-paragraph 1.3.3.3 of this paragraph, one rem of neutron radiation may, for the purposes of these regulations, be assumed to be equivalent to 14 million neutrons per square centimeter incident upon the body; of, if there exists sufficient information to estimate with reasonable accuracy the approximate distribution in energy of the neutrons, the incident number of neutrons per square centimeter equivalent to one rem may be estimated from the following table:

NEUTRON FLUX DOSE EQUIVALENTS

Neutron Energy (Mev)	Number per square centimeter equivalent to a dose of 1 rem (Neutrons/cm ^{2})	Average Flux to deliver 100 millirem in 40 hrs. (Neutrons/cm ^{2}/sec.)
Thermal	970×10^6	670
0.0001	720×10^6	500
0.005	820×10^6	570
0.02	400×10^6	280
0.1	120×10^6	80
0.5	43×10^6	30
1.0	26×10^6	18
2.5	29×10^6	20
5.0	26×10^6	18
7.5	24×10^6	17
10.0	24×10^6	17
10 to 30	14×10^6	10

1.3.3.5 For determining the doses specified in RHA 3.2 a dose from ×- or gamma rays up to 3 mev may, for purposes of these regulations, be assumed to be equivalent to the exposure measured in air at or near body surfaces in the region of the highest dose rate by a properly calibrated appropriate instrument.

History: Amended by SCSR 44–11, eff November 27, 2020 (errata).

RHA 1.4. Units of Radioactivity.

1.4.1 For the purposes of this part, activity is expressed in the special unit of curies (Ci) or in the SI unit of becquerels (Bq), or their multiples, or disintegrations (transformations) per unit of time.

1.4.1.1 One becquerel = 1 disintegration per second (s^{-1}).

1.4.1.2 One curie = 3.7 X 10^{10} disintegrations per second = 3.7 X 10^{10} becquerels =2.22 X 10^{12} disintegrations per minute. Commonly used submultiples of the curie are the millicurie (mCi) and the microcurie (uCi). One mCi = .001 curie (Ci) = 3.7 X 10^{7} dps or 2.22 X 10^{9} dpm. One uCi = .000001 Ci = 2.22 X 10^{6} dpm.

1.4.2 For purposes of these regulations, it may be assumed that the daughter activity concentrations in the following table are equivalent to an air concentration of 10^{-7} microcuries of Radon 222 per milliliter of air in equilibrium with the daughters RaA, RaB, RaC, and RaC[1]:

Maximum time between collection and measurement (hours) *	Alpha-emitting daughter activity collected per millimeter of air	
	Microcuries/ml.	Total alpha disintegrations per minute per ml.
0.5	7.2×10^{-8}	0.16
1	4.5×10^{-8}	0.10
2	1.3×10^{-8}	0.029
3	0.3×10^{-8}	0.0067

* The duration of sample collection and the duration of measurement should be sufficiently short compared to the time between collection and measurement, as not to have a statistically significant effect upon the results.

History: Amended by SCSR 44–11, eff November 27, 2020 (errata).

RHA 1.5. Records.

1.5.1 Each licensee shall keep records showing the receipt, transfer, and disposal of all sources of radiation and any other records as specifically required by these regulations.

RHA 1.6. Inspections.

1.6.1 Each licensee shall afford, at all reasonable times, the Department or its duly authorized representative, the opportunity to inspect sources of radiation and the premises and installations wherein such sources of radiation are used or stored.

1.6.2 Each licensee shall make available for inspection, to the Department, or its duly authorized representative, records maintained pursuant to these regulations.

RHA 1.7. Tests and Surveys.

1.7.1 Each licensee shall make or cause to be made such surveys as are necessary for him to comply with these regulations.

1.7.2 Each licensee shall perform, upon instruction from the Department, or shall permit the Department to perform such reasonable tests as the Department deems appropriate and necessary including, but not limited to tests of:

Sources of radiation;

Location wherein sources of radiation are used or stored;

Radiation detection and monitoring instruments;

Other equipment and devices used in connection with utilization or storage of licensed sources of radiation.

RHA 1.8. Impounding.

1.8.1 Sources of radioactive material shall be subject to impounding pursuant to the Act.

RHA 1.9. Exemptions from Licensing.

The following are exempt from the provisions of Part II, Licensing of Radioactive Materials:

1 Note: The unit 'Ci' is the currently used abbreviation for 'curie' replacing the older unit 'c'. Where the unit 'c' occurs in the text or tables of these regulations, it is to be interpreted to mean 'Ci', likewise uc = uCi and mc = mCi.

1.9.1 Carriers. Common and contract carriers, freight forwarders and warehousemen operating within this State are exempt from these regulations to the extent that they transport or store sources of radiation in the regular course of their carriage for another or storage incident thereto.

1.9.2 U. S. Department of Energy contractors and U. S. Nuclear Regulatory Commission contractors. Any U. S. Department of Energy contractor or subcontractor and any U. S. Nuclear Regulatory Commission contractor or subcontractor of the following categories operating within the state is exempt from these regulations to the extent that such contractor or subcontractor under his contract receives, possesses, uses, transfers, or acquires sources of radiation:

1.9.2.1 Prime contractors performing work for the Department of Energy at U. S. Government-owned or controlled sites, including the transportation of sources of radiation to or from such sites and the performance of contract services during temporary interruptions of such transportation;

1.9.2.2 Prime contractors of the Department of Energy performing research in, or development, manufacture, storage, testing, or transportation of, atomic weapons or components thereof;

1.9.2.3 Prime contractors of the Department of Energy using or operating nuclear reactors or other nuclear devices in a United States Government-owned vehicle or vessel; and

1.9.2.4 Any other prime contractor or subcontractor of the Department of Energy or of the Nuclear Regulatory Commission when the State and the Nuclear Regulatory Commission jointly determine:

1.9.2.4.1 that the exemption of the prime contractor or subcontractor is authorized by law, and

1.9.2.4.2 that under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety.

RHA 1.10. Exemptions from Requirements of These Regulations.

1.10.1 The Department may, upon application thereof or upon its own initiative, grant such exemptions or exceptions from the requirements of these regulations as it determines are authorized by law and will not result in undue hazard to public health and safety or property.

RHA 1.11. Additional Requirements.

1.11.1 The Department may, by rule, regulation, or order, impose upon any licensee such requirements in addition to those established in these regulations as it deems appropriate or necessary to minimize danger to public health and safety or property.

RHA 1.12. Violations.

1.12.1 An injunction or other court order may be obtained prohibiting any violation of any provision of the Act or any regulation or order issued thereunder. Any person who willfully violates any provision of the Act or any regulation or order issued thereunder shall be guilty of a misdemeanor and, upon conviction, may be punished by fine or imprisonment or both, as provided by law.

1.12.2 The Department is authorized to hold public hearings, compel attendance of witnesses, make findings of fact and determinations and to assess fines and civil penalties relating to violations of the provisions of the Act or any regulation, license or license condition, temporary or permanent order, or final determination of the Department. Any person violating any provision of the Act or any regulation, license or license condition, temporary or permanent order, or final determination of the Department is subject to the schedule of fines and civil penalties in RHA 1.15, Schedule A of this Part, provided that the maximum penalty for any violation shall not exceed twenty-five thousand dollars. Each day of noncompliance shall constitute a separate violation.

RHA 1.13. Communications.

1.13.1 All communications and reports concerning these regulations, and applications filed thereunder, should be addressed to the Department at its office located at:

South Carolina Department of Health and Environmental Control

Bureau of Radiological Health

2600 Bull Street

Columbia, South Carolina 29201

RHA 1.14. Annual Fees.

1.14.1 Any person issued or granted a specific radioactive material license by the Department for the possession, use, storage, or distribution of radioactive material, or for the storage or disposal of radioactive material shall pay an annual license fee in accordance with a schedule of fees issued by the Department.

1.14.2 Payment of fees shall be made in accordance with the instructions of a "Statement of Fees Due" issued annually by the Department.

1.14.3 Persons failing to pay the fees required by paragraph 1.14.1 within thirty days after payment is due shall also pay a penalty of Fifty Dollars. If failure to pay the required fee continues for more than sixty days after payment is due, the licensee shall be notified by the Department by certified mail to be sent to his last known address that his license is revoked, and that any activities permitted under the authority of the license must cease immediately.

1.14.4 A license suspended for failure to pay the required fee under paragraph 1.14.3 may be reinstated by the Department upon payment of the required fee, the penalty of Fifty Dollars, and an additional penalty of One Hundred Dollars, if the licensee is otherwise in good standing and presents to the Department a satisfactory explanation for his failure to pay the required fee.

1.14.5 Fees required by paragraph 1.14.1 for a specific radioactive materials license which is issued during a calendar year shall be prorated for the remainder of that year based on the date of issuance of the license.

RHA 1.15. Financial Assurances and Recordkeeping for Decommissioning.

1.15.1 The Department shall consider on a case-by-case basis, and require if found necessary before issuance of a license, financial assurances for the purpose of decommissioning or decontaminating facilities and the environment prior to closure and release for unrestricted use, or cleanup of the environment and facilities due to operations and accidental and unexpected releases of radioactive materials. The form and amount of such financial assurances shall be specifically determined by the Department.

1.15.2 Financial or surety arrangements generally acceptable to the Department include surety bonds, cash deposits, certificates of deposits, deposits of government securities, escrow accounts, irrevocable letters or lines of credit, trust funds, and combinations of the above or such other types of arrangements as may be approved by the Department.

1.15.3 Notwithstanding the requirements of RHA 1.15.1 and 1.15.2 above, each applicant for a specific license of the types described in RHA 1.15.3.1 through 1.15.3.4 shall submit a decommissioning funding plan as described in RHA 1.15.11.

1.15.3.1 Authorizing the possession and use of unsealed byproduct material of half-life greater than 120 days and in quantities exceeding 10^5 times the applicable quantities set forth in Appendix C, RHA 3.54 or when a combination of isotopes is involved if R divided by 10^5 is greater than 1 (unity rule), where R is defined here as the sum of the ratios of the quantity of each isotope to the applicable value in Appendix C, RHA 3.54.

1.15.3.2 Authorizing the possession and use of sealed sources or plated foils of half-life greater than 120 days and in quantities exceeding 10^{12} times the applicable quantities set forth in Appendix C, RHA 3.54 (or when a combination of isotopes is involved if R, as defined in RHA 1.15.3.1, divided by 10^{12} is greater than 1).

1.15.3.3 Authorizing the possession and use of more than 100 millicuries of source material in a readily dispersible form.

1.15.3.4 Authorizing the possession of unsealed special nuclear material in quantities exceeding 10^5 times the applicable quantities set forth in Appendix C, RHA 3.54 or when a combination of isotopes is involved if R divided by 10^5 is greater than 1 (unity rule), where R is the sum of the ratios of the quantity of each isotope to the applicable value in Appendix C, RHA 3.54.

1.15.4 Each applicant for a specific license as described in 1.15.3 and in quantities specified in RHA 1.15.10 of this section shall either---

1.15.4.1 Submit a decommissioning funding plan as described in RHA 1.15.11 of this section; or

1.15.4.2 Submit a certification that financial assurance for decommissioning has been provided in the amount prescribed by RHA 1.15.10 of this section using one of the methods described in RHA 1.15.12 of this section. For an applicant, this certification may state that the appropriate assurance will be obtained after the application has been approved and the license issued but prior to the receipt of licensed material. If the applicant defers execution of the financial instrument until after the license has been issued, a signed original of the financial instrument obtained to satisfy the requirements of RHA 1.15.12 must be submitted to the Department before receipt of licensed material. If the applicant does not defer execution of financial instrument, the applicant shall submit to the Department, as part of the certification, a signed original of the financial instrument obtained to satisfy the requirements of RHA 1.15.12.

1.15.5 Each holder of a specific license issued on or after the effective date of these regulations, which is of a type described in RHA 1.15.3 or 1.15.4 of this section, shall provide financial assurance for decommissioning in accordance with. RHA 1.15.12.

1.15.6 Each holder of a specific license of a type described in RHA 1.15.3 of this section shall submit a decommissioning funding plan as described in RHA 1.15.11 or a certification of financial assurance for decommissioning in an amount at least equal to $1,125,000 in accordance with the criteria set forth in this section. If the licensee submits the certification of financial assurance rather than a decommissioning funding plan, the licensee shall include a decommissioning funding plan in any application for license renewal.

1.15.7 Each holder of a specific license of a type described in RHA 1.15.4 shall submit a decommissioning funding plan as described in RHA 1.15.11 or a certification of financial assurance for decommissioning in accordance with RHA 1.15.12.

1.15.8 Any licensee who has submitted an application for renewal of license in accordance with RHA 2.12 shall provide financial assurance for decommissioning in accordance with RHA 1.15.3 and RHA 1.15.4.

1.15.9 Waste collectors and waste processors, as defined in RHA 3.2, must provide financial assurance in an amount based on a decommissioning funding plan as described in RHA 1.15.11. The decommissioning funding plan must include the cost of disposal of the maximum amount (curies) of radioactive material permitted by license, and the cost of disposal of the maximum quantity, by volume, of radioactive material which could be present at the licensee's facility at any time, in addition to the cost to remediate the licensee's site to meet the license termination criteria of RHA 2.11. The decommissioning funding plan must be submitted by June 30, 2007.

1.15.10 Required Amounts of Financial Assurance for Decommissioning by Quantity of Material. Licensees required to submit the $1,125,000 must do so by June 30, 2007. Licensees required to submit $113,000 or $225,000 amount must do so by June 30, 2007. Licensees having possession limits exceeding the upper bounds of this table must base financial assurance on a decommissioning funding plan.

TABLE I

(i) greater than 10^4 but less than or equal to 10^5 times the applicable quantities of Appendix C, RHA 3.54 in unsealed form. (For a combination of isotopes, if R, as defined in RHA 1.15.3.1, divided by 10^4 is greater than 1 but R divided by 10^5 is less than or equal to 1)	$1,125,000
(ii) greater than 10^3 but less than or equal to 10^4 times the applicable quantities of Appendix C, RHA 3.54 in unsealed form. (For a combination of isotopes, if R, as defined in RHA 1.15.3.1, divided by 10^3 is greater than 1 but R divided by 10^4 is less than or equal to 1.)	$225,000
(iii) greater than 10^{10} times the applicable quantities of Appendix C, RHA 3.54 in sealed sources or plated foils. (For a combination of isotopes, if R, as defined in RHA 1.15.3.1, divided by 10^{10} is greater than 1, but R divided by 10^{12} is less than or equal to 1.)	$113,000

1.15.10.1 Prepayment. Prepayment is the deposit prior to the start of the operation into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets such that the amount of funds would be sufficient to pay decommissioning costs.

Prepayment may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities.

1.15.10.2 A surety method, insurance, or other guarantee method. These methods guarantee that decommissioning costs will be paid should the licensee default. A surety method may be in the form of a surety bond, letter of credit, or line of credit. A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in RHA 1.17, Appendix A to this part. A parent company guarantee may not be used in combination with other financial methods to satisfy the requirements of this section. A guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in Appendix B of this part. A guarantee by the applicant or licensee may not be used in combination with any other financial methods to satisfy the requirements of this section or in any situation where the applicant or licensee has a parent company holding majority control of the voting stock of the company. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

(i) The surety method or insurance must be open-ended or, if written for a specified term, such as five years, must be renewed automatically unless 90 days or more prior to the renewal date, the issuer notifies the Department, the beneficiary, and the licensee of its intention not to renew. The surety method or insurance must also provide that the full face amount be paid to the beneficiary automatically prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the Department within 30 days after receipt of notification of cancellation.

(ii) The surety method or insurance must be payable to a trust established for decommissioning costs. The trustee and trust must be acceptable to the Department. An acceptable trustee includes an appropriate State or Federal government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency.

(iii) The surety method or insurance must remain in effect until the Department has terminated the license.

1.15.10.3 An external sinking fund in which deposits are made at least annually, coupled with a surety method or insurance, the value of which may decrease by the amount being accumulated in the sinking fund. An external sinking fund is a fund established and maintained by setting aside funds periodically in an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of funds would be sufficient to pay decommissioning costs at the time termination of operation is expected. An external sinking fund may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities. The surety or insurance provisions must be as stated in RHA 1.15.10.2 of this section.

1.15.10.4 In the case of Federal, State, or local government licensees, a statement of intent containing a cost estimate for decommissioning or an amount based on the Table in RHA 1.15.8 of this section, and indicating that funds for decommissioning will be obtained when necessary.

1.15.11 Decommissioning Funding Plan.

1.15.11.1 Each decommissioning funding plan must be submitted for review and approval and must contain:

1.15.11.1.1 A detailed cost estimate for decommissioning, in an amount reflecting:

1.15.11.1.1.1 The cost of an independent contractor to perform all decommissioning activities;

1.15.11.1.1.2 The cost of meeting the RHA 3.57.2 criteria for unrestricted use, provided that, if the applicant or licensee can demonstrate its ability to meet the provisions of RHA 3.57.3, the cost estimate may be based on meeting the RHA 3.57.3 criteria;

1.15.11.1.1.3 The volume of onsite subsurface material containing residual radioactivity that will require remediation to meet the criteria for license termination; and

1.15.11.1.1.4 An adequate contingency factor.

1.15.11.1.2 Identification of and justification for using the key assumptions contained in the DCE;

1.15.11.1.3 A description of the method of assuring funds for decommissioning from RHA 1.15.12, including means for adjusting cost estimates and associated funding levels periodically over the life of the facility;

1.15.11.1.4 A certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning; and

1.15.11.1.5 A signed original of the financial instrument obtained to satisfy the requirements of RHA 1.15.12 of this section (unless a previously submitted and accepted financial instrument continue to cover the cost estimate for decommissioning).

1.15.11.2 At the time of license renewal and at intervals not to exceed 3 years, the decommissioning funding plan must be resubmitted with adjustments as necessary to account for changes in costs and the extent of contamination. If the amount of financial assurance will be adjusted downward, this cannot be done until the updated decommissioning funding plan is approved. The decommissioning funding plan must update the information submitted with the original or prior approved plan, and must specifically consider the effect of the following events on decommissioning costs:

1.15.11.2.1 Spills of radioactive material producing additional residual radioactivity in onsite subsurface material;

1.15.11.2.2 Waste inventory increasing above the amount previously estimated;

1.15.11.2.3 Waste disposal costs increasing above the amount previously estimated;

1.15.11.2.4 Facility modifications;

1.15.11.2.5 Changes in authorized possession limits;

1.15.11.2.6 Actual remediation costs that exceed the previous cost estimate;

1.15.11.2.7 Onsite disposal; and

1.15.11.2.8 Use of a settling pond.

1.15.12 The financial instrument must include the licensee's name, license number, and docket number; and the name, address, and other contact information of the issuer, and, if a trust is used, the trustee. When any of the foregoing information changes, the licensee must, within 30 days, submit financial instruments reflecting such changes. The financial instrument submitted must be a signed original or signed original duplicate, except where a copy is specifically permitted. Financial assurance for decommissioning must be provided by one or more of the following methods:

1.15.12.1 Prepayment. Prepayment is the deposit prior to the start of the operation into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets such that the amount of funds would be sufficient to pay decommissioning costs. Prepayment may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities.

1.15.12.2 A surety method, insurance, or other guarantee method. These methods guarantee that decommissioning costs will be paid should the licensee default. A surety method may be in the form of a surety bond, letter of credit, or line of credit. A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in RHA 1.17, Appendix A to this part. A parent company guarantee may not be used in combination with other financial methods to satisfy the requirements of this section. A guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in Appendix B of this part. A guarantee by the applicant or licensee may not be used in combination with any other financial methods to satisfy the requirements of this section or in any situation where the applicant or licensee has a parent company holding majority control of the voting stock of the company. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

(i) The surety method or insurance must be open-ended or, if written for a specified term, such as five years, must be renewed automatically unless 90 days or more prior to the renewal date, the issuer notifies the Department, the beneficiary, and the licensee of its intention not to renew. The surety method or insurance must also provide that the full face amount be paid to the beneficiary automatically prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the Department within 30 days after receipt of notification of cancellation.

(ii) The surety method or insurance must be payable to a trust established for decommissioning costs. The trustee and trust must be acceptable to the Department. An acceptable trustee includes an appropriate State or Federal government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a federal or State agency.

(iii) The surety method or insurance must remain in effect until the Department has terminated the license.

1.15.12.3 An external sinking fund in which deposits are made at least annually, coupled with a surety method or insurance, the value of which may decrease by the amount being accumulated in the sinking fund. An external sinking fund is a fund established and maintained by setting aside funds periodically in an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of funds would be sufficient to pay decommissioning costs at the time termination of operation is expected. An external sinking fund may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities. The surety or insurance provisions must be stated in RHA 1.15.12.2 of this section.

1.15.12.4 In the case of Federal, State or local government licensees, a statement of intent containing a cost estimate for decommissioning or an amount backed on the Table in RHA 1.15.10 of this section, and indicating that funds for decommissioning will be obtained when necessary.

1.15.13 Each person licensed under this part or Parts II, IV or V of these regulations shall keep records of information important to the decommissioning of a facility in an identified location until the site is released for unrestricted use. Before licensed activities are transferred or assigned in accordance with RHA 2.10.2, licensees shall transfer all records described in this paragraph to the new license. In this case, the new licensee will be responsible for maintaining these records until the license is terminated. If records important to the decommissioning of a facility are kept for other purposes, reference to these records and their locations may be used. Information the Department considers important to decommissioning consists of:

1.15.13.1 Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. These records may be limited to instances when contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas as in the case of possible seepage into porous materials such as concrete. These records must include any known information on identification of involved nuclides, quantities, forms, and concentrations.

1.15.13.2 As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored, and of locations of possible inaccessible contamination such as buried pipes, which may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations.

1.15.13.3 Except for areas containing sealed sources (provided the sources have not leaked or not contamination remains after any leak), or where licensed material has been used in a device or component and is intact (for example depleted uranium used only for shielding or as penetrators in unused munitions), or byproduct materials having only half-lives of less than 65 days, a list contained in a single document and updated every 2 years of the following:

1.15.13.3.1 All areas designated and formerly designated restricted areas as defined RHA 1.2;

1.15.13.3.2 All areas outside of restricted areas that required documentation under RHA 1.15;

1.15.13.3.3 All areas outside of restricted areas where current and previous wastes have been buried as documented under RHA 3.41; and

1.15.13.3.4 All areas outside of restricted areas, which contain material such that, if the license expired, the licensee would be required to either decontaminate the area to unrestricted levels or apply for approval for disposal under RHA 3.28.

1.15.13.4 Records of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and records of the funding method used for assuring funds if either a funding plan or certification is used.

HISTORY: Amended by State Register Volume 38, Issue No. 10, Doc. No. 4462, eff October 24, 2014.

RHA 1.16. Schedule A.

SCHEDULE OF CIVIL PENALTIES

A. Severity I Category Level: Not less than Twenty Thousand Dollars, nor more than Twenty-Five Thousand Dollars, per violation.

B. Severity II Category Level: Not less than Ten Thousand Dollars, nor more than Twenty Thousand Dollars, per violation.

C. Severity III Category Level: Not less than Five Thousand Dollars, nor more than Ten Thousand Dollars, per violation.

D. Severity IV Category Level: Not less than Two Thousand Dollars, nor more than Five Thousand Dollars, per violation.

E. Severity V Category Level: Not less than One Thousand Dollars, nor more than Two Thousand Dollars, per violation.

F. Severity VI Category Level: Not more than One Thousand Dollars, per violation.

SCHEDULE OF SEVERITY CATEGORIES

I. Health Physics and Radiation Protection:

A. Severity I—Very Significant violations involving:

1. Single exposure or a quarterly accumulation of exposures to a worker in excess of 25 rems of radiation to the whole body, 150 rems to the skin of the whole body, or 375 rems to the feet, ankles, hands, or forearms, when such exposures are contrary to the provisions of RHA 3.2, Title A;

2. Annual whole body exposure of a member of the public in excess of 2.5 rems of radiation;

3. Release of radioactive material to an unrestricted area in excess of ten times the limits of RHA 3.5, Title A;

4. Disposal of licensed material in quantities or concentrations in excess of ten times the limits of RHA 3.13, Title A; or

5. Exposure of a worker in restricted areas in excess of ten times the limits of RHA 3.3, Title A.

B. Severity II—Very Significant violations involving:

1. Single exposure or a quarterly accumulation of exposures to a worker in excess of 5 rems of radiation to the whole body, 30 rems to the skin of the whole body, or 75 rems to the feet, ankles, hands, or forearms, when such exposures are contrary to the provisions of RHA 3.2, Title A;

2. Annual whole body exposure of a member of the public in excess of 0.5 rems of radiation;

3. Release of radioactive material to an unrestricted area in excess of five times the limits of RHA 3.5, Title A;

4. Failure to make an immediate notification as required by RHA 3.18, Title A;

5. Disposal of licensed material in quantities or concentrations in excess of five times the limits of RHA 3.13, Title A; or

6. Exposure of a worker in restricted areas in excess of five times the limits of RHA 3.3, Title A.

C. Severity III—Significant violations involving:

1. Single exposure or a quarterly accumulation of exposures to a worker in excess of 3 rems of radiation to the whole body, 7.5 rems to the skin of the whole body, or 18.75 rems to the feet, ankles, hands, or forearms, when such exposures are contrary to the provisions of RHA 3.2, Title A;

2. A radiation level in an unrestricted area that exceeds 100 millirems/hour for a one-hour period;

3. Failure to make a 24-hour notification as required by RHA 3.18, Title A, or an immediate notification required by RHA 3.17, Title A;

4. Substantial potential for an exposure or release in excess of limits specified in Part III, Title A, where such exposure or release does not occur (e.g., entry into high radiation areas in the vicinity of exposed radiographic sources without having performed an adequate survey, failure to provide security or prevent unauthorized entry into a high radiation area, operation of a radiation facility with a nonfunctioning interlock system);

5. Release of radioactive material to an unrestricted area in excess of the limits of RHA 3.5, Title A;

6. Improper disposal of licensed material not covered in Severity Levels I or II;

7. Exposure of a worker in restricted areas in excess of the limits of RHA 3.3, Title A;

8. Release for unrestricted use of contaminated or radioactive material or equipment which poses a realistic potential for exposure to members of the public, or failure to decontaminate facility areas as required;

9. Cumulative worker exposure above regulatory limits when such cumulative exposure reflects a programmatic, rather than an isolated weakness in radiation protection;

10. Conduct of licensee activities by a technically unqualified person or person not meeting training requirements specified by regulation or license conditions; or

11. Failure to control or provide security for licensed material.

D. Severity IV—Violations involving:

1. Failure to follow requirements not covered in Severity Levels I, II, or III, that substantially reduces the margin of safety (e.g., inadequate survey, incomplete dosimetry, improper posting, failure to maintain proper security);

2. A radiation level in an unrestricted area such that an individual may receive greater than 2 millirems in a one hour period or 100 millirems in any seven consecutive days; or

3. Failure to make a 30-day written notification required by RHA 3.19, Title A.

E. Severity V—Violations involving any other matter involving failure to follow procedures, rules and regulations or license conditions, that has other than minor safety or environmental significance.

F. Severity VI—Violations that have minor safety or environmental significance.

II. Radioactive Materials Operations:

A. Severity I—Very Significant violations involving:

1. A technically unqualified or unauthorized person conducting a licensee activity that results in radiation levels, contamination levels, or releases that exceed ten times regulatory limits or limits specified in the license;

2. Use of unauthorized equipment that results in radiation levels, contamination levels, or releases that exceed ten times regulatory limits or limits specified in the license;

3. Possession or use of unauthorized radioactive materials requiring a license that results in radiation levels, contamination levels, or releases that exceed ten times regulatory limits;

4. Failure to perform required surveys, tests, or evaluations, or to institute required safety precautions that results in radiation levels, contamination levels, or releases that exceed ten times regulatory limits or limits specified in the license; or

5. A system designed to prevent or mitigate a serious safety event being inoperable when actually required to perform its design function.

B. Severity II—Violations involving:

1. A technically unqualified or unauthorized person conducting a licensee activity that results in radiation levels, contamination levels, or releases that exceed five times regulatory limits, or limits specified in the license;

2. Possession or use of unauthorized equipment or material in the conduct of licensed activities that results in radiation levels, contamination levels, or releases that exceed five times regulatory limits or limits specified in the license;

3. Possession or use of unauthorized radioactive materials requiring a license that results in radiation levels, contamination levels, or releases that exceed five times regulatory limits.

4. Failure to perform required surveys, tests, or evaluations that results in radiation levels, contamination levels or releases that exceed five times regulatory limits, or limits specified in the license; or

5. Failure to make required initial notifications associated with Severity Level I or II violations.

C. Severity III—Violations involving:

1. Failure to control access to licensed materials for radiation purposes as specified by regulatory requirements;

2. Possession or use of unauthorized equipment, materials or facilities in the conduct of licensed activities;

3. Possession or use of unauthorized radioactive materials requiring a license;

4. Use of radioactive materials on humans where such use is not authorized;

5. Conduct of licensee activities by a technically unqualified or unauthorized person;

6. Degradation of a system designed to prevent or mitigate a serious safety event;

7. Failure to provide adequate measures to prevent loss or theft of radioactive materials; or

8. Radiation levels, contamination levels, or releases that exceed regulatory limits or limits specified in the license.

D. Severity IV—Violations involving:

1. Failure to maintain patients containing Cobalt-60, Cesium-137, Iridium-192, or Radium implants hospitalized, or failure to conduct and record surveys of such patients prior to release;

2. Failure to conduct required leakage or contamination tests; or

3. Use of improperly calibrated survey equipment or counting equipment.

E. Severity V—Other violations such as failure to follow procedures, rules and regulations, or license conditions that have other than minor safety or environmental significance.

F. Severity VI—Violations that have minor safety or environmental significance.

III. Transportation of Radioactive Materials:

For purposes of this Schedule, radioactive material transported as radioactive waste into or within South Carolina is subject to the provisions of the S.C. Department of Health and Environmental Control Regulation 61-83, Regulation for the Transportation of Radioactive Waste Into or Within South Carolina. Radioactive materials, other than radioactive wastes as defined in S.C. Department of Health and Environmental Control Regulation 61-83, are subject to the following Severity Categories:

A. Severity I—Very Significant violations of State and Federal Regulations involving:

1. Annual whole body exposure of a member of the public in excess of 2.5 rem of radiation; or

2. Breach of package integrity resulting in surface contamination or external radiation levels in excess of ten times the Nuclear Regulatory Commission (NRC) or Department of Transportation (DOT) limits.

B. Severity II—Very Significant violations of State and Federal Regulations involving:

1. Annual whole body exposure of a member of the public in excess of 0.5 rem of radiation;

2. Breach of package integrity resulting in surface contamination or external radiation levels less than ten times in excess of NRC or DOT limits.

3. Surface contamination or external radiation levels in excess of three times NRC or DOT limits that did not result from a breach of package integrity; or

4. Failure to make required initial notifications associated with Severity Level I or II violations.

C. Severity III—Violation of State and Federal Regulations involving:

1. Breach of package integrity;

2. Surface contamination or external radiation levels in excess of but less than a factor of three above NRC or DOT requirements that did not result from a breach of package integrity;

3. Any noncompliance with labelling, placarding, shipping paper, packaging, loading or other requirements that could reasonably result in the following:

a. Improper identification of the type, quantity, or form of material;

b. Failure of the carrier or recipient to exercise adequate controls;

c. Substantial potential for personnel exposure or contamination; or

4. Failure to make required initial notification associated with Severity Level III violations.

D. Severity IV—Violation of State and Federal regulation involving any noncompliance of package selection or preparation requirements which does not result in a breach of package integrity or surface contamination, or external radiation levels in excess of NRC or DOT requirements.

E. Severity V—Other violations such as failure to follow procedures or rules and regulations that have other than minor safety or environmental significance.

F. Severity VI—Violations that have minor safety or environmental significance.

RHA 1.17. [Appendix A] Criteria Relating to Use of Financial Tests and Parent Company Guarantees for Providing Reasonable Assurance of Funds for Decommissioning.

I. INTRODUCTION

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on obtaining a parent company guarantee that funds will be available for decommissioning costs and on a demonstration that the parent company passes a financial test. This appendix establishes criteria for passing the financial test and for obtaining the parent company guarantee.

II. FINANCIAL TEST

A. To pass the financial test, the parent company must meet the criteria of either paragraph A.1 or A.2 of this section:

1. The parent company must have:

(i) Two of the following three ratios: A ratio of total liabilities to net worth less than 2.0; a ratio of the sum of net income plus depreciation, depletion, and amortization to total liabilities greater than 0.1; and a ratio of current assets to current liabilities greater than 1.5; and

(ii) Net working capital and tangible net worth each at least six times the current decommissioning cost estimates (or prescribed amount if a certification is used); and

(iii) Tangible net worth of at least $10 million; and

(iv) Assets located in the United States amounting to at least 90 percent of total assets or at least six times the current decommissioning cost estimates (or prescribed amount if a certification is used).

2. The parent company must have:

(i) A current rating for its most recent bond issuance of AAA, AA, A, or BBB as issued by Standard and Poor's or Aaa, Aa, A, or Baa as issued by Moody's; and

(ii) Tangible net worth at least six times the current decommissioning cost estimate (or prescribed amount if a certification is used); and

(iii) Tangible net worth of at least $10 million; and

(iv) Assets located in the United States amounting to at least 90 percent of total assets or at least six times the current decommissioning cost estimates (or prescribed amount if certification is used).

B. The parent company's independent certified public accountant must have compared the data used by the parent company in the financial test, which is derived from the independently audited, year end financial statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure the licensee shall inform the Department within 90 days of any matters coming to the auditor's attention which cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

C.1. After the initial financial test, the parent company must repeat the passage of the test within 90 days after the close of each succeeding fiscal year.

2. If the parent company no longer meets the requirements of paragraph A of this section, the licensee must send notice to the Department of intent to establish alternate financial assurance as specified in the Department's regulations. The notice must be sent by certified mail within 90 days after the end of the fiscal year for which the year end financial data show that the parent company no longer meets the financial test requirements. The licensee must provide alternate financial assurance within 120 days after the end of such fiscal year.

III. PARENT COMPANY GUARANTEE

The terms of a parent company guarantee which an applicant or licensee obtains must provide that:

A. The parent company guarantee will remain in force unless the guarantor sends notice of cancellation by certified mail to the licensee and the Department. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by both the licensee and the Department, as evidenced by the return receipts.

B. If the licensee fails to provide alternate financial assurance as specified in the Department's regulations within 90 days after receipt by the licensee and Department of a notice of cancellation of the parent company guarantee from the guarantor, the guarantor will provide such alternative financial assurance in the name of the licensee.

C. The parent company guarantee and financial test provisions must remain in effect until the Department has terminated the license.

D. If a trust is established for decommissioning costs, the trustee and trust must be acceptable to the Department. An acceptable trustee includes an appropriate State or Federal Government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency.

RHA 1.18. [Appendix B] Criteria Relating to Use of Financial Tests and Self Guarantees for Providing Reasonable Assurance of Funds for Decommissioning.

I. INTRODUCTION

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the company passes the financial test of Section II of this appendix. The terms of the self-guarantee are Section III of this appendix. This appendix establishes criteria for passing the financial test for the self guarantee and establishes the terms for a self-guarantee.

II. FINANCIAL TEST

A. To pass the financial test, a company must meet all of the following criteria:

1. Tangible net worth at least 10 times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.

2. Assets located in the United States amounting to at least 90 percent of total assets or at least 10 times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.

3. A current rating for its most recent bond issuance of AAA, AA, A as issued by Standard and Poors (S&P), or Aaa, Aa, or A as issued by Moodys.

B. To pass the financial test, a company must meet all of the following additional requirements:

1. The company must have at least one class of equity securities registered under the Securities Exchange Act of 1934.

2. The company's independent certified public accountant must have compared the data used by the company in the financial test which is derived from the independently audited, year end financial statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall notify the Department within 90 days of any matters coming to the attention of the auditor that cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

3. After the initial financial test, the company must repeat passage of the test within 90 days after the close of each succeeding fiscal year.

C. If the licensee no longer meets the requirements of Section II.A, of this appendix, the licensee must send immediate notice to the Department of its intent to establish alternate financial assurance as specified in the Department's regulations within 120 days of such notice.

III. COMPANY SELF-GUARANTEE

The terms of a self-guarantee which as applicant or licensee furnishes must provide that:

A. The guarantee will remain in force unless the licensee sends notice of cancellation by certified mail to the Department. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by the Department, as evidenced by the return receipt.

B. The licensee shall provide alternative financial assurance as specified in the Department's regulations within 90 days following receipt by the Department of a notice of cancellation of the guarantee.

C. The guarantee and financial test provisions must remain in effect until the Department has terminated the license or until another financial assurance method acceptable to the Department has been put in effect by the licensee.

D. The licensee will promptly forward to the Department and the licensee's independent auditor all reports covering the latest fiscal year filed by the licensee with the Securities and Exchange Commission pursuant to the requirements of section 13 of the Securities And Exchange Act of 1934.

E. If at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poors or Moodys, the licensee will provide notice in writing of such fact to the Department within 20 days after publication of the change by the rating service. If the licensee's most recent bond issuance ceases to be rated in any category of A or above by both Standard and Poors and Moodys, the licensee no longer meets the requirements of Section II.A, of this appendix.

F. The applicant or licensee must provide to the Department a written guarantee (a written commitment by a corporate officer) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the Department, the licensee will set up and fund a trust in the amount of the current cost estimate for decommissioning.

PART II
LICENSING OF RADIOACTIVE MATERIAL

RHA 2.1. Purpose and Scope.

2.1.1 No person shall manufacture, produce, transfer, receive, acquire, own, possess, or use byproduct material except as authorized in a specific or general license issued pursuant to these regulations, or as otherwise provided in these regulations.

NOTE: Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source, by-product, or special nuclear material, intended for use by the general public may be obtained only from the United States Nuclear Regulatory Commission, Washington, D.C. 20555.

2.1.2 Deliberate misconduct

2.1.2.1 Any licensee, applicant for a license, employee of a licensee or applicant; or any contractor (including a supplier or consultant), subcontractor, employee of a contractor or subcontractor of any licensee or applicant for a license, who knowingly provides to any licensee, applicant, contractor, or subcontractor, any components, equipment, materials, or other goods or services that relate to a licensee's or applicant's activities in this part, may not:

2.1.2.1.1 Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license issued by the Department; or

2.1.2.1.2 Deliberately submit to the Department, a licensee, an applicant, or a licensee's or applicant's contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the Department.

2.1.2.2 A person who violates RHA 2.1.2.1.1 or 2.1.2.1.2 of this section may be subject to enforcement action in accordance with the procedures in RHA 1.12.

2.1.2.3 For the purposes of RHA 2.1.2.1.1, deliberate misconduct by a person means an intentional act or omission that the person knows:

2.1.2.3.1 Would cause a licensee or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation, of any license issued by the Department; or

2.1.2.3.2 Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, applicant, contractor, or subcontractor.

RHA 2.2. Types of Licenses.

Licenses for radioactive materials are of two types; general and specific.

The Department issues a specific license to a named person who has filed an application for the license under the provisions of this regulation (61–63). A general license is provided by regulation, grants authority to a person for certain activities involving radioactive material, and is effective without the filing of an application with the Department or the issuance of a licensing document to a particular person. However, registration with the Department may be required by the particular general license.

RHA 2.3. General Licenses—Source Material.

2.3.1 A general license is hereby issued authorizing commercial and industrial firms; research, educational, and medical institutions; and Federal, State, and local government agencies to receive, possess, use, and transfer uranium and thorium, in their natural isotopic concentrations and in the form of depleted uranium, for research, development, educational, commercial, or operational purposes in the following forms and quantities:

2.3.1.1 No more than 1.5 kg (3.3 lb) of uranium and thorium in dispersible forms (e.g., gaseous, liquid, powder, etc.) at any one time. Any material processed by the general licensee that alters the chemical or physical form of the material containing source material must be accounted for as a dispersible form. A person authorized to possess, use, and transfer source material under this paragraph may not receive more than a total of 7 kg (15.4 lb) of uranium and thorium in any one calendar year. Persons possessing source material in excess of these limits as of August 27, 2013, may continue to possess up to 7 kg (15.4 lb) of uranium and thorium at any one time for one year beyond this date, or until the Department takes final action on a pending application submitted on or before August 27, 2014, for a specific license for such material; and receive up to 70 kg (154 lb) of uranium or thorium in any one calendar year until December 31, 2014, or until the Department takes final action on a pending application submitted on or before August 27, 2014, for a specific license for such material; and

2.3.1.2 No more than a total of 7 kg (15.4 lb) of uranium and thorium at any one time. A person authorized to possess, use, and transfer source material under this paragraph may not receive more than a total of 70 kg (154 lb) of uranium and thorium in any one calendar year. A person may not alter the chemical or physical form of the source material possessed under this paragraph unless it is accounted for under the limits of RHA 2.3.1.1; or

2.3.1.3 No more than 7 kg (15.4 lb) of uranium, removed during the treatment of drinking water, at any one time. A person may not remove more than 70 kg (154 lb) of uranium from drinking water during a calendar year under this paragraph; or

2.3.1.4 No more than 7 kg (15.4 lb) of uranium and thorium at laboratories for the purpose of determining the concentration of uranium and thorium contained within the material being analyzed at any one time. A person authorized to possess, use, and transfer source material under this paragraph may not receive more than a total of 70 kg (154 lb) of source material in any one calendar year.

2.3.2 Any person who receives, possesses, uses, or transfers source material in accordance with the general license in RHA 2.3.1:

2.3.2.1 Is prohibited from administering source material, or the radiation there from, either externally or internally, to human beings except as may be authorized by the Department in a specific license.

2.3.2.2 Shall not abandon such source material. Source material may be disposed of as follows:

2.3.2.2.1 A cumulative total of 0.5 kg (1.1 lb) of source material in a solid, non-dispersible form may be transferred each calendar year, by a person authorized to receive, possess, use, and transfer source material under this general license to persons receiving the material for permanent disposal. The recipient of source material transferred under the provisions of this paragraph is exempt from the requirements to obtain a license under this part to the extent the source material is permanently disposed. This provision does not apply to any person who is in possession of source material under a specific license issued under this chapter; or

2.3.2.2.2 In accordance with RHA 3.27.

2.3.2.3 Is subject to the provisions in Part II of Title A.

2.3.2.4 Shall not export such source material except in accordance with 10 CFR Part 110.

2.3.3 Any person who receives possesses, uses, or transfers source material in accordance with RHA 2.3.1 shall conduct activities so as to minimize contamination of the facility and the environment. When activities involving such source material are permanently ceased at any site, if evidence of significant contamination is identified, the general licensee shall notify the Department about such contamination and may consult with the Department as to the appropriateness of sampling and restoration activities to ensure that any contamination or residual source material remaining at the site where source material was used under this general license is not likely to result in exposures that exceed the limits in RHA 3.57.2.

2.3.4 Any person who receives, possesses, uses, or transfers source material in accordance with the general license granted in RHA 2.3.1 is exempt from the provisions of Parts III and VI of this Regulation to the extent that such receipt, possession, use, and transfer are within the terms of this general license, except that such person shall comply with the provisions of RHA 3.27 and 3.57.2 to the extent necessary to meet the provisions of RHA 2.3.2.2 and 2.3.3. However, this exemption does not apply to any person who also holds a specific license issued under this Part.

2.3.5 No person may initially transfer or distribute source material to persons generally licensed under RHA 2.3.1.1 and 2.3.1.2, or equivalent regulations of the NRC or of an Agreement State, unless authorized by a specific license issued in accordance with RHA 2.6 or equivalent provisions of the NRC or an Agreement State. This prohibition does not apply to analytical laboratories returning processed samples to the client who initially provided the sample. Initial distribution of source material to persons generally licensed by RHA 2.3.1 of this section before August 27, 2013, without specific authorization may continue for one (1) year beyond this date. Distribution may also be continued until the Department takes final action on a pending application for license or license amendment to specifically authorize distribution submitted on or before August 27, 2014.

2.3.6 A general license is hereby issued authorizing the receipt of title to source material without regard to quantity. This general license does not authorize any person to receive, possess, use, or transfer source material.

2.3.7 Depleted Uranium in Industrial Products and Devices.

2.3.7.1 A general license is hereby issued to receive, acquire, possess, use, or transfer, in accordance with the provisions of subparagraphs 2.3.4.2, 2.3.4.3, 2.3.4.4, and 2.3.4.5, depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.

2.3.7.2 The general license in subparagraph 2.3.4.1 applies only to industrial products or devices which have been manufactured either in accordance with a specific license issued to the manufacturer of the products or devices pursuant to RHA 2.27 or in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission or an Agreement State which authorizes manufacture of the products or devices for distribution to persons generally licensed by the U.S. Nuclear Regulatory Commission or an Agreement State.

2.3.7.3 Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license established by subparagraph 2.3.4.1 shall file Department Form RHA 100-2 "Registration Certificate Use of Depleted Uranium Under General License," with the Department. The Form shall be submitted within 30 days after the first receipt or acquisition of such depleted uranium. The registrant shall furnish on Department Form RHA 100-2 the following information and such other information as may be required by that form:

2.3.7.3.1 Name and address of the registrant.

2.3.7.3.2 A statement that the registrant has developed and will maintain procedures designed to establish physical control over the depleted uranium described in subparagraph 2.3.4.1 and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and

2.3.7.3.3 Name and/or title, address, and telephone number of the individual duly authorized to act for and on behalf of the registrant in supervising the procedures identified in 2.3.4.3.2.

The registrant possessing or using depleted Uranium under the general license established by subparagraph 2.3.7.1 shall report, in writing, to the Department any changes in information furnished by him in Department Form RHA 100-2 "Registration Certificate—Use of Depleted Uranium." The report shall be submitted within 30 days after the effective date of such change.

2.3.7.4 A person who receives, acquires, possesses, or uses depleted uranium pursuant to the general license established by subparagraph 2.3.4.1:

2.3.7.4.1 Shall not introduce such depleted uranium, in any form, into a chemical, physical, or metallurgical treatment or process, except a treatment or process for repair or restoration of any plating or other covering of the depleted uranium.

2.3.7.4.2 Shall not abandon such depleted uranium.

HISTORY: Amended by State Register Volume 38, Issue No. 10, Doc. No. 4462, eff October 24, 2014; SCSR 42–2 Doc. No. 4791, eff February 23, 2018.

RHA 2.4. General Licenses—Radioactive Material Other Than Source Material.

2.4.1 Purpose and Scope.

This part establishes general licenses for the possession and use of radioactive material and a general license for ownership of radioactive material. Specific provisions of Part II are applicable to general licenses established by this section. These provisions are specified herein or in the particular general license. The general licenses provided in this part are subject to the general provisions of Part II and RHA 1.5, 1.6, 1.7, 1.8, 1.11, 1.12, 2.9, 2.17, 2.18, 2.20.2.1.2, Part III and Part VI of these regulations unless indicated otherwise in the specific provision of the general license.[1]

2.4.2 Certain Detecting, Measuring, Gauging or Controlling Devices and Certain Devices for Producing Light or an Ionized Atmosphere.

2.4.2.1 A general license is hereby issued to commercial and industrial firms and to research, educational and medical institutions, individuals in the conduct of their business, and State or local government agencies to own, receive, acquire, possess, use or transfer in accordance with the provisions of RHA 2.4.2.2, 2.4.2.3, and 2.4.2.4, radioactive material, excluding special nuclear material, contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

2.4.2.2 The general license in RHA 2.4.2.1 applies only to radioactive material contained in devices which have been manufactured or initially transferred and labeled in accordance with the specifications contained in the subparagraphs below. The devices must have been received from one of the specific licensees described in the following subparagraphs or through a transfer made under RHA 2.4.2.3.8 of this part:

2.4.2.2.1 A specific license issued under Part 2 of this Regulation; or

2.4.2.2.2 An equivalent specific license issued by an Agreement State; or

2.4.2.2.3 An equivalent specific license issued by a State with provisions comparable to Part 2 of this Regulation.

2.4.2.3 Any person who receives, acquires, possesses, uses, or transfers radioactive material in a device pursuant to the general license in RHA 2.4.2.1:

2.4.2.3.1 shall assure that all labels affixed to the device at the time of receipt, and bearing a statement that removal of the label is prohibited, are maintained thereon and shall comply with all instructions and precautions provided by such labels;

[1] Attention is directed particularly to the provisions of Part III of this regulation concerning labeling of containers.

2.4.2.3.2 shall assure that the device is tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at no longer than six-month intervals or at such other intervals as are specified in the label; however;

2.4.2.3.2.1 devices containing only krypton need not be tested for leakage of radioactive material, and

2.4.2.3.2.2 devices containing only tritium or not more than 100 microcuries of other beta and/or gamma emitting material or 10 microcuries of alpha emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose;

2.4.2.3.3 Shall assure that the tests required by RHA 2.4.2.3.2 and other testing, installation, servicing, and removal from installation involving the radioactive materials, its shielding or containment, are performed:

2.4.2.3.3.1 in accordance with the instructions provided by the labels; or

2.4.2.3.3.2 by a person holding a specific license from the Department, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State to perform such activities;

2.4.2.3.4 Shall maintain records showing compliance with the requirements of RHA 2.4.2.3.2 and 2.4.2.3.3. The records shall show the results of tests. The records also shall show the dates of performance of, and the names of the persons performing, testing installation services, and removal from installation concerning the radioactive material, its shielding or containment;

The licensee shall retain these records as follows:

2.4.2.3.4.1 Each record of a test for leakage of radioactive material required by paragraph RHA 2.4.2.3.2 of this section must be retained for three years after the next required leak test is performed or until the sealed source is transferred or disposed of.

2.4.2.3.4.2 Each record of a test of the on-off mechanism and indicator required by paragraph RHA 2.4.2.3.2 of this section must be retained for three years after the next required test of the on-off mechanism and indicator is performed or until the sealed source is transferred or disposed of.

2.4.2.3.4.3 Each record that is required by paragraph RHA 2.4.2.3.3 of this section must be retained for three years from the date of the recorded event or until the device is transferred or disposed of.

2.4.2.3.5 Shall immediately suspend operation of the device if there is a failure of, or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 0.005 microcurie (185 bequerel) or more of removable radioactive material. The device may not be operated until it has been repaired by the manufacturer or other person holding a specific license to repair such devices that was issued by the Department or by the U.S. Nuclear Regulatory Commission or an Agreement State. The device and any radioactive material from the device may only be disposed of by transfer to a person authorized by a specific license to receive the radioactive material in the device or as otherwise approved by the Department. A report containing a brief description of the event and the remedial action taken; and, in the case of detection of 0.005 microcurie or more removable radioactive material or failure of or damage to a source likely to result in contamination of the premises or the environs, a plan for ensuring that the premises and environs are acceptable for unrestricted use, must be furnished to the Department within 30 days. Under these circumstances, the criteria set out in RHA 3.57.2 "Radiological criteria for unrestricted use," may be applicable, as determined by the Department on a case-by-case basis;

2.4.2.3.6 shall not abandon the device containing radioactive material;

2.4.2.3.7 Shall transfer or dispose of the device containing radioactive material only by export as provided by RHA 2.4.2.3.14 of this section, by transfer to another general licensee as authorized in RHA 2.4.2.3.8 or to a person authorized to receive the device by a specific license issued by this Department or by the U.S. Nuclear Regulatory Commission or an Agreement State or as otherwise approved under RHA 2.4.2.3.7.2. In complying with this section, the licensee:

2.4.2.3.7.1 Shall furnish a report to the Department within 30 days after the transfer of a device to a specific licensee or export. The report must contain the identification of the device

by manufacturer's (or initial transferor's) name, model number, and serial number; the name, address, and license number of the person receiving the device (license number not applicable if exported); and the date of the transfer.

2.4.2.3.7.2 Shall obtain written Departmental approval before transferring the device to any other specific licensee not specifically identified in RHA 2.4.2.3.7; however, a holder of a specific license may transfer a device for possession and use under its own specific license without prior approval, if, the holder:

2.4.2.3.7.2.1 Verifies that the specific license authorizes the possession and use, or applies for and obtains an amendment to the license authorizing the possession and use;

2.4.2.3.7.2.2 Removes, alters, covers, or clearly and unambiguously augments the existing label (otherwise required by RHA 2.4.2.3.1) so that the device is labeled in compliance with RHA 3.24; however the manufacturer, model number, and serial number must be retained;

2.4.2.3.7.2.3 Obtains manufacturer's or initial transferor's information concerning maintenance that would be applicable under the specific license (such as leak testing procedures); and

2.4.2.3.7.2.4 Reports the transfer under RHA 2.4.2.3.7.1.

2.4.2.3.8 Shall transfer the device to another general licensee only:

2.4.2.3.8.1 Where the device remains in use at a particular location. In this case, the transferor shall give the transferee a copy of this regulation, a copy of RHA 2.4.1, 2.18, 3.44, and 3.45 of this chapter, and any safety documents identified in the label of the device. Within 30 days of the transfer, the transferor shall report to the Department the manufacturer's (or initial transferor's) name; the model number and the serial number of the device transferred; the transferee's name and mailing address for the location of use; and the name, title, and phone number of the responsible individual identified by the transferee in accordance with RHA 2.4.2.3.10 to have knowledge of and authority to take actions to ensure compliance with the appropriate regulations and requirements or:

2.4.2.3.8.2 Where the device is held in storage by an intermediate person in the original shipping container at its intended location of use prior to initial use by a general licensee.

2.4.2.3.9 shall comply with the provisions of RHA 3.17 and 3.18 for reporting radiation incidents, theft, or loss of licensed material, but shall be exempt from the other requirements of Parts III and VI.

2.4.2.3.10 Shall appoint an individual responsible for having knowledge of the appropriate regulations and requirements and the authority for taking required actions to comply with appropriate regulations and requirements. The general licensee, through this individual, shall ensure the day-to-day compliance with appropriate regulations and requirements. This appointment does not relieve the general licensee of any of its responsibility in this regard.

2.4.2.3.11 Shall register generally licensed devices:

2.4.2.3.11.1 When the device contains at least 10 mCi (370 MBq) of cesium-137, 0.1 mCi (3.7 MBq) of strontium-90, 1 mCi (37 MBq) of cobalt-60, 0.1 mCi (3.7 MBq) of radium-226, or 1 mCi (37 MBq) of americium-241 or any other transuranic (i.e., element with atomic number greater than uranium (92)), based on the activity indicated on the label. Each address for a location of use, as described under paragraph RHA 2.4.2.3.11.3 (iv), represents a separate general licensee and requires a separate registration and fee.

2.4.2.3.11.2 Annually, if in possession of a device meeting the criteria of RHA 2.4.2.3.11.1. Registration shall be made with the Department and the fee required by Department Regulation 61–30 shall be paid. Registration must be done by verifying, correcting, and/or adding to the information provided in a request for registration received from the Department. The registration information must be submitted to the Department within 30 days of the date of the request for registration or as otherwise indicated in the request. In addition, a general licensee holding devices meeting the criteria of RHA 2.4.2.3.11.1 is subject to the bankruptcy notification requirement in RHA 2.10.6.

2.4.2.3.11.3 In registering devices, the general licensee shall furnish the following information and any other information specifically requested by the Department:

(i) Name and mailing address of the general licensee.

(ii) Information about each device: the manufacturer (or initial transferor), model number, serial number, the radioisotope and activity (as indicated on the label).

(iii) Name, title, and telephone number of the responsible person designated as a representative of the general licensee under RHA 2.4.2.3.10.

(iv) Address or location at which the device(s) are used and/or stored. For portable devices, the address of the primary place of storage.

(v) Certification by the responsible representative of the general licensee that the information concerning the device(s) has been verified through a physical inventory and checking of label information.

(vi) Certification by the responsible representative of the general licensee that they are aware of the requirements of the general license.

2.4.2.3.11.4 Persons generally licensed by the U.S. Nuclear Regulatory Commission with respect to devices meeting the criteria in RHA 2.4.2.3.11.1 are not subject to registration requirements if the devices are used in areas subject to Departmental jurisdiction for a period less than 180 days in any calendar year. The Department will not request registration information from such licensees.

2.4.2.3.12 Shall report changes to the mailing address for the location of use (including change in name of general licensee) to the Department within 30 days of the effective date of the change. For a portable device, a report of address change is only required for a change in the device's primary place of storage.

2.4.2.3.13 May not hold devices that are not in use for longer than 2 years. If devices with shutters are not being used, the shutter must be locked in the closed position. The testing required by RHA 2.4.2.3.2 need not be performed during the period of storage only. However, when devices are put back into service or transferred to another person, and have not been tested within the required test interval, they must be tested for leakage before use or transfer and the shutter tested before use. Devices kept in standby for future use are excluded from the two-year time limit if the general licensee performs quarterly physical inventories of these devices while they are in standby.

2.4.2.3.14 Shall not export the device containing radioactive material except in accordance with 10CFR part 110, Code of Federal Regulations;

2.4.2.3.15 Shall respond to written requests from the Department to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by providing the Chief of the Bureau of Radiological Health, SC Department of Health and Environmental Control, by an appropriate method listed in RHA 1.13 of this regulation, a written justification for the request.

2.4.2.4 The general license in RHA 2.4.2.1 does not authorize the manufacture or import of devices containing radioactive material.

2.4.2.5 The general license provided in RHA 2.4.2.1 is subject to the provisions of RHA 1.5 through 1.8, RHA 1.11, RHA 1.12, RHA 2.10, RHA 2.18, RHA 2.19, and RHA 2.22.

2.4.2.6 Any person who holds a specific license issued by the NRC or an Agreement State authorizing the holder to manufacture, install, or service a device described in RHA 2.4.2 through 2.4.2.5 is hereby granted a general license to install and service such device and a general license to install and service such device in South Carolina, provided that:

2.4.2.6.1 [Reserved]

2.4.2.6.2 The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the NRC or Agreement State.

2.4.2.6.3 Such person assures that any labels required to be affixed to the device under regulations of the NRC or Agreement State which licensed manufacture of the device bear a statement that removal of the label is prohibited.

2.4.3 General License for in Vitro Clinical or Laboratory Testing

2.4.3.1 A general license is hereby issued to any physician, veterinarian in the practice of veterinary medicine, clinical laboratory or hospital to receive, acquire, possess, transfer, or use, for any of the following stated tests, in accordance with the provisions of subparagraphs 2.4.3.2, 2.4.3.3, 2.4.3.4, 2.4.3.5, and 2.4.3.6 of this paragraph:

2.4.3.1.1 Iodine-125 in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

2.4.3.1.2 Iodine-131, in units not exceeding 10 microcuries each from use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

2.4.3.1.3 Carbon-14, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

2.4.3.1.4 Hydrogen-3 (tritium), in units not exceeding 50 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

2.4.3.1.5 Iron-59, in units not exceeding 20 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

2.4.3.1.6 Cobalt-57, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

2.4.3.1.7 Selenium-75, in units not to exceed 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom; to human beings or animals.

2.4.3.1.8 Mock Iodine-125 reference or calibration sources, in units not exceeding 0.05 microcurie of Iodine-129 and 0.005 microcurie of Americium-241 each for use in in vitro clinical or laboratory administration of radioactive material, or the radiation therefrom, to human beings or animals.

2.4.3.2 No person shall receive, acquire, possess, use or transfer radioactive material pursuant to the general license established by subparagraph 2.4.3.1 of this paragraph until he has filed Form RHA-100-1, "Certificate—In Vitro Testing with Radioactive Material Under General License," with the Department and received from the Department a validated copy of Form RHA-100-1 with a certification number assigned. The physician, veterinarian, clinical laboratory or hospital shall furnish on Form RHA-100-1 the following information and such other information as may be required by that form:

2.4.3.2.1 Name and address of the physician, veterinarian, clinical laboratory, or hospital;

2.4.3.2.2 The location of use; and,

2.4.3.2.3 A Statement that the physician, veterinarian, laboratory or hospital has appropriate radiation measuring instruments to carry out in vitro clinical or laboratory tests with radioactive materials as authorized under the general license in subparagraph 2.4.3.1 of this paragraph and that such tests will be performed only by personnel competent in the use of such instruments and in the handling of the radioactive materials.

2.4.3.3 A person who receives, acquires, possesses or uses radioactive material pursuant to the general license established by subparagraph 2.4.3.1 of this paragraph shall comply with the following:

2.4.3.3.1 The general licensee shall not possess at any one time, pursuant to the general license in subparagraph 2.4.3.1 of this paragraph, at any one location of storage or use a total amount of Iodine 125 and/or Iodine 131 in excess of 200 microcuries.

2.4.3.3.2 The general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection.

2.4.3.3.3 The general licensee shall use the radioactive material only for the uses authorized by subparagraph 2.4.3.1 of this paragraph.

2.4.3.3.4 The general licensee shall only transfer radioactive material to a person who is authorized to receive it pursuant to a license issued by the Department, the U.S. Nuclear Regulatory Commission, any Agreement State, or a Licensing State nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.

2.4.3.3.5 The general licensee shall dispose of the Mock Iodine-125 reference or calibration sources described in subparagraph 2.4.3.1.8 as required by RHA 3.12.

2.4.3.4 The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to subparagraph 2.4.3.1 of this paragraph:

2.4.3.4.1 Except as prepackaged units which are labeled in accordance with the provisions of a specific license issued under Paragraph 2.7.5 of this Part or in accordance with the provisions of a specific license issued by the U.S. Nuclear Regulatory Commission, any Agreement State, or a Licensing State which authorizes the manufacture of Iodine-125, Iodine-131 or Cobalt 57 for distribution to persons generally licensed under Paragraph 2.4.3 or its equivalent.

2.4.3.4.2 Unless the following statement, or a substantially similar statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

> This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for *in vitro* clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State.
>
> _____
>
> Name of Manufacturer

2.4.3.5 The physician, veterinarian, clinical laboratory or hospital possessing or using radioactive materials under the general license of subparagraph 2.4.3.1 of this paragraph shall report in writing to the Department, any changes in the information furnished by him in the "Certificate—In Vitro Testing With Radioactive Material Under General License," Form RHA-100-1. The report shall be furnished within 30 days after the effective date of such change.

2.4.3.6 Any person using radioactive material pursuant to the general license of subparagraph 2.4.3.1 of this paragraph is exempt from the requirements of Part III and Part VI of these regulations with respect to radioactive materials covered by that general license, except that such persons using the Mock Iodine-125 described in subparagraphs 2.4.3.1.8 shall comply with the provisions RHA 3.14, RHA 3.17, and RHA 3.18.

2.4.4 Luminous Safety Devices for Aircraft.

2.4.4.1 A general license is hereby issued to own, receive, acquire, possess and use tritium or promethium 147 contained in luminous safety devices for use in aircraft provided:

2.4.4.1.1 Each device contains not more than ten curies of tritium or 300 millicuries of promethium 147; and

2.4.4.1.2 Each device has been manufactured, assembled, or imported in accordance with a specific license issued by the United States Nuclear Regulatory Commission, or each device has been manufactured or assembled in accordance with the specifications contained in a specific license or equivalent licensing document issued by the Department or any Agreement State to the manufacturer or assembler of such device pursuant to licensing requirements equivalent to those

in Section 32.53 of 10 CFR Part 32 of the regulations of the United States Nuclear Regulatory Commission.

2.4.4.2 Persons who own, receive, acquire, possess, or use luminous safety devices pursuant to the general license in 2.4.4.1 are exempt from the requirements of Part III and Part VI, except that they shall comply with the provisions of RHA 3.17 and RHA 3.18.

2.4.4.3 This general license does not authorize the manufacture, assembly, or repair of luminous safety devices containing tritium or promethium 147.

2.4.4.4 This general license does not authorize the ownership, receipt, acquisition, possession, or use of promethium 147 contained in instrument dials.

2.4.4.5 The general license provided in RHA 2.4.4 is subject to the provisions of RHA 1.5 through RHA 1.8, RHA 1.12, RHA 1.13, RHA 2.10, RHA 2.18, RHA 2.19, and RHA 2.22.

2.4.5 Calibration and Reference Sources.

2.4.5.1 A general license is hereby issued to those persons listed below to own, receive, acquire, possess, use and transfer, in accordance with the provisions of 2.4.5.3, and 2.4.5.4, americium 241 in the form of calibration or reference sources:

2.4.5.1.1 Any person who holds a specific license issued by the Department which authorizes him to receive, possess, use, and transfer radioactive material; and

2.4.5.1.2 Any person who holds a specific license issued by the U. S. Nuclear Regulatory Commission which authorizes him to receive, possess, use, and transfer special nuclear material.

2.4.5.2 A general license is hereby issued to receive, possess, use and transfer, plutonium and radium 226 in the form of calibration or reference sources in accordance with the provisions of 2.4.5.3 and 2.4.5.4, to any person who holds a specific license issued by the Department which authorizes him to receive, possess, use, and transfer radioactive material.

2.4.5.3 The general licenses in paragraphs 2.4.5.1 and 2.4.5.2 of this subsection apply only to calibration or reference sources which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer or importer of the sources by the U.S. Nuclear Regulatory Commission pursuant to Section 32.57 of 10 CFR, Part 32, Section 70.39 of 10 CFR, Part 70 or which have been manufactured in accordance with the specifications contained in a specific license or equivalent licensing document issued to the manufacturer by the Department, any Agreement State, or a Licensing State pursuant to licensing requirements equivalent to those contained in Section 32.57 of 10 CFR, Part 32 or Section 70.39 of 10 CFR, Part 70 of the regulations of the U.S. Nuclear Regulatory Commission.

2.4.5.4 The general licenses in paragraphs 2.4.5.1 and 2.4.5.2 of this subsection are subject to the provisions of Section RHA 1.5 through RHA 1.8, RHA 1.12, RHA 1.13, RHA 2.10, RHA 2.18, RHA 2.19, RHA 2.22, Part III and Part VI of these regulations. In addition, persons who own, receive, acquire, possess, use and transfer one or more calibration or reference sources pursuant to these general licenses;

2.4.5.4.1 Shall not possess at any one time, at any one location of storage or use, more than 5 microcuries of americium 241, 5 microcuries of plutonium or 5 microcuries of radium 226 in such sources;

2.4.5.4.2 Shall not receive, possess, use or transfer such source unless the source or the storage container bears a label which includes the following statement or a substantially similar statement which contains the information called for in the following statement:

The receipt, possession, use and transfer of this source, Model ____, Serial No. ____, are subject to a general license and the regulations of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State. Do not remove this label.

CAUTION—RADIOACTIVE MATERIAL—THIS SOURCE CONTAINS (AMERICIUM 241). (PLUTONIUM).* DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____

(Name of Manufacturer of Importer)

* Showing only the name of the appropriate material.

2.4.5.4.3 Shall not transfer, abandon, or dispose of such source except by transfer to a person authorized by a license from the Department, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State to receive the source;

2.4.5.4.4 Shall store such source, except when the source is being used, in a closed container, adequately designed and constructed to contain americium 241, plutonium or radium 226 which might otherwise escape during storage; and,

2.4.5.4.5 Shall not use such source for any purpose other than the calibration of radiation detectors or the standardization of other sources.

2.4.5.5 These general licenses do not authorize the manufacture of calibration or reference sources containing americium 241, plutonium or radium 226.

2.4.6 Medical Diagnostic Uses.

2.4.6.1 A general license is hereby issued to any physician to receive, possess, transfer, or use for any of the following stated diagnostic uses, in accordance with the provisions of 2.4.6.2, 2.4.6.3, and 2.4.6.4, the following radioactive materials in capsules, disposable syringes, or other forms of prepackaged individual doses,** and the radioactive material has been manufactured in accordance with a specific license issued pursuant to RHA 2.7.4 by the Department, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State authorizing distribution under the general license granted in this paragraph or its equivalent:

2.4.6.1.1 Iodine 131 as sodium iodide (NaI-131) for measurement of thyroid uptake;

2.4.6.1.2 Iodine 131 as iodinated human serum albumin (IHSA) for determinations of blood and blood plasma volume;

2.4.6.1.3 Iodine 125 as iodinated human serum albumin (IHSA) for determinations of blood and blood plasma volume;

2.4.6.1.4 Cobalt 57 for the measurement of intestinal absorption of cyanocobalamin;

2.4.6.1.5 Cobalt 58 for the measurement of intestinal absorption of cyanocobalamin;

2.4.6.1.6 Cobalt 60 for the measurement of intestinal absorption of cyanocobalamin;

2.4.6.1.7 Chromium 51 as sodium radiochromate for determination of red blood cell volumes and studies of red blood cell survival time.

2.4.6.2 No physician shall receive, possess, use, or transfer radioactive material pursuant to the general license established by 2.4.6.1 until he has filed Form RHA-100, "Certificate-Medical Use of Radioactive Material Under General License" with the Department and received from the Department a validated copy of the Form RHA-100. The generally licensed physician shall furnish on Form RHA-100 the following information and such other information as may be required by that form;

2.4.6.2.1 Name and address of the generally licensed physician;

2.4.6.2.2 A statement that the generally licensed physician is a duly licensed physician authorized to dispense drugs in the practice of medicine in the State of South Carolina and specifying the license number; and,

2.4.6.2.3 A statement that the generally licensed physician has appropriate radiation measuring instruments to carry out the diagnostic procedures for which he proposed to use radioactive material under the general license of 2.4.6 and that he is competent in the use of such instruments.

2.4.6.3 A physician who receives, possesses or uses a pharmaceutical containing radioactive material pursuant to the general license established by 2.4.6.1 shall comply with the following:

2.4.6.3.1 He shall not possess at any one time pursuant to the general license in 2.4.6.1 more than:

2.4.6.3.1.1 200 microcuries of Iodine 131,

2.4.6.3.1.2 200 microcuries of Iodine 125,

2.4.6.3.1.3 5 microcuries of Cobalt 57

** Note: RHA 2.7.8 requires manufacturers of radiopharmaceuticals which are under the general license in this paragraph to affix a certain identifying label to the container or in the leaflet or brochure which accompanies the radiopharmaceutical.

2.4.6.3.1.4 5 microcuries of Cobalt 60, and

2.4.6.3.1.5 5 microcuries of Cobalt 58, and

2.4.6.3.1.6 200 microcuries of Chromium 51;

2.4.6.3.2 He shall store the pharmaceutical, until administered, in the original shipping container or a container providing the equivalent radiation protection;

2.4.6.3.3 He shall use the pharmaceutical only for the uses authorized by 2.4.6.1;

2.4.6.3.4 He shall not administer the pharmaceutical to a woman with confirmed pregnancy or to a person under 18 years of age;

2.4.6.3.5 He shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the Department, the U.S. Nuclear Regulatory Commission, any Agreement State, or a Licensing State, or in any manner other than in the unopened, labeled shipping container as received from the supplier, except by administering it to a patient.

2.4.6.4 The generally licensed physician possessing or using radioactive material under the general license of 2.4.6.1 shall report in duplicate to the Department, any changes in the information furnished by him in the "Certificate-Medical Use of Radioactive Material Under General License," Form RHA-100. The report shall be submitted within 30 days after the effective date of change.

2.4.6.5 Any person using radioactive material pursuant to the general license of 2.4.6.1 is exempt from the requirements of Part III and Part VI of these regulations with respect to the radioactive materials covered by the general license.

2.4.7 Ice Detection Devices.

2.4.7.1 A general license is hereby issued to own, receive, acquire, possess, use, and transfer strontium 90 contained in ice detection devices, provided each device contains not more than fifty microcuries of strontium 90 and each device has been manufactured or imported in accordance with a specific license issued by the U. S. Nuclear Regulatory Commission or each device has been manufactured in accordance with specifications contained in a specific license or equivalent licensing document issued by the Department or any agreement state to the manufacturer of such device pursuant to licensing requirements equivalent to those in Section 32.61 of CFR 32 of the regulations of the U. S. Nuclear Regulatory Commission.

2.4.7.2 Persons who own, receive, acquire, possess, use or transfer strontium 90 contained in ice detection devices pursuant to the general license in paragraph 2.4.7.1:

2.4.7.2.1 Shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating, to the device, discontinue use of the device until it has been inspected, tested for leakage and repaired by a person holding a specific license or equivalent licensing document from the U. S. Nuclear Regulatory Commission or agreement state to manufacture or service such devices; or shall dispose of the device pursuant to the provisions of this regulation;

2.4.7.2.2 Shall assure that all labels affixed to the device at the time of receipt, and which bear a statement which prohibits removal of the labels, are maintained thereon; and

2.4.7.2.3 Are exempt from the requirements of Part III and Part VI except that such persons shall comply with the provisions of Sections RHA 3.12, RHA 3.17, and RHA 3.18 of these regulations.

2.4.7.3 This general license does not authorize the manufacture, assembly, disassembly, or repair of strontium 90 in ice detection devices.

2.4.7.4 The general license provided in this paragraph is subject to the provisions of Sections RHA 1.5, through RHA 1.8, RHA 1.11, RHA 1.12, RHA 2.10, RHA 2.18, RHA 2.19, and RHA 2.22.

2.4.8 Self-Luminous Products Containing Ra-226

2.4.8.1 A general license is hereby issued to any person to acquire, receive, possess, use, or transfer, in accordance with the provisions of paragraphs 2.4.8.2, 2.4.8.3, and 2.4.8.4 of this section, Radium-226 contained in the following products manufactured prior to November 30, 2007.

2.4.8.1.1 Antiquities originally intended for use by the general public. For the purposes of this paragraph, antiquities mean products originally intended for use by the general public and

distributed in the late 19th and early 20th centuries, such as radium emanator jars, revigators, radium water jars, radon generators, refrigerator cards, radium bath salts, and healing pads.

2.4.8.1.2 Intact timepieces containing greater than 0.037 megabecquerel (1 microcurie), nonintact timepieces, and timepiece hands and dials no longer installed in timepieces.

2.4.8.1.3 Luminous items installed in air, marine, or land vehicles.

2.4.8.1.4 All other luminous products, provided that no more than 100 items are used or stored at the same location at any one time.

2.4.8.1.5 Small radium sources containing no more than 0.037 megabecquerel (1 microcurie) of Radium-226. For the purposes of this paragraph, "small radium sources" means discrete survey instrument check sources, sources contained in radiation measuring instruments, sources used in educational demonstrations (such as cloud chambers and spinthariscopes), electron tubes, lightning rods, ionization sources, static eliminators, or as designated by the NRC.

2.4.8.2 Persons who acquire, receive, possess, use, or transfer byproduct material under the general license issued in 2.4.8.1 of this section are exempt from the provisions of Parts 3 and 6 of this Regulation, to the extent that the receipt, possession, use, or transfer of byproduct material is within the terms of the general license; provided, however, that this exemption shall not be deemed to apply to any such person specifically licensed under this chapter.

2.4.8.3 Any person who acquires, receives, possesses, uses, or transfers byproduct material in accordance with the general license in 2.4.8.1 of this section:

2.4.8.3.1 Shall notify the Department should there be any indication of possible damage to the product so that it appears it could result in a loss of the radioactive material. A report containing a brief description of the event, and the remedial action taken, must be furnished to the Director of the Division of Waste Management, South Carolina Department of Health & Environmental Control, 2600 Bull Street, Columbia SC, 29201 within 30 days.

2.4.8.3.2 Shall not abandon products containing Radium-226. The product, and any radioactive material from the product, may only be disposed of according to Part 3 of this Regulation or by transfer to a person authorized by a specific license to receive the Radium- 226 in the product or as otherwise approved by the Department.

2.4.8.3.3 Shall not export products containing Radium-226 except in accordance with this Regulation.

2.4.8.3.4 Shall dispose of products containing Radium-226 at a disposal facility authorized to dispose of radioactive material in accordance with any Federal or State solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005, by transfer to a person authorized to receive Radium-226 by a specific license issued under this Regulation, or equivalent regulations of an Agreement State, or as otherwise approved by the Department.

2.4.8.3.5 Shall respond to written requests from the Department to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by providing the Director of the Division of Waste Management, South Carolina Department of Health & Environmental Control, 2600 Bull Street, Columbia SC, 29201, a written justification for the request.

2.4.8.4 The general license in paragraph 2.4.8.1 of this section does not authorize the manufacture, assembly, disassembly, repair, or import of products containing Radium-226, except that timepieces may be disassembled and repaired.

HISTORY: Amended by State Register Volume 38, Issue No. 10, Doc. No. 4462, eff October 24, 2014; SCSR 42–2 Doc. No. 4791, eff February 23, 2018.

Editor's Note

Scrivener errors corrected in 2012.

RHA 2.5. Filing of Application for Specific Licenses.

2.5.1 Applications for specific licenses shall be filed on a form prescribed by the Department. The applicant shall set forth all applicable information called for by the form.

2.5.2 The Department may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the Department to determine whether the application should be granted or denied or whether a license should be modified or revoked. Prelicensing visits may be made to the applicant's facility for purpose of amplying information furnished in the original application.

2.5.3 Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on his behalf.

2.5.4 An application for a license may include a request for a license authorizing one or more activities.

2.5.5 In his application, the applicant may incorporate by reference information contained in previous applications, statements, or reports filed with the Department provided such references are clear and specific.

2.5.6 Applications and documents submitted to the Department may be made available for public inspection except that the Department may withhold upon request, any document or part thereof from public inspection if disclosure of its contents is not required in the public interest and would adversely affect the interest of a person concerned.

2.5.7 Application for a specific license in form of sealed source.

2.5.7.1 Except as provided in RHA 2.5.7.2, 2.5.7.3, and 2.5.7.4, an application for a specific license to use byproduct material in the form of a sealed source or in a device that contains the sealed source must either—

2.5.7.1.1 Identify the source or device by manufacturer and model number as registered with the Department under RHA 2.29 or comparable regulation, or for a source or a device containing radium 226 or accelerator-produced radioactive material with a State under provisions comparable to RHA 2.29; or

2.5.7.1.2 Contain the information identified in RHA 2.29.

2.5.7.2 For sources or devices manufactured before October 23, 2012 that are not registered with the Commission under 10 CFR 32.210 or with an Agreement State, and for which the applicant is unable to provide all categories of information specified in RHA 2.29, the application must include:

2.5.7.2.1 All available information identified in RHA 2.29 concerning the source, and, if applicable, the device; and

2.5.7.2.2 Sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Such information must include a description of the source or device, a description of radiation safety features, the intended use and associated operating experience, and the results of a recent leak test.

2.5.7.3 For sealed sources and devices allowed to be distributed without registration of safety information in accordance with RHA 2.29, the applicant may supply only the manufacturer, model number, and radionuclide and quantity.

2.5.7.4 If it is not feasible to identify each sealed source and device individually, the applicant may propose constraints on the number and type of sealed sources and devices to be used and the conditions under which they will be used, in lieu of identifying each sealed source and device.

2.5.8 An application from a medical facility, educational institution, or Federal facility to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to licensees in its consortium authorized for medical use under Part 4 of this Regulation shall include:

2.5.8.1 A request for authorization for the production of PET radionuclides or evidence of an existing license issued under Part 2 of this Regulation for a PET radionuclide production facility within its consortium from which it receives PET radionuclides.

2.5.8.2 Evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in Part 2 of this Regulation.

2.5.8.3 Identification of individual(s) authorized to prepare the PET radioactive drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an authorized nuclear pharmacist as specified in Part 2 of this Regulation.

2.5.8.4 Information identified in Part 2 of this Regulation on the PET drugs to be noncommercially transferred to members of its consortium.

HISTORY: Amended by State Register Volume 38, Issue No. 10, Doc. No. 4462, eff October 24, 2014.

RHA 2.6. General Requirements for the Issuance of Specific Licenses.

A license application will be approved if the Agency determines that:

2.6.1 The applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with these regulations and in such a manner as to protect health and minimize danger to life and property; and

2.6.2 The applicant's proposed equipment, facilities, and procedures are adequate to protect health and minimize danger to life and property; and

2.6.3 The issuance of the license will not be inimical to the health and safety of the public; and

2.6.4 The applicant satisfies any applicable special requirements in RHA 2.7 and RHA 2.8.

RHA 2.7. Special Requirements for Issuance of Certain Specific Licenses for Radioactive Materials.

2.7.1 Licensing the Manufacture and the Distribution of Devices to Persons Generally Licensed under RHA 2.4.2.

2.7.1.1 An application for a specific license to manufacture or distribute devices containing radioactive material, excluding special nuclear material, to persons generally licensed under RHA 2.4.2 or equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State will be approved if:

2.7.1.1.1 the applicant satisfies the general requirements of RHA 2.6;

2.7.1.1.2 the applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:

2.7.1.1.2.1 the device can be safely operated by persons not having training in radiological protection;

2.7.1.1.2.2 Under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in one year a dose in excess of 10% of the annual limits specified in RHA 3.5.1; and

2.7.1.1.2.3 under accident conditions (such as fire and explosion) associated with handling, storage, and the use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the following organ doses: Whole body: 15 rems head and trunk; active bloodforming organs; gonads; or lens of eye: Hands and forearms; 200 rems feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter. Other organs 50 rems.

2.7.1.1.3 Each device bears a durable, legible, clearly visible label or labels approved by the Department, which contain in a clearly identified and separate statement:

2.7.1.1.3.1 instructions and precautions necessary to assure safe installation, operation, and servicing of the device (documents such as operating and service manuals may be identified in the label and used to provide this information);

2.7.1.1.3.2 the requirement, or lack of requirement, for leak testing, or for testing any on-off mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by isotope, quantity of radioactivity, and date of determination of the quantity; and

2.7.1.1.3.3 The information called for in the following statement in the same or substantially similar form:

Receipt, possession, use, and transfer of this device Mode [3*], Serial No [3*], containing (Identity and quantity of radioactive material) are subject to a general license or the equivalent and the

[3*] The model, serial number, and name of manufacturer, assembler, or initial transferor may be omitted from this label provided they are elsewhere specified in labeling affixed to the device.

regulations of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION–RADIOACTIVE MATERIAL

(Name of manufacturer or initial transferor)[3*]

2.7.1.1.4 Each device having a separable source housing that provides the primary shielding for the source also bears, on the source housing, a durable label containing the device model number and serial number, the isotope and quantity, the words, "Caution–Radioactive Material," the radiation symbol described in RHA 3.21, and the name of the manufacturer or initial distributor.

2.7.1.1.5 Each device meeting the criteria of RHA 2.4.2.3.11.1 bears a permanent (e.g., embossed, etched, stamped, or engraved) label affixed to the source housing if separable, or the device if the source housing is not separable, that includes the words, "Caution–Radioactive Material," and, if practicable the radiation symbol described in RHA 3.21.

2.7.1.1.6 The device has been registered in the Sealed Source and Device Registry.

2.7.1.2 In the event the applicant desires that the device be required to be tested at intervals longer than six months, either for proper operation of the on-off mechanism and indicator, if any, or for leakage of radioactive material or for both, he shall include in his application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices and by design features which have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the on-off mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the Department will consider information which includes, but is not limited to:

2.7.1.2.1 primary containment (source capsule);

2.7.1.2.2 protection of primary containment;

2.7.1.2.3 method of sealing containment;

2.7.1.2.4 containment construction materials;

2.7.1.2.5 form of contained radioactive material;

2.7.1.2.6 maximum temperature withstood during prototype test;

2.7.1.2.7 maximum pressure withstood during prototype tests;

2.7.1.2.8 maximum quantity of contained radioactive material;

2.7.1.2.9 radiotoxicity of contained radioactive material; and

2.7.1.2.10 operating experience with identical devices or similarly designed and constructed devices.

2.7.1.3 In the event the applicant desires that the general licensee under RHA 2.4.2, or under the equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the on-off mechanism and indicator, or remove the device from installation, he shall include in his application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and bases for such estimates. The submitted information shall demonstrate that performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a calendar quarter dose in excess of 10% of the limits specified in the table in RHA 3.2.1.

2.7.1.4 If a device containing radioactive material is to be transferred for use under the general license contained in RHA 2.4.2 of this part, each person that is licensed under RHA 2.7.1 shall provide the information specified in this paragraph to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes—

2.7.1.4.1 A copy of the general license contained in RHA 2.4.2; if RHA 2.4.2.3.2 through 2.4.2.3.4 or RHA 2.4.2.3.11 do not apply to the particular device, those paragraphs may be omitted.

2.7.1.4.2 A copy of RHA 2.4.1, 2.18, 3.44, and 3.45 of this part;

2.7.1.4.3 A list of the services that can only be performed by a specific licensee;

2.7.1.4.4 Information on acceptable disposal options including estimated costs of disposal; and

2.7.1.4.5 An indication that the Department's policy is to issue high civil penalties for improper disposal.

2.7.1.5 If radioactive material is to be transferred in a device for use under an equivalent general license of the NRC or an Agreement State, each person that is licensed under RHA 2.7.1 shall provide the information specified in this paragraph to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes—

2.7.1.5.1 A copy of the NRC or Agreement State or regulations equivalent to RHA 2.4.1, 2.4.2, 2.18, 3.44 and 3.45 of this part or a copy of these Agreement State regulations. If a copy of the Department's regulations is provided to a prospective general licensee in lieu of the NRC regulations, it shall be accompanied by a note explaining that use of the device is regulated by the NRC or other Agreement State; if certain paragraphs of the regulations do not apply to the particular device, those paragraphs may be omitted.

2.7.1.5.2 A list of the services that can only be performed by a specific licensee;

2.7.1.5.3 Information on acceptable disposal options including estimated costs of disposal; and

2.7.1.5.4 The name or title, address, and phone number of the contact at the appropriate regulatory agency, NRC or Agreement State, having jurisdiction at the devices new location, from which additional information may be obtained.

2.7.1.6 An alternative approach to informing customers may be proposed by the licensee for approval by the Department.

2.7.1.7 Each device that is transferred after February 2004 must meet the labeling requirements in RHA 2.7.1.4.3 through 2.7.1.4.5.

2.7.1.8 If a notification of bankruptcy has been made under RHA 2.10.6 or the license is to be terminated, each person licensed under RHA 2.7.1 shall provide, upon request, to the Department and to the appropriate regulatory agency, NRC or Agreement State, having jurisdiction at the devices new location, records of final disposition required under RHA 2.7.1.9.2.

2.7.1.9 Each person licensed under RHA 2.7.1 to initially transfer devices to generally licensed persons shall comply with the requirements of this section.

2.7.1.9.1 The person shall report all transfers of devices to persons for use under the general license in RHA 2.4.2 of these regulations and for use under equivalent NRC regulations (10 CFR 31.5) or other Agreement State's regulations and all receipts of devices from persons licensed under RHA 2.4.2 to the Department or to the appropriate NRC office or other Agreement State office. The report must be submitted on a quarterly basis on NRC Form 653—"Transfers of Industrial Devices Report" or in a clear and legible report containing all of the data required by the form. (NRC Form 653 may be obtained from the Department or found in NUREG–1556, Vol. 16.)

2.7.1.9.1.1 The required information for transfers to general licensees includes—

(i) The identity of each general licensee by name and mailing address for the location of use; if there is no mailing address for the location of use, an alternate address for the general licensee shall be submitted along with information on the actual location of use.

(ii) The name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;

(iii) The date of transfer;

(iv) The type, model number, and serial number of the device transferred; and

(v) The quantity and type of radioactive material contained in the device.

2.7.1.9.1.2 If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).

2.7.1.9.1.3 For devices received from a general licensee, the report must include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

2.7.1.9.1.4 If the licensee makes changes to a device possessed by a general licensee, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the changes to information on the device label.

2.7.1.9.1.5 The report must cover each calendar quarter, must be filed within 30 days of the end of the calendar quarter, and must clearly indicate the period covered by the report.

2.7.1.9.1.6 The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

2.7.1.9.1.7 If no transfers have been made to or from persons generally licensed under RHA 2.4.2 during the reporting period, the report must so indicate. If no transfers have been made to or from an NRC or other Agreement State during the reporting period, this information should be made available to the responsible agency upon their request.

2.7.1.9.2 The person shall maintain all information concerning transfers and receipts of devices that supports the reports required by this section. Records required by this paragraph must be maintained for a period of 3 years following the date of the recorded event.

2.7.2 Licensing the Introduction of Radioactive Material Into Products in Exempt Concentration

In addition to the requirements set forth in RHA 2.6, a specific license authorizing the introduction of radioactive material into a product or material owned by or in the possession of a licensee or another to be transferred to persons exempt under 2.20.2.1.1 will be issued only if:

2.7.2.1 The applicant submits a description of the product or material into which the radioactive material will be introduced, intended use of the radioactive material and the product or material into which it is introduced, method of introduction, initial concentration of the radioactive material in the product or material, control methods to assure that no more than the specified concentration is introduced into the product or material, estimated time interval between introduction and transfer of the radioactive material in the product or material at the time of transfer; and

2.7.2.2 The applicant provides reasonable assurance that the concentrations of radioactive material at the time of transfer will not exceed the concentrations in RHA 2.25 Schedule C, that reconcentration of the radioactive material in concentrations exceeding those in RHA 2.25 Schedule C is not likely, that use of lower concentrations is not feasible, and that the product or material is not likely to be incorporated in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being. Each person licensed under this section 2.7.2 shall file an annual report with the Department which shall identify the type and quantity of each product or material into which radioactive material has been introduced during the reporting period; name and address of the person who owned or possessed the product or material, into which radioactive material has been introduced, at the time of introduction; the type and quantity of radionuclide introduced into each such product or material; and the initial concentrations of the radionuclide in the product or material at time of transfer of the radioactive material by the licensee. If no transfers of radioactive material have been made pursuant to this section 2.7.2 during the reporting period, the report shall so indicate. The report shall cover the year ending June 30, and shall be filed within 30 days thereafter.

2.7.3 Manufacture and Distribution of Radioactive Materials for Medical Use Under General License.

In addition to the requirements set forth in RHA 2.6 above, a specific license authorizing the distribution of radioactive material for use by physicians under the general license of 2.4.6 will be issued only if:

2.7.3.1 The applicant submits evidence that the radioactive material is to be manufactured, labeled and packaged in accordance with a new drug application Administration has approved, or in accordance with a license for a biologic product issued by the Secretary, Department of Health, Education, and Welfare; and,

2.7.3.2 The following statement, or a substantially similar statement which contains information called for in the following statement, appears on the label affixed to the container or appears in the leaflet or brochure which accompanies the package: "This radioactive drug may be received, possessed, and used only by physicians licensed to dispense drugs in the practice of medicine. Its receipt, possession, use and transfer are subject to the regulations and a general license (or the equivalent) of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State."

_____

(Name of Manufacturer)

2.7.4 Manufacture and Distribution of Radioactive Materials for Certain In Vitro Clinical, or Laboratory Testing Under General License

An application for a specific license to manufacture or distribute radioactive material for use under the general license of 2.4.3 of this part will be applied if:

2.7.4.1 The applicant satisfies the general requirements specified in RHA 2.6.

2.7.4.1.1 Has specialized training in the diagnostic or therapeutic use of the sealed source considered or has experience equivalent to such training, and

2.7.4.1.2 Is a physician.

2.7.4.2 The radioactive material is to be prepared for distribution in prepackaged units of:

2.7.4.2.1 Iodine-125 in units not exceeding 10 microcuries each.

2.7.4.2.2 Iodine-131 in units not exceeding 10 microcuries each.

2.7.4.2.3 Carbon-14 in units not exceeding 10 microcuries each.

2.7.4.2.4 Hydrogen-3 (tritium) in units not exceeding 50 microcuries each.

2.7.4.2.5 Iron-59 in units not exceeding 20 microcuries each.

2.7.4.2.6 Cobalt-57 in units not exceeding 10 microcuries (0.37 MBq) each.

2.7.4.2.7 Selenium-75 in units not exceeding 10 microcuries each.

2.7.4.2.8 Mock Iodine-125 in units not exceeding 0.05 microcuries of Iodine 129 and 0.005 microcuries of Americium 241 each.

2.7.4.3 Each prepackage unit bears a durable, clearly visible label:

2.7.4.3.1 Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 10 microcuries (0.37 MBq) of Iodine-125, Iodine-131, Selenium-75, or Carbon-14; 50 microcuries (1.85 MBq) of Hydrogen-3 (tritium); or 20 microcuries (0.74 MBq) of Iron-59; or Mock Iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of Iodine-129 and 0.005 microcurie (0.185 kBq) of Americium-241 each; or Cobalt-57 in units not exceeding 10 microcuries (0.37 MBq); and

2.7.4.3.2 Displaying the radiation caution symbol described in RHA 3.8 (3.8.1) of Part III and the words, "CAUTION, RADIOACTIVE MATERIAL," and "Not for Internal or External Use in Humans or Animals."

2.7.4.4 The following statement, or substantially similar statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package.

"This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians in the practice of veterinary medicine, clinical laboratories, or hospitals and only for In Vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition,

possession, use and transfer are subject to the regulations and a general license of the United States Nuclear Regulatory Commission, an Agreement State, or a licensing State."

_____

Name of Manufacturer

2.7.4.5 The label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such radioactive material. In the case of the Mock Iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements set out in RHA 3.12.

2.7.5 Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing radioactive material for medical use under Part IV.

2.7.5.1 An application for a specific license to manufacture, prepare, or transfer for commercial distribution radioactive drugs containing radioactive material for use by persons licensed pursuant to Part IV of these regulations will be approved if:

2.7.5.1.1 The applicant satisfies the general requirements specified in RHA 2.6;

2.7.5.1.2 The applicant submits evidence that the applicant is at least one of the following:

2.7.5.1.2.1 Registered with the U.S. Food and Drug Administration (FDA) as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR 207.20(a);

2.7.5.1.2.2 Licensed as a pharmacy by a State Board of Pharmacy;

2.7.5.1.2.3 Operating as a nuclear pharmacy within a Federal medical institution; or

2.7.5.1.2.4 A Positron Emission Tomography (PET) drug production facility registered with a State agency.

2.7.5.1.3 The applicant submits information on the radionuclide; the chemical and physical form; the maximum activity per vial, syringe, generator, or other container of the radioactive drug; and the shielding provided by the packaging to show it is appropriate for the safe handling and storage of the radioactive drugs by medical use licensees; and

2.7.5.1.4 The applicant commits to the following labeling requirements:

2.7.5.1.4.1 A label is affixed to each transport radiation shield, whether it is constructed of lead glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL"; the name of the radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half life greater than 100 days, the time may be omitted.

2.7.5.1.4.2 A label is affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER RADIOACTIVE MATERIAL" and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

2.7.5.2 A licensee described by paragraph 2.7.5.1.2.3 or 2.7.5.1.2.4 of this section:

2.7.5.2.1 May prepare radioactive drugs for medical use, as defined in RHA 4.2 provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in 2.7.5.2.2 and 2.7.5.2.4 of this section, or an individual under the supervision of an authorized nuclear pharmacist as specified in RHA 4.15.

2.7.5.2.2 May allow a pharmacist to work as an authorized nuclear pharmacist if:

2.7.5.2.2.1 This individual qualifies as an authorized nuclear pharmacist as defined in RHA 4.2.

2.7.5.2.2.2 This individual meets the requirements specified in Part 4 of this Regulation, and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist; or

2.7.5.2.2.3 This individual is designated as an authorized nuclear pharmacist in accordance with 2.7.5.2.4 of this section.

2.7.5.2.3 The actions authorized in 2.7.5.2.1 and 2.7.5.2.2 of this section are permitted in spite of more restrictive language in license conditions.

2.7.5.2.4 May designate a pharmacist (as defined in RHA 4.2) as an authorized nuclear pharmacist if:

2.7.5.2.4.1 The individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material; and

2.7.5.2.4.2 The individual practiced at a pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the NRC.

2.7.5.2.5 Shall provide to the Department:

2.7.5.2.5.1 A copy of each individual's certification by a specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State as specified in RHA 4.22.1; or

2.7.5.2.5.2 The Commission or Agreement State license; or

2.7.5.2.5.3 Commission master materials licensee permit; or

2.7.5.2.5.4 The permit issued by a licensee or Commission master materials permittee of broad scope or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist; or

2.7.5.2.5.5 Documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC; and

2.7.5.2.5.6 A copy of the State pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, under paragraphs RHA 2.7.5.2.2.1 and 2.7.5.2.2.3, the individual to work as an authorized nuclear pharmacist.

2.7.5.3 A licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radioactive drugs prior to transfer for commercial distribution. In addition, the licensee shall:

2.7.5.3.1 Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and

2.7.5.3.2 Check each instrument for constancy and proper operation at the beginning of each day of use.

2.7.5.4 A licensee shall satisfy the labeling requirements in paragraph 2.7.5.1.4 of this section.

2.7.5.5 Nothing in this section relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

2.7.6 [Deleted]

2.7.7 Manufacture and Distribution of Sources or Devices Containing Radioactive Material for Medical Use

2.7.7.1 An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to Part IV of these regulations for use as a calibration, transmission, or reference source or for the uses listed in RHA 4.46, 4.56, 4.58 and 4.88 of Part IV of these regulations will be approved if:

2.7.7.1.1 The applicant satisfies the general requirements in RHA 2.6 of this Part; and

2.7.7.1.2 The applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:

2.7.7.1.2.1 The radioactive material contained, its chemical and physical form, and amount;

2.7.7.1.2.2 Details of design and construction of the source or device;

2.7.7.1.2.3 Procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents;

2.7.7.1.2.4 For devices containing radioactive material, the radiation profile of a prototype device;

2.7.7.1.2.5 Details of quality control procedures to assure that production sources and devices meet the standards of design and prototype tests;

2.7.7.1.2.6 Procedures and standards for calibrating sources and devices;

2.7.7.1.2.7 Legend and methods for labeling sources and devices as to their radioactive content;

2.7.7.1.2.8 Instruction for handling and storing the source or device from the radiation safety standpoint; these instructions are to be included on a durable label attached to a permanent storage container for the source or device; provided, that instructions which are too lengthy for such label may be summarized on the label and printed in detail on a brochure which is referenced on the label;

2.7.7.1.3 The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity, and date of assay, and a statement that (insert name of source or device) is licensed by the Department for distribution to persons licensed pursuant to RHA 4.28, RHA 4.46, 4.56 and 4.58 of Part IV of these regulations or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State.

2.7.7.1.4 The source or device has been registered in the Sealed Source and Device Registry.

2.7.7.2 In the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than six months, he shall include in his application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source. In determining the acceptable interval for test of leakage of radioactive material, the Department will consider information that includes, but is not limited to:

2.7.7.2.1 Primary containment (source capsule);

2.7.7.2.2 Protection of primary containment;

2.7.7.2.3 Method of sealing containment;

2.7.7.2.4 Containment construction materials;

2.7.7.2.5 Form of contained radioactive material;

2.7.7.2.6 Maximum temperature withstood during prototype tests;

2.7.7.2.7 Maximum pressure withstood during prototype tests;

2.7.7.2.8 Maximum quantity of contained radioactive material;

2.7.7.2.9 Radiotoxicity of contained radioactive material; and

2.7.7.2.10 Operating experience with identical sources or devices or similarly designed and constructed sources or devices.

2.7.7.3 If an application is filed pursuant to RHA 2.7.7.1 on or before August 9, 1977, for a license to manufacture and distribute a source or device that was distributed commercially on or before July 9, 1977, the applicant may continue the distribution of such source or device to authorized licenses until the Department issues the license or notifies the applicant otherwise.

2.7.8 Manufacture and distribution of radioactive materials for medical use under general license. In addition to the requirements set forth in RHA 2.6 above, a specific license authorizing the distribution of radioactive material for use by physicians under the general license of 2.4.6 will be issued only if:

2.7.8.1 The applicant submits evidence that the radioactive material is to be manufactured, labeled and packaged in accordance with a new drug application which the Commissioner of Food

and Drug Administration, has approved, or in accordance with a license for a biologic product issued by the Secretary, Department of Health, Education, and Welfare; and,

2.7.8.2 The following statement, or a substantially similar statement which contains information called for in the following statement, appears on the label affixed to the container or appears in the leaflet or brochure which accompanies the package:

"This radioactive drug may be received, possessed, and used only by physicians licensed to dispense drugs in the practice of medicine. Its receipt, possession, use and transfer are subject to the regulations and a general license or the equivalent of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State.

_____

(Name of Manufacturer)

2.7.9 Manufacture and Distribution of Radioactive Materials for Certain in Vitro Clinical, or Laboratory Testing Under General License. An application for a specific license to manufacture or distribute radioactive material for use under the general license of 2.4.3 of this Part will be approved if:

2.7.9.1 The applicant satisfies the general requirements specified in RHA 2.6.

2.7.9.2 The radioactive material is to be prepared for distribution in prepackaged units of:

2.7.9.2.1 Iodine 125 in units not exceeding 10 microcuries each.

2.7.9.2.2 Iodine 131 in units not exceeding 10 microcuries each.

2.7.9.2.3 Carbon 14 in units not exceeding 10 microcuries each.

2.7.9.2.4 Hydrogen 3 (tritium) in units not exceeding 50 microcuries each.

2.7.9.2.5 Iron 59 in units not exceeding 20 microcuries each.

2.7.9.2.6 Cobalt-57 in units not exceeding 10 microcuries each.

2.7.9.2.7 Selenium-75 in units not exceeding 10 microcuries each.

2.7.9.2.8 Mock Iodine-125 in units not exceeding 0.05 microcuries of Iodine-129 and 0.005 microcuries of Americium-241 each.

2.7.9.3 Each prepackaged unit bears a durable, clearly visible label:

2.7.9.3.1 Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 10 microcuries of iodine-125, Iodine-131, Carbon-14, Cobalt-57, Selenium-75; 50 microcuries of Hydrogen-3; 20 microcuries of Iron-59; or Mock Iodine-125 in units not exceeding 0.05 microcurie of Iodine-129 and 0.005 microcurie of Americium-241 each; and

2.7.9.3.2 Displaying the radiation caution symbol described in RHA 3.8 (3.8.1) of Part III and the words, "CAUTION, RADIOACTIVE MATERIAL," and "Not for Internal or External Use in Humans or Animals."

2.7.9.4 The following statement, or a substantially similar statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package.

This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians in the practice of veterinary medicine, clinical laboratories, or hospitals and only for **In Vitro** clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of the United States Nuclear Regulatory Commission, an Agreement State, or a Licensing State.

_____

Name of Manufacturer

2.7.9.5 The label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such radioactive material.

2.7.10 Manufacture and Distribution of Radiopharmaceuticals Containing Radioactive Material for Medical Use Under Group Licenses.

2.7.10.1 An application for a specific license to manufacture and distribute radiopharmaceuticals containing radioactive material for use by persons licensed pursuant to RHA 2.7.3 for the uses listed in Group I, Group II, IV, or V of RHA 2.26 Schedule D of this part will be approved if:

2.7.10.1.1 The applicant satisfies the general requirements specified in RHA 2.6 of this part;

2.7.10.1.2 The applicant submits evidence that:

2.7.10.1.2.1 The radiopharmaceutical containing radioactive material will be manufactured, labeled and packed in accordance with the Federal Food, Drug and Cosmetic Act or the Public Health Service Act, such as a new drug application (NDA) approved by the Food and Drug Administration (FDA), a biologic product license issued by FDA or a "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by the FDA; or

2.7.10.1.2.2 The manufacture and distribution of the radiopharmaceutical containing radioactive material is not subject to the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act.

2.7.10.1.3 The applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material which is appropriate for safe handling and storage of radiopharmaceuticals by group licensees; and

2.7.10.1.4 The label affixed to each package of the radiopharmaceutical contains information on the radionuclide, quantity, and date of assay and the label affixed to each package, or the leaflet or brochure which accompanies each package, contains a statement that the radiopharmaceutical is licensed by the Department for distribution to persons licensed pursuant to RHA 2.7.3 and RHA 2.26 Schedule D, Group I, Group II, Group IV, and V of Part II, as appropriate, or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State or that an application for such license has been filed with the Department on or before August 9, 1977 and is still pending.

The labels, leaflets, or brochures required by this paragraph are in addition to the labeling required by the Food and Drug Administration (FDA) and they may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA.

2.7.10.2 If an application is filed pursuant to RHA 2.7.10.1 on or before ** [Aug. 9, 1977], for a license to manufacture and distribute a radiopharmaceutical that was distributed commercially on or before * the applicant may continue the distribution of such radiopharmaceutical to group licensees until the Department issues the license or notifies the applicant otherwise.

2.7.11 Manufacture and Distribution of Generators or Reagent Kits for Preparation of Radiopharmaceuticals Containing Radioactive Material.

2.7.11.1 An application for a specific license to manufacture and distribute generators or reagent kits containing radioactive material for preparation of radiopharmaceuticals by persons licensed pursuant to RHA 2.7.3 for the uses listed in Group III of RHA 2.26 Schedule D of this part will be approved if:

2.7.11.1.1 The applicant satisfies the general requirements specified in RHA 2.6 of this part;

2.7.11.1.2 The applicant submits evidence that:

The generator or reagent kit is to be manufactured, labeled and packaged in accordance with the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act, such as a new drug application (NDA) approved by the Food and Drug Administration (FDA), a biologic product license issued by FDA, or a "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by the FDA; or

The manufacture and distribution of the generator or reagent kit are not subject to the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act.

2.7.11.1.3 The applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material contained in the generator or reagent kit;

** Adoption date of these Regulatory changes

* 30 days prior to adoption date

2.7.11.1.4 The label affixed to the generator or reagent kit contains information on the radionuclide, quantity, and date of assay; and

2.7.11.1.5 The label affixed to the generator or reagent kit, or the leaflet or brochure which accompanies the generator or reagent kit, contains:

2.7.11.1.5.1 Adequate information, from a radiation safety standpoint, on the procedures to be followed and the equipment and shielding to be used in eluting the generator or processing radioactive material with the reagent kit, and

2.7.11.1.5.2 A statement that this generator reagent kit (as appropriate) is approved for use by persons licensed by the Department pursuant to RHA 2.7.3 and RHA 2.26 Schedule D, Group III of Part II or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State or that an application for such license has been filed with the Department on or before August 9, 1977 and is still pending. The labels, leaflets or brochures required by this paragraph are in addition to the labeling required by FDA and they may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA.

2.7.11.2 If an application is filed pursuant to RHA 2.7.11.1 on or before ** [Aug. 9, 1977], for a license to manufacture and distribute a generator or reagent kit that was distributed commercially on or before * the applicant may continue the distribution of such generator or reagent kit until the Department issues the license or notifies the applicant otherwise.

2.7.12 Manufacture and Distribution of Sources or Devices Containing Radioactive Material for Medical Use.

2.7.12.1 An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to RHA 2.7.3 for use as a calibration or reference source or for the uses listed in Group VI of RHA 2.26 Schedule D of this part will be approved if:

2.7.12.1.1 The applicant satisfies the general requirements in RHA 2.6 of this Part; and

2.7.12.1.2 The applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:

NOTE: Although the Department does not regulate the manufacture and distribution of reagent kits that do not contain radioactive material, it does regulate the use of such reagent kits for the preparation of radiopharmaceuticals containing radioactive material as part of its licensing and regulation of the users of radioactive material. Any manufacturer of reagent kits that do not contain radioactive material who desires to have his reagent kits approved by the Department for use by persons licensed pursuant to RHA 2.7.3 and Group III of RHA 2.26 Schedule D of this part may submit the pertinent information specified in RHA 2.7.11.

2.7.12.1.2.1 The radioactive material contained, its chemical and physical form, and amount;

2.7.12.1.2.2 Details of design and construction of the source or device;

2.7.12.1.2.3 Procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents;

2.7.12.1.2.4 For devices containing radioactive material, the radiation profile of a prototype device;

2.7.12.1.2.5 Details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests;

2.7.12.1.2.6 Procedures and standards for calibrating sources and devices;

2.7.12.1.2.7 Legend and methods for labeling sources and devices as to their radioactive content;

2.7.12.1.2.8 Instruction for handling and storing the source or device from the radiation safety standpoint; these instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device; Provided, that instructions which are too lengthy for such label and printed in detail on a brochure which is referenced on the label;

2.7.12.1.3 The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity, and date of assay, and a statement that the (name of source or device) is licensed by the Department for distribution to persons licensed pursuant to RHA 2.7.3 and RHA 2.26 Schedule D, Group VI of this part or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State, or that a pending application for such license has been filed with the Department on or before August 9, 1977; provided, that such labeling for sources which do not require long term storage (e.g., gold-198 seeds) may be on a leaflet or brochure which accompanies the source.

2.7.12.2 In the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than six months, he shall include in his application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source.

In determining the acceptable interval for test of leakage of radioactive material, the Department will consider information that includes, but is not limited to:

2.7.12.2.1 Primary containment (source capsule);

2.7.12.2.2 Protection of primary containment;

2.7.12.2.3 Method of sealing containment;

2.7.12.2.4 Containment construction materials;

2.7.12.2.5 Form of contained radioactive material;

2.7.12.2.6 Maximum temperature withstood during prototype tests;

2.7.12.2.7 Maximum pressure withstood during prototype tests;

2.7.12.2.8 Maximum quantity of contained radioactive material;

2.7.12.2.9 Radiotoxicity of contained radioactive material; and

2.7.12.2.10 Operating experience with identical sources or devices or similarly designed and constructed sources or devices.

2.7.12.3 If an application is filed pursuant to RHA 2.7.12.1 on or before ** [Aug. 9, 1977], for a license to manufacture and distribute a source or device that was distributed commercially on or before *, the applicant may continue the distribution of such source or device to group licensees until the Department issues the license or notifies the applicant otherwise.

2.7.13 Calibration or reference sources containing Americium-241 or Radium-226: Requirements for license to manufacture or initially transfer.

2.7.13.1 An application for a specific license to manufacture or initially transfer calibration or reference sources containing Americium-241 or Radium-226, for distribution to persons generally licensed under RHA 2.4, will be approved if:

2.7.13.1.1 The applicant satisfies the general requirements of RHA 2.6;

2.7.13.1.2 The applicant submits sufficient information regarding each type of calibration or reference source pertinent to evaluation of the potential radiation exposure, including:

2.7.13.1.2.1 Chemical and physical form and maximum quantity of Americium 241 or Radium-226 in the source;

2.7.13.1.2.2 Details of construction and design;

2.7.13.1.2.3 Details of the method of incorporation and binding of the Americium-241 or Radium-226 in the source;

2.7.13.1.2.4 Procedures for and results of prototype testing of sources, which are designed to contain more than 0.005 microcurie of Americium-241 or Radium-226, to demonstrate that the Americium-241 or Radium-226 contained in each source will not be released or be removed from the source under normal conditions of use;

2.7.13.1.2.5 Details of quality control procedures to be followed in manufacture of the source;

2.7.13.1.2.6 Description of labeling to be affixed to the source or the storage container for the source;

2.7.13.1.2.7 Any additional information, including experimental studies and tests, required by the Department to facilitate a determination of the safety of the source.

2.7.13.1.3 Each source will contain no more than 5 microcuries of Americium-241 or Radium-226.

2.7.13.1.4 The Department determines, with respect to any type of source containing more than 0.005 microcuries of Americium-241 or Radium-226, that:

2.7.13.1.4.1 The method of incorporation and binding of the Americium-241 or Radium-226 in the source is such that the Americium-241 will not be released or be removed from the source under normal conditions of use and handling of the source; and

2.7.13.1.4.2 The source has been subjected to and has satisfactorily passed the appropriate tests prescribed by 2.7.8.4.

2.7.13.1.5 The applicant shall subject at least five prototypes of each source that is designed to contain more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226 to tests as follows:

2.7.13.1.5.1 The initial quantity of radioactive material deposited on each source is measured by direct counting of the source.

2.7.13.1.5.2 The sources are subjected to tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment or binding of americium-241 or radium-226, such as physical handling, moisture, and water immersion.

2.7.13.1.5.3 The sources are inspected for evidence of physical damage and for loss of americium-241 or radium-226, after each stage of testing, using methods of inspection adequate for determining compliance with the criteria in RHA 2.7.8.1.5.4.

2.7.13.1.5.4 Source designs are rejected for which the following has been detected for any unit: removal of more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226 from the source or any other evidence of physical damage.

2.7.13.2 Each person licensed under this Section shall affix to each source, or storage container for the source, a label which shall contain sufficient information relative to safe use and storage of the source and shall include the following statement or a substantially similar statement which contains the information called for in the following statement:

The receipt, possession, use, and transfer of this source, Model, Serial No., are subject to a general license and the regulations of the United States Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION-RADIOACTIVE MATERIAL-THIS SOURCE CONTAINS AMERICIUM-241 (or RADIUM-226). DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

Name of manufacturer or initial transferor

2.7.13.3 Each person licensed under RHA 2.7.8 shall perform a dry wipe test upon each source containing more than 3.7 kilobecquerels (0.1 microcurie) of Americium-241 or Radium-226 before transferring the source to a general licensee under RHA 2.4.5, or comparable regulation. This test shall be performed by wiping the entire radioactive surface of the source with a filter paper with the application of moderate finger pressure. The radioactivity on the paper shall be measured by using methods capable of detecting 0.185 kilobecquerel (0.005 microcurie) of Americium-241 or Radium-226. If a source has been shown to be leaking or losing more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226 by the methods described in this section, the source must be rejected and must not be transferred to a general licensee RHA 2.4.5 or comparable regulation.

2.7.13.4 An applicant for a license under this Section shall, for any type of source which is designed to contain more than 0.185 kilobecquerel (0.005 microcurie) of Americium-241 or Radium-226, conduct prototype tests, in the order listed, on each of five prototypes of the source,

which contains more than 0.185 kilobecquerel (0.005 microcurie) of Americium-241 or Radium-226, as follows:

2.7.13.4.1 *Initial measurement*. The quantity of radioactive material deposited on the source shall be measured by direct counting of the source.

2.7.13.4.2 *Dry wipe test*. The entire radioactive surface of the source shall be wiped with filter paper with the application of moderate finger pressure. Removal of radioactive material from the source shall be determined by measuring the radioactivity on the filter paper or by direct measurement of the radioactivity on the source following the dry wipe.

2.7.13.4.3 *Wet wipe test*. The entire radioactive surface of the source shall be wiped with filter paper, moistened with water, with the application of moderate finger pressure. Removal of radioactive material from the source shall be determined by measuring the radioactivity on the filter paper after it has dried or by direct measurement of the radioactivity on the source following the wet wipe.

2.7.13.4.4 *Water soak test*. The source shall be immersed in water at room temperature for a period of 24 consecutive hours. The source shall then be removed from the water. Removal of radioactive material from the source shall be determined by direct measurement of the radioactivity on the source after it has dried or by measuring the radioactivity in the residue obtained by evaporation of the water in which the source was immersed.

2.7.13.4.5 *Dry wipe test*. On completion of the preceding test in this section, the dry wipe test described in 2.7.13.4.2 shall be repeated.

2.7.13.4.6 *Observations*. Removal of more than 0.005 microcurie of radioactivity in any test prescribed by this section shall be cause for rejection of the source design. Results of prototype tests submitted to the Commission shall be given in terms of radioactivity in microcuries and percent of removal from the total amount of radioactive material deposited on the source.

2.7.14 Luminous safety devices for use in aircraft: Requirements for license to manufacture, assemble, repair or initially transfer. An application for a specific license to manufacture, assemble, repair or initially transfer luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed under RHA 2.4.4, will be approved if:

2.7.14.1 The applicant satisfies the general requirements specified in RHA 2.6;

2.7.14.2 The applicant submits sufficient information regarding each device pertinent to evaluation of the potential radiation exposure, including:

2.7.14.2.1 Chemical and physical form and maximum quantity of tritium or promethium-147 in each device;

2.7.14.2.2 Details of construction and design;

2.7.14.2.3 Details of the method of binding or containing the tritium or promethium-147;

2.7.14.2.4 Procedures for and results of prototype testing to demonstrate that the tritium or promethium 147 will not be released to the environment under the most severe conditions likely to be encountered in normal use;

2.7.14.2.5 Quality assurance procedures to be followed that are sufficient to ensure compliance with § 32.55;

2.7.14.2.6 Any additional information, including experimental studies and tests, required by the Department to facilitate a determination of the safety of the device.

2.7.14.3 Each device will contain no more than 10 curies of tritium or 300 millicuries of promethium 147. The levels of radiation from each device containing promethium-147 will not exceed 0.5 millirad per hour at 10 centimeters from any surface when measured through 50 milligrams per square centimeter of absorber.

2.7.14.4 The Department determines that:

2.7.14.4.1 The method of incorporation and binding of the tritium or promethium-147 in the device is such that the tritium or promethium-147 will not be released under the most severe conditions which are likely to be encountered in normal use and handling of the device;

2.7.14.4.2 The tritium or promethium-147 is incorporated or enclosed so as to preclude direct physical contact by any person with it;

2.7.14.4.3 The device is so designed that it cannot easily be disassembled; and

2.7.14.4.4 Prototypes of the device have been subjected to and have satisfactorily passed the tests required by 2.7.14.5.

2.7.14.5 The applicant shall subject at least five prototypes of the device to tests as follows:

2.7.14.5.1 The devices are subjected to tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment of tritium or promethium-147, such as temperature, moisture, absolute pressure, water immersion, vibration, shock, and weathering.

2.7.14.5.2 The devices are inspected for evidence of physical damage and for loss of tritium or promethium-147, after each stage of testing, using methods of inspection adequate for determining compliance with the criteria in RHA 2.7.14.5.3.

2.7.14.5.3 Device designs are rejected for which the following has been detected for any unit:

2.7.14.5.3.1 A leak resulting in a loss of 0.1 percent or more of the original amount of tritium or promethium-147 from the device; or

2.7.14.5.3.2 Surface contamination of tritium or promethium-147 on the device of more than 2,200 disintegrations per minute per 100 square centimeters of surface area; or

2.7.14.5.3.3 Any other evidence of physical damage.

2.7.14.6 The device has been registered in the Sealed Source and Device Registry.

2.7.14.7 Quality assurance and prohibition of transfer for luminous safety devices for use in aircraft.

2.7.14.7.1 Each person licensed under RHA 2.7.14 shall visually inspect each device and shall reject any that has an observable physical defect that could adversely affect containment of the tritium or promethium-147.

2.7.14.7.2 Each person licensed under RHA 2.7.14 shall:

2.7.14.7.2.1 Maintain quality assurance systems in the manufacture of the luminous safety device in a manner sufficient to provide reasonable assurance that the safety-related components of the distributed devices are capable of performing their intended functions; and

2.7.14.7.2.2 Subject inspection lots to acceptance sampling procedures, by procedures specified in paragraph (c) of this section and in the license issued under RHA 2.7.14, to provide at least 95 percent confidence that the Lot Tolerance Percent Defective of 5.0 percent will not be exceeded.

2.7.14.7.3 The licensee shall subject each inspection lot to:

2.7.14.7.3.1 Tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment of tritium or promethium-147, such as absolute pressure and water immersion.

2.7.14.7.3.2 Inspection for evidence of physical damage, containment failure, or for loss of tritium or promethium-147 after each stage of testing, using methods of inspection adequate for applying the following criteria for defective:

2.7.14.7.3.2.1 A leak resulting in a loss of 0.1 percent or more of the original amount of tritium or promethium-147 from the device;

2.7.14.7.3.2.2 Levels of radiation in excess of 5 microgray (0.5 millirad) per hour at 10 centimeters from any surface when measured through 50 milligrams per square centimeter of absorber, if the device contains promethium-147; and

2.7.14.7.3.2.3 Any other criteria specified in the license issued under RHA 2.7.14.

2.7.14.7.4 No person licensed under RHA 2.7.14 shall transfer to persons generally licensed under RHA 2.4.4, or under an equivalent general license of an Agreement State:

2.7.14.7.4.1 Any luminous safety device tested and found defective under any condition of a license issued under RHA 2.7.14, or RHA 2.7.14.8, unless the defective luminous safety device has been repaired or reworked, retested, and determined by an independent inspector to meet the applicable acceptance criteria; or

2.7.14.7.4.2 Any luminous safety device contained within any lot that has been sampled and rejected as a result of the procedures in RHA 2.7.14.8.2, unless:

2.7.14.7.4.2.1 A procedure for defining sub-lot size, independence, and additional testing procedures is contained in the license issued under RHA 2.7.14; and

2.7.14.7.4.2.2 Each individual sub-lot is sampled, tested, and accepted in accordance with RHA 2.7.14.8.2 and RHA 2.7.14.10.2.1 and any other criteria that may be required as a condition of the license issued under RHA 2.7.14.

2.7.14.8 Material transfer reports for luminous safety devices for use in aircraft.

2.7.14.8.1 Each person licensed under RHA 2.7.14 shall file an annual report with the Director, Division of Radioactive Material, Bureau of Radiological Health, which must state the total quantity of tritium or promethium-147 transferred to persons generally licensed under RHA 2.4.4. The report must identify each general licensee by name, state the kinds and numbers of luminous devices transferred, and specify the quantity of tritium or promethium-147 in each kind of device. Each report must cover the year ending June 30 and must be filed within thirty (30) days thereafter. If no transfers have been made to persons generally licensed under RHA 2.4.4 during the reporting period, the report must so indicate.

2.7.14.8.2 Each person licensed under RHA 2.7.14 shall report annually all transfers of devices to persons for use under a general license in an NRC or Agreement State's regulations that are equivalent to RHA 2.4.4 to the NRC or responsible Agreement State agency. The report must state the total quantity of tritium or promethium-147 transferred, identify each general licensee by name, state the kinds and numbers of luminous devices transferred, and specify the quantity of tritium or promethium-147 in each kind of device. If no transfers have been made to a particular NRC licensee or Agreement State during the reporting period, this information must be reported to the NRC or responsible Agreement State agency upon request of the Department.

2.7.15 Ice detection devices containing strontium-90; requirements for license to manufacture or initially transfer. An application for a specific license to manufacture or initially transfer ice detection devices containing strontium-90 for distribution to persons generally licensed under RHA 2.4.7 will be approved if:

2.7.15.1 The applicant satisfies the general requirements specified in RHA 2.6

2.7.15.2 The applicant submits sufficient information regarding each type of device pertinent to evaluation of the potential radiation exposure, including:

2.7.15.2.1 Chemical and physical form and maximum quantity of strontium-90 in the device;

2.7.15.2.2 Details of construction and design of the source of radiation and its shielding;

2.7.15.2.3 Radiation profile of a prototype device;

2.7.15.2.4 Procedures for and results of prototype testing of devices to demonstrate that the strontium-90 contained in each device will not be released or be removed from the device under the most severe conditions likely to be encountered in normal handling and use;

2.7.15.2.5 Details of quality control procedures to be followed in manufacture of the device;

2.7.15.2.6 Description of labeling to be affixed to the device;

2.7.15.2.7 Instructions for handling and installation of the device;

2.7.15.2.8 Any additional information, including experimental studies and tests, required by the Department to facilitate a determination of the safety of the device;

2.7.15.3 Each device will contain no more than 50 microcuries of strontium-90 in an insoluble form;

2.7.15.4 Each device will bear durable, legible labeling which includes the radiation caution symbol prescribed by Part 3, a statement that the device contains strontium-90 and the quantity thereof, instructions for disposal and statements that the device may be possessed pursuant to a

general license, that the manufacturer or civil authorities should be notified if the device is found, that removal of the labeling is prohibited and that disassembly and repair of the device may be performed only by a person holding a specific license to manufacture or service such devices;

2.7.15.5 The Department determines that:

2.7.15.5.1 The method of incorporation and binding of the strontium-90 in the device is such that the strontium-90 will not be released from the device under the most severe conditions which are likely to be encountered in normal use and handling of the device;

2.7.15.5.2 The strontium-90 is incorporated or enclosed so as to preclude direct physical contact by any individual with it and is shielded so that no individual will receive a radiation exposure to a major portion of his body in excess of 0.5 rem in a year under ordinary circumstances of use;

2.7.15.5.3 The device is so designed that it cannot be easily disassembled;

2.7.15.5.4 Prototypes of the device have been subjected to and have satisfactorily passed the tests required by RHA 2.7.15.6 of this section.

2.7.15.5.5 Quality control procedures have been established to satisfy the requirements of 10 CFR 32.62.

2.7.15.6 The applicant shall subject at least five prototypes of the device to tests as follows:

2.7.15.6.1 The devices are subjected to tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment of strontium-90, such as temperature, moisture, absolute pressure, water immersion, vibration, shock, and weathering.

2.7.15.6.2 The devices are inspected for evidence of physical damage and for loss of strontium-90 after each stage of testing, using methods of inspection adequate for determining compliance with the criteria in RHA 2.7.15.6.3.

2.7.15.6.3 Device designs are rejected for which the following has been detected for any unit:

2.7.15.6.3.1 A leak resulting in a loss of 0.1 percent or more of the original amount of strontium-90 from the device; or

2.7.15.6.3.2 Surface contamination of strontium-90 on the device of more than 2,200 disintegrations per minute per 100 square centimeters of surface area; or

2.7.15.6.3.3 Any other evidence of physical damage.

2.7.15.7 The device has been registered in the Sealed Source and Device Registry.

2.7.16 Requirements for license to initially transfer source material for use under the 'small quantities of source material' general license

2.7.16.1 An application for a specific license to initially transfer source material for use under RHA 2.3, or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State, will be approved if:

2.7.16.1.1 The applicant satisfies the general requirements specified in RHA 2.6; and

2.7.16.1.2 The applicant submits adequate information on, and the Department approves the methods to be used for quality control, labeling, and providing safety instructions to recipients.

2.7.16.2 Conditions of licenses to initially transfer source material for use under the 'small quantities of source material' general license: Quality control, labeling, safety instructions, and records and reports

2.7.16.2.1 Each person licensed under RHA 2.7.16 shall label the immediate container of each quantity of source material with the type of source material and quantity of material and the words, "radioactive material."

2.7.16.2.2 Each person licensed under RHA 2.7.16 shall ensure that the quantities and concentrations of source material are as labeled and indicated in any transfer records.

2.7.16.2.3 Each person licensed under RHA 2.7.16 shall provide the information specified in this paragraph to each person to whom source material is transferred for use under RHA 2.3, or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State

provisions. This information must be transferred before the source material is transferred for the first time in each calendar year to the particular recipient. The required information includes:

2.7.16.2.3.1 A copy of RHA 2.3 and RHA 2.18, or relevant equivalent regulations of the Agreement State.

2.7.16.2.3.2 Appropriate radiation safety precautions and instructions relating to handling, use, storage, and disposal of the material.

2.7.16.2.4 Each person licensed under RHA 2.7.16 shall report transfers as follows:

2.7.16.2.4.1 File a report with the Department. The report shall include the following information:

2.7.16.2.4.1.1 The name, address, and license number of the person who transferred the source material;

2.7.16.2.4.1.2 For each general licensee under RHA 2.3,or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State provisions, to whom greater than 50 grams (0.11 lb) of source material has been transferred in a single calendar quarter, the name and address of the general licensee to whom source material is distributed; a responsible agent, by name and/or position and phone number, of the general licensee to whom the material was sent; and the type, physical form, and quantity of source material transferred; and

2.7.16.2.4.1.3 The total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients.

2.7.16.2.4.2 File a report with each responsible Agreement State agency that identifies all persons, operating under provisions equivalent to RHA 2.3, to whom greater than 50 grams (0.11 lb) of source material has been transferred within a single calendar quarter. The report shall include the following information specific to those transfers made to the Agreement State being reported to:

2.7.16.2.4.2.1 The name, address, and license number of the person who transferred the source material; and

2.7.16.2.4.2.2 The name and address of the general licensee to whom source material was distributed; a responsible agent, by name and/or position and phone number, of the general licensee to whom the material was sent; and the type, physical form, and quantity of source material transferred.

2.7.16.2.4.2.3 The total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients within the Agreement State.

2.7.16.2.4.3 Submit each report by January 31 of each year covering all transfers for the previous calendar year. If no transfers were made to persons generally licensed under RHA 2.3, or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State provisions, during the current period, a report shall be submitted to the Department indicating so. If no transfers have been made to general licensees during the reporting period, this information shall be reported to the Department upon request.

2.7.16.2.5 Each person licensed under RHA 2.7.16 shall maintain all information that supports the reports required concerning each transfer to a general licensee for a period of 1 year after the event is included in a report to the Department.

HISTORY: Amended by State Register Volume 38, Issue No. 10, Doc. No. 4462, eff October 24, 2014; SCSR 42–2 Doc. No. 4791, eff February 23, 2018; SCSR 42–4 Doc. No. 4123, eff April 27, 2018 (errata); SCSR 44–11, eff November 27, 2020 (errata); SCSR 45–5 Doc. No. 5036, eff May 28, 2021.

Editor's Note

Scrivener errors corrected in 2012.

RHA 2.8. Special Requirements for Specific License of Broad Scope.

This section prescribes requirements for the issuance of specific licenses of broad scope for

radioactive material ("broad licenses") and certain regulations governing holders of such licenses.[5]

2.8.1 The Different Types of Board Licenses are Set Forth Below.

2.8.1.1 A "Type A specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of the radioactive material specified in the license, but not exceeding quantities specified in the license, for any authorized purpose. The quantities specified are usually in the multicurie range.

2.8.1.2 A "Type B specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in Schedule E, RHA 2.27 for any authorized purpose. The possession limit for a Type B broad license, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in RHA 2.27 Schedule E, Column I, If two or more radionuclides are possessed thereunder, the possession limit for each is determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in RHA 2.27 Schedule E, Column I, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

2.8.1.3 A "Type C specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in RHA 2.27 Schedule E, for any authorized purpose. The possession limit for a Type C broad license, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in RHA 2.27 Schedule E, Column II. If two or more radionuclides are possessed thereunder, the possession limit is determined for each as follows: For each radionuclide determined the ratio of the quantity possessed to the applicable quantity specified in RHA 2.27, Schedule E, Column II, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

2.8.2 An application for a Type A specific license of broad scope will be approved if:

2.8.2.1 The applicant satisfies the general requirements specified in RHA 2.6 and;

2.8.2.2 The applicant has engaged in a reasonable number of activities involving the use of radioactive material; and

2.8.2.3 The applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that are necessary to assure safe operations, including:

2.8.2.3.1 The establishment of a radiation safety committee composed of such persons as a radiological safety officer, a representative of management, and persons trained and experienced in the safe use of radioactive materials;

2.8.2.3.2 The appointment of a radiological safety officer who is qualified by training and experienced in radiation protection, and who is available for advice and assistance on radiological safety matters; and

2.8.2.3.3 The establishment of appropriate administrative procedures to assure:

2.8.2.3.3.1 Control of procurement and use of radioactive material;

2.8.2.3.3.2 Completion of safety evaluation of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and

2.8.2.3.3.3 Review, approval, and recording by the radiation safety committee of safety evaluation of proposed uses prepared in accordance with 2.8.2.3.3.2 of this subparagraph 2.8.2.3.3 prior to use of the radioactive material.

2.8.3 An Application for a Type B Specific License of Broad Scope will be Approved if:

2.8.3.1 The applicant satisfies the general requirements specified in RHA 2.6; and

[5] Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source material or byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U. S. Nuclear Regulatory Commission, Washington, D. C. 20545.

2.8.3.2 The applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that are necessary to assure safe operations, including:

2.8.3.2.1 The appointment of a radiological safety officer who is qualified by training experience in radiation protection, and who is available for advice and assistance on radiological safety matters; and

2.8.3.2.2 The establishment of appropriate administrative procedures to assure:

2.8.3.2.2.1 Control of procurement and use of radioactive material;

2.8.3.2.2.2 Completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and

2.8.3.2.2.3 Review, approval, and recording by the radiological safety officer of safety evaluations of proposed uses prepared in accordance with 2.8.3.2.2.2 of this subparagraph 2.8.3.2.2 prior to use of the radioactive material.

2.8.4 An Application for a Type C Specific License of Broad Scope will be Approved if:

2.8.4.1 The applicant satisfies the general requirements specified in RHA 2.6; and

2.8.4.2 The applicant submits a statement that radioactive material will be used only by, or under the direct supervision of, individuals who have received:

2.8.4.2.1 A college degree at the bachelor level, or equivalent training and experience, in the physical or biological sciences or in engineering; and

2.8.4.2.2 At least 40 hours of training and experience in the safe handling of radioactive materials, and in the characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation, and biological hazards of exposure to radiation appropriate to the type and forms of radioactive material to be used; and

2.8.4.3 The applicant has established administrative controls and provisions relating to procurement of radioactive material, procedures, record keeping, material control and accounting, and management review necessary to assure safe operations.

2.8.5 Specific Licenses of Broad Scope are Subject to the Following Conditions:

2.8.5.1 Persons licensed pursuant to RHA 2.8 shall not:

2.8.5.1.1 Conduct tracer studies in the environment involving direct release of radioactive material;

2.8.5.1.2 Receive, acquire, own, possess, use or transfer devices containing 100,000 curies or more of radioactive material in sealed sources used for irradiation of materials;

2.8.5.1.3 Conduct activities for which a specific license issued by the Department under 2.7 is required; or

2.8.5.1.4 Add or cause the addition of radioactive material to any food, beverage, cosmetic, drug, or other product designed for ingestion or inhalation by, or application to, a human being.

2.8.5.2 Each Type A specific license of broad scope issued under this part shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety committee.

2.8.5.3 Each Type B specific license of broad scope issued under this part shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiological safety officer.

2.8.5.4 Each Type C specific license of broad scope issued under this part shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals who satisfy the requirements of 2.8.4 of RHA 2.8.

Editor's Note

Scrivener errors corrected in 2012.

RHA 2.9. Issuance of Specific Licenses.

2.9.1 Upon a determination that an application meets the requirements of the Act and the regulations of the Department, the Department will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.

2.9.2 The Department may incorporate in any license at the time of issuance or thereafter, such additional requirements and conditions with respect to the licensee's receipt, possession, use, and transfer of radioactive material subject to this Part as it deems appropriate or necessary in order to:

2.9.2.1 Protect health or to minimize danger to life and property;

2.9.2.2 Require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be appropriate or necessary; and

2.9.2.3 Prevent loss or theft of license material.

RHA 2.10. Specific Terms and Conditions of Licenses.

2.10.1 Each license issued pursuant to these regulations shall be subject to all the provisions of the Act, and to all rules, regulations, and orders of the Department, now or hereafter in effect.

2.10.2 Specific license transfer requirements.

2.10.2.1 No license issued or granted pursuant to the regulations in Parts II, VII, and XI nor any right under a license shall be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person, unless the Department shall, after securing full information, find that the transfer is in accordance with the provisions of the Act and shall give its consent in writing.

2.10.2.2 An application for transfer of license must include:

2.10.2.2.1 The identity, technical and financial qualifications of the proposed transferee; and

2.10.2.2.2 Financial assurance for decommissioning information required by RHA 1.15.

2.10.3 Each person licensed by the Department pursuant to these regulations shall confine his use and possession of the material licensed to the locations and purposes authorized in the license.

2.10.4 Each specific licensee authorized under 2.7.5 to distribute certain devices to generally licensed persons.

2.10.5 Each licensee shall notify the Department in writing when the licensee decides to permanently discontinue all activities involving materials authorized under the license.

2.10.6 Each general licensee that is required to register by RHA 2.4.2.3.11 of this Part and each specific licensee shall notify the Department, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against:

2.10.6.1 The licensee:

2.10.6.2 An entity (as that term is defined in 11 U.S.C. 101 (15)) controlling the licensee or listing the license or licensee as property of the estate; or

2.10.6.3 An affiliate (as that term is defined in 11 U.S.C. 101 (2)) of the licensee.

2.10.7 Security requirements for portable gauges.

2.10.7.1 Each portable gauge licensee shall use a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal, whenever portable gauges are not under the control and constant surveillance of the licensee.

2.10.8 Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with RHA 4.38. The licensee shall record the results of each test and retain each record for 3 years after the record is made. The licensee shall report the results of any test that exceeds the permissible concentration listed in 4.38.1 of this chapter at the time of generator elution, in accordance with RHA 4.120 of this chapter.

2.10.9.1 Authorization under Part 2 of this Regulation to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

2.10.9.2 Each licensee authorized under Part 2 of this Regulation to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:

2.10.9.2.1 Satisfy the labeling requirements in Part 2 of this Regulation for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium.

2.10.9.2.2 Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in Part 2 of this Regulation.

2.10.9.3 A licensee that is a pharmacy authorized under Part 2 of this Regulation to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radioactive drugs shall be:

2.10.9.3.1 an authorized nuclear pharmacist that meets the requirements in Part 2 of this Regulation; or

2.10.9.3.2 an individual under the supervision of an authorized nuclear pharmacist as specified in Part 2 of this Regulation.

2.10.9.4 A pharmacy, authorized under Part 2 of this Regulation to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirements of Part 2 of this Regulation.

2.10.10 Conditions of licenses.

2.10.10.1 Each license shall contain and be subject to the following conditions:

2.10.10.1.1 [Reserved]

2.10.10.1.2 No right to the special nuclear material shall be conferred by the license except as defined by the license;

2.10.10.1.3 Neither the license nor any right under the license shall be assigned or otherwise transferred in violation of the provisions of the Act;

2.10.10.1.4 [Reserved]

2.10.10.1.5 [Reserved]

2.10.10.1.6 [Reserved]

2.10.10.1.7 [Reserved]

2.10.10.1.8 The license shall be subject to and the licensee shall observe, all applicable rules, regulations, and orders of the Department.

2.10.10.1.9 Notification of Bankruptcy.

2.10.10.1.9.1 Each licensee shall notify the Department, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against:

2.10.10.1.9.1.1 The licensee;

2.10.10.1.9.1.2 An entity (as that term is defined in 11 U.S.C. 101(14)) controlling the licensee or listing the license or licensee as property of the estate; or

2.10.10.1.9.1.3 An affiliate (as that term is defined in 11 U.S.C. 101(a)) of the licensee.

2.10.10.1.9.2 The notification required in 2.10.10.1.9.1 must indicate:

2.10.10.1.9.2.1 The bankruptcy court in which the petition for bankruptcy was filed; and

2.10.10.1.9.2.2 The date of the filing of the petition.

HISTORY: Amended by State Register Volume 38, Issue No. 10, Doc. No. 4462, eff October 24, 2014; SCSR 45–5 Doc. No. 5036, eff May 28, 2021.

RHA 2.11. Expiration and Termination of Licenses and Decommissioning of Sites and Separate Buildings or Outdoor Areas.

2.11.1 Each specific license expires at midnight on the expiration date stated in the license unless the licensee has filed an application for renewal under RHA 2.12 not less than 30 days before the expiration date stated in the existing license. If an application for renewal has been filed at least 30 days prior to the expiration date stated in the existing license, the existing license expires at the end of the day on which the Department makes a final determination to deny the renewal application or, if the determination states an expiration date, the expiration date stated in the determination.

2.11.2 Each specific license revoked by the Department expires at midnight on the date of the Department's final determination to revoke the license, or on the expiration date stated in the determination, or as otherwise provided by the Department Order.

2.11.3 Each specific license continues in effect, beyond the expiration date if necessary, with respect to possession of byproduct material, source material, or special nuclear material until the Department notifies the licensee in writing that the license is terminated. During this time, the licensee shall:

2.11.3.1 Limit actions involving byproduct material, source material, or special nuclear material to those related to decommissioning; and

2.11.3.2 Continue to control entry to restricted areas until they are suitable for release in accordance with Department requirements.

2.11.4 Within 60 days of the occurrence of any of the following, consistent with administrative directions in RHA 2.32, each licensee shall provide notification to the Department in writing of such occurrence, and either begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity so that the building or outdoor area is suitable for release in accordance with Department requirements, or submit within 12 months of notification a decommissioning plan, if required by RHA 2.11.6.1, and begin decommissioning upon approval of that plan if:

2.11.4.1 The license has expired pursuant to RHA 2.11.1 or 2.11.2; or

2.11.4.2 The licensee has decided to permanently cease principal activities, as defined, at the entire site or in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with Department requirements; or

2.11.4.3 No principal activities under the license have been conducted for a period of 24 months; or

2.11.4.4 No principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with Department requirements.

2.11.5 Coincident with the notification required by RHA 2.11.4, the licensee shall maintain in effect all decommissioning financial assurances established by the licensee pursuant to RHA 1.15 in conjunction with a license issuance or renewal or as required by this section. The amount of the financial assurance must be increased, or may be decreased, as appropriate, to cover the detailed cost estimate for decommissioning established pursuant to RHA 2.11.7.4.5.

2.11.5.1 Any licensee who has not provided financial assurance to cover the detailed cost estimate submitted with the decommissioning plan shall do so when this rule becomes effective November 24, 1998.

2.11.5.2 Following approval of the decommissioning plan, a licensee may reduce the amount of the financial assurance as decommissioning proceeds and radiological contamination is reduced at the site with the approval of the Department.

2.11.6 The Decommissioning Plan.

2.11.6.1 A decommissioning plan must be submitted if required by license condition or if the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area have not been previously approved by the Department and these procedures could increase potential health and safety impacts to workers or the public, such as in any of the following cases:

2.11.6.1.1 Procedures would involve techniques not applied routinely during cleanup or maintenance operations;

2.11.6.1.2 Workers would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation;

2.11.6.1.3 Procedures could result in significantly greater airborne concentrations of radioactive materials than are present during operation; or

2.11.6.1.4 Procedures could result in significantly greater releases of radioactive material to the environment than those associated with operation.

2.11.6.2 The Department may approve an alternate schedule for submittal of a decommissioning plan required pursuant to RHA 2.11.4 if the Department determines that the alternative schedule is necessary to the effective conduct of decommissioning operations and presents no undue risk from radiation to the public health and safety and is otherwise in the public interest.

2.11.6.3 Procedures such as those listed in RHA 2.11.6.1 with potential health and safety impacts may not be carried out prior to approval of the decommissioning plan.

2.11.6.4 The proposed decommissioning plan for the site or separate building or outdoor area must include:

2.11.6.4.1 A description of the condition of the site or separate building or outdoor area sufficient to evaluate the acceptability of the plan;

2.11.6.4.2 A description of planned decommissioning activities;

2.11.6.4.3 A description of methods used to ensure protection of workers and the environment against radiation hazards during decommissioning;

2.11.6.4.4 A description of the planned final radiation survey; and

2.11.6.4.5 An updated detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and a plan for assuring the availability of adequate funds for completion of decommissioning.

2.11.6.4.6 For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, the plan shall include a justification for the delay based on the criteria in RHA 2.11.8.

2.11.6.4.7 A description of the physical security plan and material control and accounting plan provisions in place during decommissioning.

2.11.6.5 The proposed decommissioning plan will be approved by the Department if the information therein demonstrates that the decommissioning will be completed as soon as practicable and that the health and safety of workers and the public will be adequately protected.

2.11.7 Decommissioning and Termination

2.11.7.1 Except as provided in RHA 2.11.8, licensees shall complete decommissioning of the site or separate building or outdoor area as soon as practicable but no later than 24 months following the initiation of decommissioning.

2.11.7.2 Except as provided in RHA 2.11.8, when decommissioning involves the entire site, the licensee shall request license termination as soon as practicable but no later than 24 months following the initiation of decommissioning.

2.11.8 The Department may approve a request for an alternative schedule for completion of decommissioning of the site or separate building or outdoor area, and license termination if appropriate, if the Department determines that the alternative is warranted by consideration of the following:

2.11.8.1 Whether it is technically feasible to complete decommissioning within the allotted 24-month period;

2.11.8.2 Whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 24-month period;

2.11.8.3 Whether a significant volume reduction in wastes requiring disposal will be achieved by allowing short-lived radionuclides to decay;

2.11.8.4 Whether a significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay; and

2.11.8.5 Other site-specific factors which the Department may consider appropriate on a case-by-case basis, such as the regulatory requirements of other government agencies, lawsuits, ground-water

treatment activities, monitored natural ground-water restoration, actions that could result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensee.

2.11.9 As the final step in decommissioning, the licensee shall:

2.11.9.1 Certify the disposition of all licensed material, including accumulated wastes, in writing to the Department; and

2.11.9.2 Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey unless the licensee demonstrates that the premises are suitable for release in some other manner. The licensee shall, as appropriate:

2.11.9.2.1 Report levels of gamma radiation in units of millisieverts and microroentgen per hour at one meter from surfaces, and report levels of radioactivity, including alpha and beta, in units of megabecquerels and disintegrations per minute or microcuries per 100 square centimeters—removable and fixed—for surfaces, megabecquerels and microcuries per milliliter for water, and becquerels and picocuries per gram for solids such as soils or concrete; and

2.11.9.2.2 Specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.

2.11.10 Specific licenses, including expired licenses, will be terminated by written notice to the licensee when the Department determines that:

2.11.10.1 Byproduct material, source material, and special nuclear material have been properly disposed;

2.11.10.2 Reasonable effort has been made to eliminate residual radioactive contamination, if present; and

2.11.10.3 A radiation survey has been performed which demonstrates that the premises are suitable for release in accordance with Department requirements, or other information has been submitted by the licensee that will be sufficient to demonstrate that the premises are suitable for release in accordance with Department requirements. Residual contamination levels must be ALARA and must be approved by the Department.

2.11.11.4 Records required by RHA 3.34.5 and 3.34.7 have been received.

The regulations in this part apply to persons licensed by the Department to receive, possess, use, transfer, or dispose of byproduct, source, or special nuclear material. The limits in this part do not apply to doses due to background radiation, due to any medical administration the individual has received, or to voluntary participation in medical research programs.

HISTORY: Amended by State Register Volume 38, Issue No. 10, Doc. No. 4462, eff October 24, 2014.

RHA 2.12. Renewal of Specific Licenses.

2.12.1 Application for renewal of specific licenses shall be filed in accordance with RHA 2.5.

2.12.2 In any case in which a licensee, not less than thirty (30) days prior to expiration of his existing license, has filed an application in proper form for renewal or for a new license including the same activities, such existing license shall not expire until the application has been finally acted upon by the Department, or the time for seeking judicial review has elapsed.

RHA 2.13. Amendment of Licenses at Request of Licensee.

Applications for amendment of a license shall be filed in accordance with RHA 2.5 and shall specify the respects in which the licensee desires his license to be amended and the grounds for such amendment.

RHA 2.14. Department Action on Applications to Renew or Amend.

In considering an application by a licensee to renew or amend his license the Department will apply the criteria set forth in RHA 2.6, RHA 2.7, and RHA 2.8 of this Part and Parts IV, V, VII and VIII of these regulations, as applicable.

RHA 2.15. Inalienability of Licenses.

2.15.1 No license issued or granted under these regulations and no right to possess or utilize radioactive material granted by any license issued pursuant to these regulations shall be transferred,

assigned, or in any manner disposed of, either voluntarily or involuntarily, indirectly or directly through transfer of control of any license to any person unless the Department shall, after securing full information, find that the transfer is in accordance with the provisions of the Act, and shall give its consent in writing.

2.15.2 An application for transfer of license must include:

2.15.2.1 The identity, technical and financial qualifications of the proposed transferee; and

2.15.2.2 Financial assurance for decommissioning information required by RHA 1.15.

HISTORY: Amended by State Register Volume 38, Issue No. 10, Doc. No. 4462, eff October 24, 2014.

RHA 2.16. Persons Possessing a License for Source, Byproduct, or Special Nuclear Material in Quantities not Sufficient to Form a Critical Mass on Effective Date of These Regulations.

Any person, who, on the effective date of these regulations possesses a general or specific license for source, byproduct, or special nuclear material in quantities not sufficient to form a critical mass, issued by the United States Nuclear Regulatory Commission, shall be deemed to possess a like license issued under these regulations and the Act, such license to expire either ninety (90) days after receipt from the Department of a notice of expiration of such license, or on the date of expiration specified in the United States Nuclear Regulatory Commission license, whichever is earlier.

RHA 2.17. Persons Possessing Radioactive Material Other Than Agreement Material on Effective Date of These Regulations.

Any person, who, on the effective date of these regulations, possesses naturally occurring or accelerator-produced radioactive material for which a specific license is required by the Act or this Part shall be deemed to possess such a license issued under the Act and this Part. Such license shall expire ninety (90) days after the effective date of these regulations; provided, however, that if within the ninety days the person possessing such material files an application in proper form for a license, such existing license shall not expire until the application has been finally determined by the Department.

RHA 2.18. Transfer of Material.

2.18.1 No licensee shall transfer radioactive material except as authorized pursuant to this regulation (RHA 2.18).

2.18.2 Any licensee may transfer radioactive material, subject to the acceptance of the transferee:

2.18.2.1 To the Department;

2.18.2.2 To the United States Nuclear Regulatory Commission;

2.18.2.3 To any person exempt from these regulations to the extent permitted under such exemption;

2.18.2.4 To any person authorized to receive such material under terms of a general license or its equivalent, or a specific license, or equivalent licensing document, issued by the Department, the U.S. Nuclear Regulatory Commission, any Agreement State, or any Licensing State or to any person otherwise authorized to receive such material by the Federal Government or any agency thereof, the Department, any Agreement State, or a Licensing State; or

2.18.2.5 As otherwise authorized by the Department in writing.

2.18.3 Before transferring radioactive material to a specific licensee of the Department, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State or to a general licensee who is required to register with the Department, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State prior to receipt of the radioactive material, the licensee transferring the material shall verify that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred.

2.18.4 The following methods for the verification required by RHA 2.18.3 are acceptable:

2.18.4.1 The transferor may have in his possession, and read, a current copy of the transferee's specific license or registration certificate;

2.18.4.2 The transferor may have in his possession a written certification by the transferee that he is authorized by license or registration certificate to receive the type, form, and quantity of

radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date;

2.18.4.3 For emergency shipments the transferor may accept oral certification by the transferee that he is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date; provided, that the oral certification is confirmed in writing within ten (10) days;

2.18.4.4 The transferor may obtain other sources of information compiled by a reporting service from official records of the Department, the U.S. Nuclear Regulatory Commission, the licensing agency of an Agreement State, or a Licensing State as to the identity of licensees and the scope and expiration dates of licenses and registration; or

2.18.4.5 When none of the methods of verification described in RHA 2.18.4.1 to 2.18.4.4 are readily available or when a transferor desires to verify that information received by one of such methods is correct or up-to-date, the transferor may obtain and record confirmation from the Department, the U.S. Nuclear Regulatory Commission, the licensing agency of an Agreement State, or a Licensing State that the transferee is licensed to receive the radioactive material.

2.18.5 Preparation for shipment and transport of radioactive material shall be in accordance with the provisions of RHA 2.22.

RHA 2.19. Modification, Revocation, and Termination of Licenses.

2.19.1 The terms and conditions of all licenses shall be subject to amendment, revision, or modification or the license may be suspended or revoked by reason of amendments to the Act, or by reason of rules, regulations, and orders issued by the Department.

2.19.2 Any license may be revoked, suspended, or modified, in whole or in part for any material false statement in the application or any statement of fact required under provisions of the Act, or because of conditions revealed by such application or statement of fact or any report, record, or inspection or other means which would warrant the Department to refuse to grant a license on an original application, or for violation of, or failure to observe any of the terms and conditions of the Act, or the license, or of any rule, regulation or order of the Department.

2.19.3 Except in cases of willful violation or those in which the public health, interest, or safety requires otherwise, no license will be modified, suspended, or revoked unless, prior to the institution of proceedings thereof, facts or conduct which may warrant such action shall have been called to the attention of the licensee in writing and the licensee shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

2.19.4 The Department may terminate a specific license upon request submitted by the licensee to the Department in writing.

RHA 2.20. Exemptions.

2.20.1 Source Material.

2.20.1.1 Any person is exempt from these regulations to the extent that such person receives, possesses, uses, or transfers source material in any chemical mixture, compound, solution, or alloy in which the source material is by weight less than 1/20 of 1 percent (0.05 percent) of the mixture, compound, solution, or alloy.

2.20.1.2 Any person is exempt from these regulations to the extent that such person receives, possesses, uses, or transfers unrefined and unprocessed ore containing source material; provided that, except as authorized in a specific license, such person shall not refine or process such ore.

2.20.1.3 Any person is exempt from the requirements for a license set forth in the Act and from the regulations in Parts III and VI of Title A to the extent that such person receives, possesses, uses, or transfers:

2.20.1.3.1 Any quantities of thorium contained in (1) incandescent gas mantles, (2) vacuum tubes, (3) welding rods, (4) electric lamps for illuminating purposes provided that each lamp does not contain more than 50 milligrams of thorium, (5) germicidal lamps, sunlamps, and lamps for outdoor or industrial lighting provided that each lamp does not contain more than 2 grams of

thorium, or (6) rare earth metals and compounds, mixtures, and products containing not more than 0.25 percent by weight thorium, uranium, or any combination of these, or (7) personnel neutron dosimeters provided that each dosimeter does not contain more than 50 milligrams of thorium.

2.20.1.3.2 Source material contained in the following products; (1) glazed ceramic tableware manufactured before August 27, 2013, provided that the glaze contains not more than 20 percent by weight source material; (2) piezoelectric ceramic containing not more than 2 percent by weight source material; (3) glassware containing not more than 2 percent by weight source material or, for glassware manufactured before August 27, 2013, 10 percent by weight source material; but not including commercially manufactured glass brick, pane glass, ceramic tile or other glass or ceramic used in constructions; and (4) glass enamel or glass enamel frit containing not more than 10 percent by weight source material imported or ordered for importation into the United States, or initially distributed by manufacturers in the United States before July 25, 1983.

2.20.1.3.3 Photographic film, negatives, and prints containing uranium or thorium;

2.20.1.3.4 Any finished product or part fabricated of, or containing, tungsten or magnesium-thorium alloys; provided that the thorium content of the alloy does not exceed 4 percent by weight and that the exemption contained in this subparagraph (2.20.1.3.4) shall not be deemed to authorize the chemical, physical or metallurgical treatment or processing or any such product or part;

2.20.1.3.5 Uranium contained in counterweights installed in aircraft, rockets, projectiles, and missiles, or stored or handled in connection with installation or removal of such counterweights: provided that:

2.20.1.3.5.1 Each counterweight has been impressed with the following legend clearly legible through any plating or other covering: "DEPLETED URANIUM";

2.20.1.3.5.2 Each counterweight is durably and legibly labeled or marked with the identification of the manufacturer, and the statement: "UNAUTHORIZED ALTERATIONS PROHIBITED";[6] and

2.20.1.3.5.3 The exemption contained in this subparagraph (2.20.1.3.5) shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such counterweights other than repair or restoration of any plating or other covering.

2.20.1.3.6 Natural or depleted uranium metal used as shielding constituting part of any shipping container, provided that:

2.20.1.3.6.1 The shipping container is conspicuously and legibly impressed with the legend: "CAUTION - RADIOACTIVE SHIELDING - URANIUM." and

2.20.1.3.6.2 The uranium metal is encased in mild steel or equally fire resistant metal of minimum wall thickness of one-eighth inch (3.2 mm);

2.20.1.3.6.3 The shipping container meets the specifications for containers for radioactive materials prescribed by Section 178.250. Specification 55, Part 178, of the regulations published by the Department of Transportation (49 CFR 178.250).

2.20.1.3.7 Thorium or uranium contained in or on finished optical lenses and mirrors, provided that each lens or mirror does not contain more than 10 percent by weight of thorium or uranium or, for lenses manufactured before August 27, 2013, 30 percent by weight of thorium. The exemption contained in this subparagraph (2.20.1.3.7) shall not be deemed to authorize either:

2.20.1.3.7.1 The shaping, grinding, or polishing of such lenses or mirror or manufacturing processes other than the assembly of such lens or mirror into optical systems and devices without any alteration of the lens or mirror; or

2.20.1.3.7.2 The receipt, possession, use or transfer of uranium or thorium contained in contact lenses, or in spectacles, or in eyepieces in binoculars or other optical instruments.

[6] The requirements specified in subdivisions RHA 2.20.1.3.5.1 and 2.20.1.3.5.2 need not be met by counterweights manufactured prior to December 31, 1969; provided, that such counterweights were manufactured under a specific license issued by the Atomic Energy Commission and were impressed with the legend required by RHA 2.20.1.3.5.2 in effect on June 30, 1969.

2.20.1.3.8 Uranium contained in detector heads for use in fire detection units, provided that each detector head contains not more than 0.005 microcurie of uranium.

2.20.1.3.9 Thorium contained in any finished aircraft engine part containing nickel-thoria alloy, provided that:

2.20.1.3.9.1 The thorium is dispersed in the nickel-thoria alloy in the form of finely divided thoria (thorium dioxide); and

2.20.1.3.9.2 The thorium content in the nickel-thoria alloy does not exceed 4 percent by weight.

2.20.1.3.10 No person may initially transfer for sale or distribution a product containing source material to persons exempt under RHA 2.20.1.3, or equivalent regulations unless authorized by a specific license to initially transfer such products for sale or distribution.

2.20.1.3.10.1 Persons initially distributing source material in products covered by the exemptions in RHA 2.20.1.3 before August 27, 2013, without specific authorization may continue such distribution for 1 year beyond this date. Initial distribution may also be continued until the Department takes final action on a pending application for license or license amendment to specifically authorize distribution submitted no later than 1 year beyond this date.

2.20.1.3.10.2 Persons authorized to manufacture, process, or produce these materials or products containing source material by the NRC or an Agreement State, and persons who import finished products or parts, for sale or distribution must be authorized by a specific license for distribution only and are exempt from the requirements of Parts III and VI of Title A, and RHA 2.6.1 and 2.6.2.

2.20.1.4 The exemptions in this subsection (2.20.1) do not authorize the manufacture, processing, or production of any of the products described herein.

2.20.2 Radioactive Materials Other Than Source Material.

2.20.2.1 Exempt concentrations.

2.20.2.1.1 Except as provided in RHA 2.20.2.1.3 and 2.20.2.1.4, any person is exempt from this part to the extent that such person receives, possesses, uses, transfers, owns or acquires products or materials containing radioactive material in concentrations not in excess of those listed in Schedule C of this part.

2.20.2.1.2 This section shall not be deemed to authorize the import of radioactive material or products containing radioactive material.

2.20.2.1.3 A manufacturer, processor, or producer of a product or material is exempt from this part to the extent that this person transfers radioactive material contained in a product or material in concentrations not in excess of those specified in Schedule C of this part and introduced into the product or material by a licensee holding a specific license issued by the NRC expressly authorizing such introduction. This exemption does not apply to the transfer of radioactive material contained in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

2.20.2.1.4 No person may introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under this section or equivalent NRC or Agreement State regulations, except in accordance with a license issued under RHA 2.7.2.

2.20.2.2 Certain items containing radioactive material. Except for persons who apply radioactive material to, or persons who incorporate radioactive material into, the following products, or persons who initially transfer for sale or distribution the following products containing radioactive material, any person is exempt from these regulations to the extent that he receives, possesses, uses, transfers, owns, or acquires the following products:[7]

[7] Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source material or byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20545.

2.20.2.2.1 Timepieces or hands or dials containing radium or not more than the following specified quantities of radioactive material and not exceeding the following specified levels of radiation:

2.20.2.2.1.1 25 millicuries of tritium per timepiece;

2.20.2.2.1.2 5 millicuries of tritium per hand;

2.20.2.2.1.3 15 millicuries of tritium per dial (bezels when used shall be considered as part of the dial);

2.20.2.2.1.4 100 microcuries of promethium 147 per watch or 200 microcuries of promethium 147 per any other timepiece.

2.20.2.2.1.5 20 microcuries of Promethium-147 per watch hand or 40 microcuries of Promethium-147 per other timepiece hand and;

2.20.2.2.1.6 60 microcuries of promethium 147 per watch dial or 120 microcuries of promethium 147 per other timepiece dial (bezels when used shall be considered as part of the dial);

2.20.2.2.1.7 The levels of radiation from hands and dials containing promethium 147 will not exceed, when measured through 50 milligrams per square centimeter of absorber:

(a) For wrist watches, 0.1 millirad per hour at 10 centimeters from any surface.

(b) For pocket watches, 0.1 millirad per hour at 1 centimeter from any surfaces;

(c) For any other timepiece, 0.2 millirad per hour at 10 centimeters from any surface.

2.20.2.2.1.8 1 microcurie (37 kBq) of Radium-226 timepiece in intact timepieces manufactured prior to November 30, 2007.

2.20.2.2.2 Reserved.

2.20.2.2.3 Balances of precision containing not more than 1 millicurie of tritium per balance or not more than 0.5 millicurie of tritium per balance part manufactured before December 17, 2007.

2.20.2.2.4 Reserved.

2.20.2.2.5 Marine compasses containing not more than 750 millicuries of tritium gas and other marine navigational instruments containing not more than 250 millicuries of tritium gas manufactured before December 17, 2007.

2.20.2.2.6 Reserved.

2.20.2.2.7 Electron tubes: Provided, that each tube does not contain more than one of the following specified quantities of radioactive material:

2.20.2.2.7.1 150 millicuries of tritium per microwave receiver protector tube or 10 millicuries of tritium per any other electron tube;

2.20.2.2.7.2 1 microcurie of cobalt 60;

2.20.2.2.7.3 5 microcuries of nickel 63;

2.20.2.2.7.4 30 microcuries of krypton 85;

2.20.2.2.7.5 5 microcuries of cesium 137;

2.20.2.2.7.6 30 microcuries of promethium 147; And provided further, that the level of radiation due to radioactive material contained in each electron tube does not exceed 1 millirad per hour at 1 centimeter from any surface when measured through 7 milligrams per square centimeter of absorber.[8]

2.20.2.2.8 Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, one or more sources of radioactive material; provided that:

2.20.2.2.8.1 Each source contains no more than one exempt quantity set forth in RHA 2.24, Schedule B.

[8] For purpose of this paragraph, 2.20.2.2.7 "electron tubes" include spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pickup tubes, radiation detection tubes, and any other completely sealed tube that is designed to conduct or control electrical currents.

2.20.2.2.8.2 Each instrument contains no more than 10 exempt quantities. For purposes of paragraph 2.20.2.2.8, instrument source(s) may contain either one type or different types of radionuclides and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in RHA 2.24, Schedule D, provided that the sum of such fractions shall not exceed unity; and

2.20.2.2.8.3 For purposes of paragraph 2.20.2.2.8, 0.05 microcuries of Americium-241 is considered an exempt quantity under RHA 2.24, Schedule B.

2.20.2.2.9 Ionization chamber smoke detectors containing not more than 1 microcurie (uCi) of americium-241 per detector in the form of a foil and designed to protect life and property from fires.

2.20.2.2.10 Static elimination devices which contain, as a sealed source or sources, byproduct material consisting of a total of not more than 18.5 MBq (500 μCi) of polonium-210 per device.

2.20.2.2.11 Ion generating tubes designed for ionization of air that contain, as a sealed source or sources, byproduct material consisting of a total of not more than 18.5 MBq (500 μCi) of polonium-210 per device or of a total of not more than 1.85 GBq (50 mCi) of hydrogen-3 (tritium) per device.

2.20.2.2.12 Such devices authorized before October 23, 2012 for use under the general license then provided in 10 CFR 31.3 and equivalent regulations of Agreement States and manufactured, tested, and labeled by the manufacturer in accordance with the specifications contained in a specific license issued by the Department.

2.20.2.2.13 Any person who desires to apply byproduct material to, or to incorporate byproduct material into, the products exempted in RHA 2.20.2.2, or who desires to initially transfer for sale or distribution such products containing byproduct material, should apply for a specific license pursuant to RHA 2.5, which license states that the product may be distributed by the licensee to persons exempt from the regulations pursuant to RHA 2.20.2.2.

2.20.2.3 Gas and aerosol detectors containing byproduct material. Except for persons who manufacture, possess, produce, or initially transfer for sale or distribution gas and aerosol detectors containing byproduct material, any person is exempt from the requirements for a license of Parts II, III, IV, V, VI, VIII, and XI in these regulations to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material in gas and aerosol detectors designed to protect health, safety, or property, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.26 of 10 CFR Part 32 which license authorizes the initial transfer of the product for use under this section. This exemption also covers gas and aerosol detectors manufactured or distributed before November 30, 2007, in accordance with a specific license issued by a Licensing State with comparable provisions to 10 CFR 32.26 authorizing distribution to persons exempt from regulatory requirements.

Any person who desires to manufacture, process, or produce gas and aerosol detectors containing byproduct material, or to initially transfer such products for use under RHA 2.20.2.3, should apply for a license under 10 CFR 32.26 and for a certificate of registration in accordance with RHA 2.29.

2.20.2.3.1 Gas and aerosol detectors containing NARM previously manufactured and distributed in accordance with a specific license issued by a Licensing State shall be considered exempt under 2.20.2.3, provided that the device is labeled in accordance with the specific license authorizing distribution, and provided further that they meet the requirements of 2.28.4.

2.20.2.4 Self-luminous products containing Tritium, Krypton-85, Promethium-147 or Radium except for persons who manufacture, process, produce, or initially transfer for sale of distribution self-luminous products containing Tritium, Krypton-85, or Promethium-147, any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, owns, or acquires Tritium, Krypton-85, or Promethium-147 in self-luminous products manufactured, processed, produced, or initially transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.22 of 10 CFR Part 32, which license authorizes the transfer of the product to persons who are exempt from regulatory requirements. The exemption in this paragraph 2.20.2.4 does not apply to Tritium, Krypton-85, or Promethium-147 used in products for frivolous purposes or in toys or adornments.

2.20.2.4.1 Any person who desires to manufacture, process, or produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147 for use under RHA 2.20.2.4, should apply for a license pursuant to Section 32.22 of 10 CFR Part 32, and for a certificate of registration in accordance with RHA 2.29.

2.20.2.5 Exempt quantities.

2.20.2.5.1 Except as provided in subparagraphs 2.20.2.5.3 through 2.20.2.5.5, any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material in individual quantities, each of which does not exceed the applicable quantity set forth in RHA 2.24, Schedule B.

2.20.2.5.2 Any person, who possesses byproduct material received or acquired before September 25, 1971, under the general license formerly provided in Paragraph 2.4.1 is exempt from the requirements for a license set forth in this Part to the extent that this person possesses, uses, transfers, or owns byproduct material.

2.20.2.5.3 This paragraph 2.20.2.5 does not authorize the production, packaging, or repackaging of radioactive material for purposes of commercial distribution, or the incorporation of radioactive material into products intended for commercial distribution.

2.20.2.5.4 No person may, for purposes of commercial distribution, transfer radioactive material in the individual quantities set forth in RHA 2.24 Schedule B, knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt under this paragraph or equivalent regulations of the U.S. Nuclear Regulatory Commission, any Agreement State, or a Licensing State except in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.18 of 10 CFR Part 32 which license states that the radioactive material may be transferred by the licensee to persons exempt under this paragraph 2.20.2.5 or the equivalent regulations of the U.S. Nuclear Regulatory Commission or any Agreement State.

2.20.2.5.5 No person may, for purposes of producing an increased radiation level, combine quantities of radioactive material covered by this exemption so that the aggregate quantity exceeds the limits set forth in RHA 2.24, Schedule B, except for radioactive material combined within a device placed in use before May 3, 1999, or as otherwise permitted by the regulations in this part.

2.20.2.5.6.1 Except for persons who manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing byproduct material designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing an ionized atmosphere, any person is exempt from the requirements for a license of Parts II, III, IV, V, VI, VIII, and XI set forth in Regulation 61–63, Radioactive Materials (Title A) to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material, in these certain detecting, measuring, gauging, or controlling devices and certain devices for producing an ionized atmosphere, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued pursuant to Section 32.30 of 10 CFR Part 32, which license authorizes the initial transfer of the device for use under this section. This exemption does not cover sources not incorporated into a device, such as calibration and reference sources.

2.20.2.5.6.2 Any person who desires to manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing byproduct material for use under 2.20.2.5.6.1, should apply for a license pursuant to Section 32.30 of 10 CFR Part 32, and for a certificate of registration in accordance with RHA 2.29.

2.20.2.6 Reserved.

2.20.2.7 Radioactive drug: Capsules containing Carbon-14 urea for "in vivo" diagnostic use for humans.

2.20.2.7.1 Except as provided in 2.20.2.7.2 and 2.20.2.7.3, any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, owns or acquires capsules containing luCi(37kBq) Carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each, for "in vivo" diagnostic use for humans.

2.20.2.7.2 Any person who desires to use the capsules for research involving human subjects shall apply for and receive a specific license pursuant to Part IV of these regulations.

2.20.2.7.3 Any person who desires to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution such capsules shall apply for and receive a specific license pursuant to RHA 2.7.5.

2.20.2.7.4 Nothing in this section relieves persons from complying with applicable FDA, Federal, and other State requirements governing receipt, administration, and use of drugs.

2.20.2.8 Any person who desires to apply byproduct material to, or to incorporate byproduct material into, the products exempted in RHA 2.20.2.2, or who desires to initially transfer for sale or distribution such products containing byproduct material, should apply for a specific license pursuant to 10 CFR 32.14, which license states that the product may be distributed by the licensee to persons exempt from the regulations pursuant to RHA 2.20.2.2.

HISTORY: Amended by State Register Volume 38, Issue No. 10, Doc. No. 4462, eff October 24, 2014; SCSR 42–2 Doc. No. 4791, eff February 23, 2018.

Editor's Note

Scrivener errors corrected in 2012.

RHA 2.21. Reciprocal Recognition of Licenses.

2.21.1 Subject to these regulations, any person who holds a specific license from the U.S. Nuclear Regulatory Commission, any Agreement State, or Licensing State, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within the State of South Carolina for a period not in excess of 180 days in any calendar year provided that:

2.21.1.1 The licensing document does not limit the activity authorized by such document to specified installations or locations; and

2.21.1.2 The out-of-state licensee notifies the Department in writing at least three (3) days prior to engaging in such activity. Such notification shall indicate the location, period, and type of proposed possession and use within the State, and shall be accompanied by a copy of the pertinent licensing document. If, for a specific case, the three (3) day period would impose an undue hardship on the out-of-state licensee, he may, upon application to the Department, obtain permission to proceed sooner; and

2.21.1.3 The out-of-state licensee complies with all applicable regulations of the Department and with all terms and conditions of his licensing document, except any such terms and conditions which may be inconsistent with applicable regulations of the Department; and

2.21.1.4 The out-of-state licensee supplies such other information as the Department may reasonably request.

2.21.1.5 The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in this section except by transfer to a person specifically licensed by the Department or by the U.S. Nuclear Regulatory Commission to receive such material.

2.21.1.6 The general license granted in RHA 2.21.1 concerning activities in offshore waters authorizes that person to possess or use radioactive materials, or engage in the activities authorized, for an unlimited period of time.

2.21.2 Notwithstanding the provisions of 2.21 any person who holds a specific license or equivalent licensing document issued by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State authorizing the holder to manufacture, transfer, install, or service a device described in 2.4.2.1 within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, and service such a device in this State.

2.21.2.1 Such person shall satisfy the requirements of 2.10.4.1 and 2.10.4.2.

2.21.2.2 The device has been manufactured, labeled, installed and serviced in accordance with applicable provisions of the specific license issued to such person by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State; and

2.21.2.3 Such person shall assure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that "Removal of this Label is Prohibited."

2.21.2.4 The holder of the specific license shall furnish to each general licensee to whom he transfers such device or on whose premises he installs such device a copy of the general license contained in Section 2.4.2.

2.21.2.5 The Department may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by another agency or Licensing State, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to protect health or minimize danger to life or property.

RHA 2.22. Transportation of Radioactive Materials

2.22.1 The transportation of radioactive material shall be in accordance with the requirements in 10 CFR Part 71, which is incorporated by reference, with the exception of the following sections: 71.2, 71.6, 71.11, 71.14(b), 71.19, 71.31, 71.33, 71.35, 71.37, 71.38, 71.39, 71.41, 71.43, 71.45, 71.51, 71.52, 71.53, 71.55, 71.59, 71.61, 71.63, 71.64, 71.65, 71.70, 71.71, 71.73, 71.74, 71.75, 71.77, 71.85(a)-(c), 71.91(b), 71.99, 71.100, 71.101(c)(2), 71.101(g), 71.107, 71.109, 71.111, 71.113, 71.115, 71.117. 71.119, 71.121, 71.123 and 71.125. The provisions of this section apply to the transportation of radioactive material, or delivery of radioactive material to a carrier for transportation, regardless of whether or not the carrier is also subject to the rules and regulations of the Nuclear Regulatory Commission contained in Title 10 CFR Part 71 and other agencies of the United States having jurisdiction.

2.22.1.1 No person shall deliver radioactive material to a carrier for transport or transport radioactive material except as authorized in a general or specific license issued by the Department or as exempted in 2.22.1.2.

2.22.1.2 Exemptions

2.22.1.2.1 Common and contract carriers, freight forwarders, and warehousemen, who are subject to the rules and regulations of the U.S. Department of Transportation or the U.S. Postal Service (39 CFR Parts 14 and 15), are exempt from RHA 2.22.1.1 to the extent that they transport or store radioactive material in the regular course of their carriage for another or storage incident thereto. Common and contract carriers who are not subject to the rules and regulations of the U.S. Department of Transportation or U.S. Postal Service are subject to RHA 2.22.1.1.

2.22.1.2.2 Physicians as defined in RHA 1.2.17 are exempt from the requirements of RHA 2.22.1.1 to the extent that they transport radioactive material for use in the practice of medicine.

2.22.1.2.3 Specific licensees are exempt from 2.22.1.1 to the extent that they deliver to a carrier for transport packages each of which contains no radioactive material having a specific activity in excess of .002 microcuries per gram.

2.22.1.2.4 Any licensee who delivers radioactive material to a carrier for transport where such transport is subject to the regulations of the U.S. Postal Service is exempt from the provisions of 2.22.1.1.

2.22.2 Preparation of Radioactive Material for Transport

2.22.2.1 A general license is hereby issued to deliver radioactive material to a carrier[9] for transport provided that:

2.22.2.2 The person complies with the applicable requirements of the regulations, appropriate to the mode of transport, of the U.S. Department of Transportation and the U.S. Postal Service insofar as such regulations relate to the packaging of radioactive material, marking and labeling of packages, loading and storage of packages, placarding of the transporting vehicle, monitoring requirements and accident reporting; and

2.22.2.3 The person has established procedures for opening and closing packages in which radioactive material is transported to provide safety and to assure that, prior to delivery to a carrier for transport, each package is properly closed for transport; and

[9] For the purposes of this regulation, a licensee who transports his own licensed material as a private carrier is considered to have delivered such material to a carrier for transport.

2.22.2.4 Prior to delivery of a package to a carrier for transport, the person shall assure that any special instruments needed to safely open the package are sent to, or have been made available to, the consignee.

2.22.3 Intrastate Transport

2.22.3.1 A general license is hereby issued to any common or contract carrier to transport and store radioactive material in the regular course of their carriage for another or storage incident thereto, provided the transportation and storage is in accordance with the applicable requirements of the regulations, appropriate to the mode of transport, of the U.S. Department of Transportation insofar as such regulations relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting.[10]

2.22.3.2 A general license is hereby issued to any private carrier to transport radioactive material, provided the transportation is in accordance with regulations, appropriate to the mode of transport, of the U.S. Department of Transportation insofar as such regulations relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting.

2.22.3.3 Persons who transport radioactive material pursuant to the general licenses in 2.22.3.1 and 2.22.3.2 are exempt from the requirements of Part III and Part VI of these regulations to the extent that they transport radioactive material.

2.22.4 Advance Notification of Nuclear Waste [11]

2.22.4.1 Prior to the transport of any nuclear waste outside of the confines of the licensee's facility or other place of use or storage, or prior to the delivery of any nuclear waste to a carrier for transport, each licensee shall provide advance notification of such transport to the governor (or governor's designee) of each State through which the waste will be transported.

2.22.4.2 Each advance notification required by 2.22.4.1 shall contain the following information:

2.22.4.2.1 The name, address, and telephone number of the shipper, carrier, and receiver of the shipment.

2.22.4.2.2 A description of the nuclear waste contained in the shipment as required by the regulations of the U.S. Department of Transportation in 49 CFR 172.202 and 172.203(d);

2.22.4.2.3 The point of origin of the shipment and the seven-day period during which departure of the shipment is estimated to occur;

2.22.4.2.4 The seven-day period during which arrival of the shipment at State boundaries is estimated to occur;

2.22.4.2.5 The destination of the shipment, and the seven-day period during which arrival of the shipment is estimated to occur; and

2.22.4.2.6 A point of contact with a telephone number for current shipment information.

2.22.4.3 The notification required by 2.22.4.1 shall be made in writing to the office of each appropriate governor (or governor's designee) and to the Department. A notification delivered by mail must be postmarked at least seven days before the beginning of the seven-day period during which departure of the shipment is estimated to occur. A notification delivered by messenger must reach the office of the governor (or governor's designee) at least four days before the beginning of the seven-day period during which departure of the shipment is estimated to occur. A copy of the notification shall be retained by the licensee for one year.

2.22.4.4 The licensee shall notify each appropriate governor (or governor's designee) and the Department of any changes to schedule information provided pursuant to 2.22.4.1. Such notification shall be by telephone to a responsible individual in the office of the governor (or governor's designee) of the appropriate State. The licensee shall maintain for one year a record of the name of the individual contacted.

2.22.4.5 Each licensee who cancels a nuclear waste shipment for which advance notification has been sent shall send a cancellation notice to the governor (or governor's designee) of each

[10] Any notification of incidents referred to in the requirements shall be filed with, or made to, the Department.

[11] For the purpose of this section, "nuclear waste" means any large quantity of source, byproduct, or special nuclear material required to be in Type B packaging while transported to, through or across State boundaries to a disposal site, or to a collection point for transport to a disposal site.

appropriate State and to the Department. A copy of the notice shall be retained by the licensee for one year.

2.22.5 General License: NRC-approved package.

2.22.5.1 A general license is issued to any licensee of the Department to transport, or to deliver to a carrier for transport, licensed material in a package for which a license, Certificate of Compliance (CoC), or other approval has been issued by the NRC.

2.22.5.2 This general license applies only to a licensee who has a quality assurance program approved by the Department as satisfying the provisions of subpart H of 10 CFR 71.

2.22.5.3 Each licensee issued a general license under 2.22.5.1 of this section shall:

2.22.5.3.1 Maintain a copy of the NRC-issued CoC, or other approval of the package, and the drawings and other documents referenced in the approval relating to the use and maintenance of the packaging and to the actions to be taken before shipment;

2.22.5.3.2 Comply with the terms and conditions of the license, certificate, or other approval, as applicable, and the applicable requirements of subparts A, G, and H of 10 CFR 71; and

2.22.5.3.3 Submit in writing before the first use of the package to: ATTN: Document Control Desk, Director, Division of Spent Fuel Storage and Transportations, Office of Nuclear Material Safety and Safeguards, using an appropriate method listed in 10 CFR 71.1(a), the licensee's name and license number, and the package identification number specified in the package approval.

2.22.5.4 This general license applies only when the package approval authorizes use of the package under this general license.

2.22.5.5 For a Type B package or fissile material package, the design of which was approved by NRC before April 1, 1996, the general license is subject to the additional restrictions of 10 CFR 71.19.

2.22.6 General License: Use of foreign-approved package.

2.22.6.1 A general license is issued to any licensee of the Department to transport, or to deliver to a carrier for transport, licensed material in a package, the design of which has been approved in a foreign national competent authority certificate, that has been revalidated by the DOT as meeting the applicable requirements of 49 CFR 171.23.

2.22.6.2 Except as otherwise provided in this section, the general license applies only to a licensee having a quality assurance program approved by the Department as satisfying the applicable provisions of subpart H of 10 CFR 71.

2.22.6.3 This general license applies only to shipments made to or from locations outside the United States.

2.22.6.4 Each licensee issued a general license under 2.22.6.1 of this section shall:

2.22.6.4.1 Maintain a copy of the applicable certificate, the revalidation, and the drawings and other documents referenced in the CoC, relating to the use and maintenance of the packaging and to the actions to be taken before shipment; and

2.22.6.4.2 Comply with the terms and conditions of the certificate and revalidation, and with the applicable requirements of subparts A, G, and H of 10 CFR 71.

2.22.7 Records.

2.22.7.1 The licensee shall make available to the Department for inspections, upon reasonable notice, all records required by this part. Records are only valid if stamped, initialed, or signed and dated by authorized personnel, or otherwise authenticated.

2.22.7.2 The licensee shall maintain sufficient written records to furnish evidence of the quality of packaging. The records to be maintained include results of the determinations required by 10 CFR 71.85; design, fabrication, and assembly records; results of reviews, inspections, tests, and audits; results of monitoring work performance and materials analyses; and results of maintenance, modification, and repair activities. Inspection, test, and audit records must identify the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any deficiencies noted. These records must be retained for three (3) years after the life of the packaging to which they apply.

2.22.8 Quality assurance requirements.

2.22.8.1 Purpose. This subpart describes quality assurance requirements applying to design, purchase, fabrication, handling, shipping, storing, cleaning, assembly inspection, testing, operation, maintenance, repair, and modification of components of packaging that are important to safety. As used in this subpart, "Quality Assurance" comprises all those planned and systematic actions necessary to provide adequate confidence that a system or component will perform satisfactorily in service. Quality Assurance includes quality control, which comprises those quality assurance actions related to control of the physical characteristics and quality of the material or component to predetermined requirements. Each licensee is responsible for satisfying the quality assurance requirements that apply to its use of a packaging for the shipment of licensed material subject to this subpart.

2.22.8.2 Establishment of program. Each licensee shall establish, maintain, and execute a quality assurance program satisfying each of the applicable criteria of 10 CFR 71.101 through 71.137 and satisfying any specific provisions that are applicable to the licensee's activities including procurement of packaging. The licensee shall execute the applicable criteria in a graded approach to an extent that is commensurate with the quality assurance requirement's importance to safety.

2.22.8.3 Approval of program. Before the use of any package for the shipment of licensed material subject to this subpart, each licensee shall obtain Department approval of its quality assurance program. Each licensee shall file a description of its quality assurance program, including a discussion of which requirements of this subpart are applicable and how they will be satisfied, by submitting the description to: ATTN: South Carolina Department of Health and Environmental Control, Division of Waste Management, 2600 Bull Street, Columbia, South Carolina 29201.

2.22.9 Quality assurance organization.

2.22.9.1 The licensee shall be responsible for the establishment and execution of the quality assurance program. The licensee may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, or any part of the quality assurance program, but shall retain responsibility for the program. These activities include performing the functions associated with attaining quality objectives and the quality assurance functions.

2.22.10 Changes to quality assurance program.

2.22.10.1 Each quality assurance program approval holder shall submit a description of a proposed change to its Department-approved quality assurance program that will reduce commitments in the program description as approved by the Department. The quality assurance program approval holder shall not implement the change before receiving Department approval.

2.22.10.1.1 The description of a proposed change to the Department-approved quality assurance program must identify the change, the reason for the change, and the basis for concluding that the revised program incorporating the change continues to satisfy the applicable requirements of subpart H of 10 CFR 71.

2.22.10.1.2 Reserved.

2.22.10.2 Each quality assurance program approval holder may change a previously approved quality assurance program without prior Department approval, if the change does not reduce the commitments in the quality assurance program previously approved by the Department. Changes to the quality assurance program that do not reduce the commitments shall be submitted to the Department every twenty-four (24) months. In addition to quality assurance program changes involving administrative improvements and clarifications, spelling corrections, and non-substantive changes to punctuation or editorial items, the following changes are not considered reductions in commitment:

2.22.10.2.1 The use of a quality assurance standard approved by the Department that is more recent than the quality assurance standard in the licensee's current quality assurance program at the time of the change;

2.22.10.2.2 The use of generic organizational position titles that clearly denote the position function, supplemented as necessary by descriptive text, rather than specific titles, provided that there is no substantive change to either the functions of the position or reporting responsibilities;

2.22.10.2.3 The use of generic organizational charts to indicate functional relationships, authorities, and responsibilities, or alternatively, the use of descriptive text, provided that there is no substantive change to the functional relationships, authorities, or responsibilities;

2.22.10.2.4 The elimination of quality assurance program information that duplicates language in quality assurance regulatory guides and quality assurance standards to which the quality assurance program approval holder has committed to on record; and

2.22.10.2.5 Organizational revisions that ensure that persons and organizations performing quality assurance functions continue to have the requisite authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations.

2.22.10.3 Each quality assurance program approval holder shall maintain records of quality assurance program changes.

2.22.11 Quality assurance records.

2.22.11.1 The licensee shall maintain sufficient written records to describe the activities affecting quality. These records must include changes to the quality assurance program as required by 2.22.10 of this part, the instructions, procedures, and drawings required by 10 CFR 71.111 to prescribe quality assurance activities, and closely related specifications such as required qualifications or personnel, procedures, and equipment. The records must include the instructions or procedures that establish a records retention program that is consistent with applicable regulations and designates factors such as duration, location, and assigned responsibility. The licensee shall retain these records for three (3) years beyond the date when the licensee last engaged in the activity for which the quality assurance program was developed. If any portion of the quality assurance program, written procedures, or instructions is superseded, the licensee shall retain the superseded material for three (3) years after it is superseded.

HISTORY: Amended by SCSR 42–2 Doc. No. 4791, eff February 23, 2018; SCSR 44–9 Doc. No. 4958, eff September 25, 2020.

Editor's Note

Scrivener errors corrected in 2012.

RHA 2.23. Schedule A. Generally Licensed Equipment when Manufactured in Accordance with the Specifications Contained in a Specific License.

2.23.1 Static Elimination Device. Devices designed for use as static eliminators which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries of polonium 210 per device.

2.23.2 Ion Generating Tube. Devices designed for ionization of air which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries of polonium 210 per device or a total of not more than 50 millicuries of hydrogen 3 (tritium) per device.

RHA 2.24. Schedule B. Exempt Quantities.

Byproduct Material	Microcuries
Antimony 122 (Sb 122)	100
Antimony 124 (Sb 124)	10
Antimony 125 (Sb 125)	10
Arsenic 73 (As 73)	100
Arsenic 74 (As 74)	10
Arsenic 76 (As 76)	10
Arsenic 77 (As 77)	100
Barium 131 (Ba 131)	10
Barium 133 (Ba 133)	10
Barium 140 (Ba 140)	10
Bismuth 210 (Bi 210)	1
Bromine 82 (Br 82)	10
Cadmium 109 (Cd 109)	10
Cadmium 115m (Cd 115m)	10
Cadmium 115 (Cd 115)	100
Calcium 45 (Ca 45)	10

Byproduct Material	Microcuries
Calcium 47 (Ca 47)	10
Carbon 14 (C 14)	100
Carbon 11 (C 11)	10
Cerium 141 (Ce 141)	100
Cerium 143 (Ce 143)	100
Cerium 144 (Ce 144)	1
Cesium-129 (Cs-129)	100
Cesium 131 (Cs 131)	1,000
Cesium 134m (Cs 134m)	100
Cesium 134 (Cs 134)	1
Cesium 135 (Cs 135)	10
Cesium 136 (Cs 136)	10
Cesium 137 (Cs 137)	10
Chlorine 36 (Cl 36)	10
Chlorine 38 (Cl 38)	10
Chromium 51 (Cr 51)	1,000

Byproduct Material	Microcuries
Cobalt 57 (Co 57)	100
Cobalt 58m (Co 58m)	10
Cobalt 58 (Co 58)	10
Cobalt 60 (Co 60)	1
Copper 64 (Cu 64)	100
Dysprosium 165 (Dy 165)	10
Dysprosium 166 (Dy 166)	100
Erbium 169 (Er 169)	100
Erbium 171 (Er 171)	100
Europium 152 (Eu 152) 9.2h	100
Europium 152 (Eu 152) 13 yr	1
Europium 154 (Eu 154)	1
Europium 155 (Eu 155)	10
Flourine 18 (F 18)	1,000
Gadolinium 153 (Gd 153)	10
Gadolinium 159 (Gd 159)	100
Gallium 67 (Ga 67)	100
Gallium 72 (Ga 72)	10
Germanium-68 (Ge-68)	10
Germanium 71 (Ge 71)	100
Gold 195 (Au 195)	20
Gold 198 (Au 198)	100
Gold 199 (Au 199)	100
Hefnium 181 (Hf 181)	10
Holmium 166 (Ho 166)	100
Hydrogen 3 (H 3)	1,000
Indium 111 (In 111)	100
Indium 113m (In 113m)	100
Indium 114m (In 114m)	10
Indium 115m (In 115m)	100
Indium 115 (In 115)	10
Iodine 123 (I 123)	100
Iodine 125 (I 125)	1
Iodine 126 (I 126)	1
Iodine 129 (I 129)	0.1
Iodine 131 (I 131)	1
Iodine 132 (I 132)	10
Iodine 133 (I 133)	10
Iodine 134 (I 134)	10
Iodine 135 (I 135)	10
Iridium 192 (Ir 192)	10
Iridium 194 (Ir 194)	100
Iron 52 (Fe 52)	10
Iron 55 (Fe 55)	100
Iron 59 (Fe 59)	10
Krypton 85 (Kr 85)	100
Krypton 87 (Kr 87)	10
Lanthanum 140 (La 140)	10
Lutetium 177 (Lu 177)	100
Manganese 52 (Mn 52)	10
Manganese 54 (Mn 54)	10
Manganese 56 (Mn 56)	10
Mercury 197m (Hg 197m)	100
Mercury 197 (Hg 197)	100
Mercury 203 (Hg 203)	10
Molybdenum 99 (Mo 99)	100
Neodymium 147 (Nd 147)	100
Neodymium 149 (Nd 149)	100
Nickel 59 (Ni 59)	100

Byproduct Material	Microcuries
Nickel 63 (Ni 63)	10
Nickel 65 (Ni 65)	100
Niobium 93m (Nb 93m)	10
Niobium 95 (Nb 95)	10
Niobium 97 (Nb 97)	10
Nitrogen 13 (N 13)	10
Osmium 185 (Os 185)	10
Osmium 191m (Os 191m)	100
Osmium 191 (Os 191)	100
Osmium 193 (Os 193)	100
Oxygen 15 (O 15)	10
Palladium 103 (Pd 103)	100
Palladium 109 (Pd 109)	100
Phosphorus 32 (P 32)	10
Platinum 191 (Pt 191)	100
Platinum 193m (Pt 193m)	100
Platinum 193 (Pt 193)	100
Platinum 197m (Pt 197m)	100
Platinum 197 (Pt 197)	100
Polonium 210 (Po 210)	0.1
Potassium 42 (K 42)	10
Potassium 43 (K 43)	10
Praseodymium 142 (Pr 142)	100
Praseodymium 143 (Pr 143)	100
Promethium 147 (Pm 147)	10
Promethium 149 (Pm 149)	10
Radium 226 (Ra 226)	0.1
Rhenium 186 (Re 186)	100
Rhenium 188 (Re 188)	100
Rhodium 103m (Rh 103m)	100
Rhodium 105 (Rh 105)	100
Rubidium 81 (Rb 81)	10
Rubidium 86 (Rb 86)	10
Rubidium 87 (Rb 87)	10
Ruthenium 97 (Ru 97)	100
Ruthenium 103 (Ru 103)	10
Ruthenium 105 (Ru 105)	10
Ruthenium 106 (Ru 106)	1
Samarium 151 (Sm 151)	10
Samarium 153 (Sm 153)	100
Scandium 46 (Sc 46)	10
Scandium 47 (Sc 47)	100
Scandium 48 (Sc 48)	10
Selenium 75 (Se 75)	10
Silicon 31 (Si 31)	100
Silver 105 (Ag 105)	10
Silver 110m (Ag 110m)	1
Silver 111 (Ag 111)	100
Sodium 22 (Na 22)	10
Sodium 24 (Na 24)	10
Strontium 85 (Sr 85)	10
Strontium 89 (Sr 89)	1
Strontium 90 (Sr 90)	0.1
Strontium 91 (Sr 91)	10
Strontium 92 (Sr 92)	10
Sulfur 35 (S 35)	100
Tantalum 182 (Ta 182)	10
Technetium 96 (Tc 96)	10
Technetium 97m (Tc 97m)	100
Technetium 97 (Tc 97)	100
Technetium 97m (Tc 97m)	100
Technetium 99m (Tc 99m)	10
Tellurium 125m (Te 125m)	10
Tellurium 127m (Te 127m)	10

Byproduct Material	Microcuries
Tellurium 127 (Te 127)	100
Tellurium 129m (Te 129m)	10
Tellurium 129 (Te 129)	100
Tellurium 131m (Te 131m)	10
Tellurium 132 (Te 132)	10
Terbium 160 (Tb 160)	10
Thallium 200 (Tl 200)	100
Thallium 201 (Tl 201)	100
Thallium 202 (Tl 202)	100
Thallium 204 (Tl 204)	10
Thulium 170 (Tm 170)	10
Thulium 171 (Tm 171)	10
Tin 113 (Sn 113)	10
Tin 125 (Sn 125)	10
Tungsten 181 (W 181)	10
Tungsten 185 (W 185)	10
Tungsten 187 (W 187)	100
Vanadium 48 (V 48)	10
Xenon 131m (Xe 131m)	1,000

Byproduct Material	Microcuries
Xenon 133 (Xe 133)	100
Xenon 135 (Xe 135)	100
Ytterbium 175 (Yb 175)	100
Yttrium 87 (Y 87)	10
Yttrium-88 (Y-88)	10
Yttrium 90 (Y 90)	10
Yttrium 91 (Y 91)	10
Yttrium 92 (Y 92)	100
Yttrium 93 (Y 93)	100
Zinc 65 (Zn 65)	10
Zinc 69m (Zn 69m)	100
Zinc 69 (Zn 69)	1,000
Zirconium 93 (Zr 93)	10
Zirconium 95 (Zr 95)	10
Zirconium 97 (Zr 97)	10
Any radioactive material not listed above other than alpha emitting radioactive material	0.1

RHA 2.25. Schedule C—Exempt Concentrations.

Element (Atomic Number)	Isotope	Column I Gas concentration uc/ml [1]	Column II Liquid and solid concentration uc/ml [2]
Antimony (51)	Sb 122		3×10^{-4}
	Sb 124		2×10^{-5}
	Sb 125		1×10^{-3}
Argon (18)	A 37	1×10^{-3}	
	A 41	4×10^{-7}	
Arsenic (33)	As 73		5×10^{-4}
	As 74		5×10^{-4}
	As 76		2×10^{-4}
	As 77		8×10^{-4}
Barium (56)	Ba 131		2×10^{-3}
	Ba 140		3×10^{-4}
Beryllium (4)	Be 7		2×10^{-2}
Bismuth (83)	Bi 206		4×10^{-4}
Bromine (35)	Br 82	4×10^{-7}	3×10^{-3}
Cadmium (85)	Cd 109		2×10^{-3}
	Cd 115m		3×10^{-4}
	Cd 115		3×10^{-4}
Calcium (20)	Ca 45		9×10^{-5}
	Ca 47		5×10^{-4}
Carbon (6)	C 14	1×10^{-6}	8×10^{-3}
Cerium (58)	Ce 141		9×10^{-4}
	Ce 143		4×10^{-4}
	Ce 144		1×10^{-4}
Cesium (55)	Cs 131		2×10^{-2}
	Cs 134m		6×10^{-2}
	Cs 134		9×10^{-5}
Chlorine (17)	Cl 38	9×10^{-7}	4×10^{-3}
Chromium (24)	Cr 51		2×10^{-2}
Cobalt (27)	Co 57		5×10^{-3}
	Co 58		1×10^{-3}
	Co 60		5×10^{-4}
Copper (29)	Cu 64		3×10^{-3}
Dysprosium (66)	Dy 165		4×10^{-3}
	Dy 166		4×10^{-4}

Element (Atomic Number)	Isotope	Column I Gas concentration uc/ml [1]	Column II Liquid and solid concentration uc/ml [2]
Erbium (68)	Er 169		9×10^{-4}
	Er 171		1×10^{-3}
Europium (63)	Eu 152 (T/2 = 9.2 Hrs)		6×10^{-4}
	Eu 155		2×10^{-3}
Fluorine (9)	F 18	2×10^{-6}	8×10^{-3}
Gadolinium (64)	Gd 153		2×10^{-3}
	Gd 159		8×10^{-4}
Gallium (31)	Ga 72		4×10^{-4}
Germanium (32)	Ge 71		2×10^{-2}
Gold (79)	Au 196		2×10^{-3}
	Au 198		5×10^{-4}
	Au 199		2×10^{-5}
Hafnium (72)	Hf 181		7×10^{-4}
Hydrogen (1)	H 3	5×10^{-6}	3×10^{-2}
Indium (49)	In 113m		1×10^{-2}
	In 114m		2×10^{-4}
Iodine (53)	I 126	3×10^{-9}	2×10^{-5}
	I 131	3×10^{-9}	2×10^{-5}
	I 132	8×10^{-8}	6×10^{-4}
	I 133	1×10^{-8}	7×10^{-5}
	I 134	2×10^{-7}	1×10^{-3}
Iridium (77)	Ir 190		2×10^{-3}
	Ir 192		4×10^{-4}
	Ir 194		3×10^{-4}
Iron (26)	Fe 55		8×10^{-3}
	Fe 59		6×10^{-4}
Krypton (36)	Kr 85m	1×10^{-6}	
	Kr 85	3×10^{-6}	
Lanthanum (57)	La 140		2×10^{-4}
Lead (82)	Pb 203		4×10^{-3}
Lutetium (71)	Lu 177		1×10^{-3}
Manganese (25)	Mn 52		3×10^{-4}
	Mn 54		1×10^{-3}
	Mn 56		1×10^{-3}
Mercury (80)	Hg 197m		2×10^{-3}
	Hg 197		3×10^{-3}
	Hg 203		2×10^{-4}
Molybdenum (42)	Mo 99		2×10^{-3}
Neodymium (60)	Nd 149		3×10^{-3}
	Nd 147		6×10^{-4}
Nickel (28)	Ni 65		1×10^{-3}
Niobium (Columbium) (41)	Nb 95		1×10^{-3}
	Nb 97		9×10^{-3}
Osmium (76)	Os 185		7×10^{-4}
	Os 191m		3×10^{-2}
	Os 191		2×10^{-3}
	Os 193		6×10^{-4}
Palladium (46)	Pd 103		3×10^{-3}
	Pd 109		9×10^{-4}
Phosphorus (15)	P 32		2×10^{-4}
Platinum (78)	Pt 191		1×10^{-3}
	Pt 193m		1×10^{-2}
	Pt 197m		1×10^{-2}
	Pt 197		1×10^{-3}
Polonium (84)	Po 210	2×10^{-10}	7×10^{-6}
Potassium (19)	K 42		3×10^{-3}
Praseodymium (59)	Pr 142		3×10^{-4}
	Pr 143		5×10^{-4}
Promethium (61)	Pm 147		2×10^{-3}

Element (Atomic Number)	Isotope	Column I Gas concentration uc/ml [1]	Column II Liquid and solid concentration uc/ml [2]
	Pm 149		4×10^{-4}
Radium (88)	Ra 226	1×10^{-11}	1×10^{-7}
	Ra 228	2×10^{-11}	3×10^{-7}
Rhenium (75)	Re 183		6×10^{-3}
	Re 186		9×10^{-4}
	Re 188		6×10^{-4}
Rhodium (45)	Rh 103m		1×10^{-1}
	Rh 105		1×10^{-3}
Rubidium (37)	Rb 86		7×10^{-4}
Ruthenium (44)	Ru 97		4×10^{-3}
	Ru 103		8×10^{-4}
	Ru 105		1×10^{-3}
	Ru 106		1×10^{-4}
Samarium (62)	Sm 153		8×10^{-4}
Scandium (21)	Sc 46		4×10^{-4}
	Sc 47		9×10^{-4}
	Sc 48		3×10^{-4}
Selenium (34)	Se 75		3×10^{-3}
Silicon (14)	Si 31		9×10^{-3}
Silver (47)	Ag 105		1×10^{-3}
	Ag 110m		3×10^{-4}
	Ag 111		4×10^{-4}
Sodium (11)	Na 24		2×10^{-3}
Strontium (38)	Sr 89		1×10^{-4}
	Sr 91		7×10^{-4}
	Sr 92		7×10^{-4}
Sulfur (16)	S 35	9×10^{-8}	6×10^{-4}
Tantalum (73)	Ta 182		4×10^{-4}
Technetium (43)	Tc 96m		1×10^{-1}
	Tc 96		1×10^{-3}
Tellurium (52)	Te 125m		2×10^{-3}
	Te 127m		6×10^{-4}
	Te 127		3×10^{-3}
	Te 129m		3×10^{-4}
	Te 131m		6×10^{-4}
	Te 132		3×10^{-4}
Terbium (65)	Tb 160		4×10^{-4}
Thallium (81)	Tl 200		4×10^{-3}
	Tl 201		3×10^{-3}
	Tl 202		1×10^{-3}
	Tl 204		1×10^{-3}
Thulium (69)	Tm 170		5×10^{-4}
	Tm 171		5×10^{-3}
Tin (50)	Sn 113		9×10^{-4}
	Sn 125		2×10^{-4}
Tungston (Wolfram) (74)	W 181		4×10^{-3}
	W 187		7×10^{-4}
Vanadium (23)	V 48		3×10^{-4}
Xenon (54)	Xe 131m	4×10^{-6}	
	Xe 133	3×10^{-6}	
	Xe 135	1×10^{-6}	
Ytterbium (70)	Yb 175		1×10^{-3}
Yttrium (39)	Y 90		2×10^{-4}
	Y 91m		3×10^{-2}
	Y 91		3×10^{-4}
	Y 92		6×10^{-4}
	Y 93		3×10^{-4}
Zinc (30)	Zn 65		1×10^{-3}
	Zn 69m		7×10^{-4}
	Zn 69		2×10^{-2}

Element (Atomic Number)	Isotope	Column I Gas concentration uc/ml [1]	Column II Liquid and solid concentration uc/ml [2]
Zirconium (40)	Zr 95		6×10^{-4}
	Zr 97		2×10^{-4}
Beta and/or gamma emitting radioactive material not listed above with half-life less than 3 years.		1×10^{-10}	1×10^{-6}

NOTE 1: Many radioisotopes disintegrate into isotopes which are also radioactive. In expressing the concentrations in Schedule C, the activity stated is that of the parent isotope and takes into account the daughters.

NOTE 2: For purposes of 2.19.2.1 where there is involved a combination of isotopes, the limit for the combination should be derived as follows: Determine for each isotope in the product the ratio between the concentration present in the product and the exempt concentration established in Schedule C for the specific isotope when not in combination. The sum of such ratios may not exceed "1" (i.r., unity).

Example:

$$\frac{\text{Concentration of Isotope A in Product}}{\text{Exempt concentration of Isotope A}} + \frac{\text{Concentration of Isotope B in Product}}{\text{Exempt concentration of Isotope B}} < 1$$

[1] Values are given only for those materials normally used as gases.

[2] uc/gm for solids.

RHA 2.26. Schedule D—Groups of Medical Uses of Radioactive Material.

Group I. Use of prepared radiopharmaceuticals for certain diagnostic studies involving measurements of uptake, dilution and excretion. This group does not include uses involving imaging and tumor localizations.

1. Iodine-131 as sodium iodide (Na^{131} I) for measurement of thyroid uptake;
2. Iodine-125 as sodium iodide (Na^{125} I) for measurement of thyroid uptake;
3. Iodine-131 as iodinated human serum albumin (IHSA) for determinations of blood and blood plasma volume and for studies of cardiovascular function and protein turnover;
4. Iodine-125 as iodinated human serum albumin (IHSA) for determination of blood and blood plasma volume and for studies of cardiovascular function and protein turnover;
5. Iodine-131 as labeled rose bengal for liver function studies;
6. Iodine-125 as labeled rose bengal for liver function studies;
7. Iodine-131 as labeled fats or fatty acids for fat absorption studies;
8. Iodine-125 as labeled fats or fatty acids for fat absorption studies;
9. Iodine-131 as labeled iodopyracet, sodium iodohippurate, sodium diatrizoate, diatrizoate methylglucamine, sodium diprotrizoate, sodium acetrizoate, or sodium iothalamate for kidney function studies;
10. Iodine-125 as labeled iodopyracet, sodium iodohippurate, sodium diatrizoate, diatrizoate methylglucamine, sodium diprotrizoate, sodium acetrizoate, or sodium iothalamate for kidney function studies;
11. Cobalt-57 as labeled cyanocobalamin for intestinal absorption studies;
12. Cobalt-58 as labeled cyanocobalamin for intestinal absorption studies;
13. Cobalt-60 as labeled cyanocobalamin for intestinal absorption studies;
14. Chromium-51 as sodium chromate for determination of red blood cell volume and studies of red blood cell survival time and gastrointestinal blood loss;
15. Chromium-51 as labeled human serum albumin for gastrointestinal protein loss studies;
16. Iron-59 as chloride, citrate, or sulfate for iron turnover studies;

17. Potassium-42 as chloride for potassium space determinations;

18. Sodium-24 as chloride for sodium space determinations;

19. Technetium-99m as pertechnetate for blood flow studies;

20. Mercury-203 as chlormerodrin for kidney function studies;

21. Any radioactive material in a radiopharmaceutical and for a diagnostic use involving measurements of uptake, dilution, or excretion for which a "Notice of Claimed Investigational Exemption for a New Drug" (IND) has been accepted by the Food and Drug Administration (FDA) or for which an NDA is in effect.

Group II. Use of prepared radiopharmaceuticals for diagnostic studies involving imaging and tumor localizations.

1. Iodine-131 as sodium iodide (Na^{131} I) for thyroid imaging;

2. Iodine-125 as sodium iodide (Na^{125} I) for thyroid imaging;

3. Iodine-125 fibrinogen for detection and monitoring of developing deep vein thrombosis.

4. Iodine-131 as iodinated human serum albumin (IHSA) for brain tumor localizations and cardiac imaging;

5. Iodine-131 as macroaggregated iodinated human serum albumin for lung imaging;

6. Iodine-131 as colloidal (microaggregated) iodinated human serum albumin for liver imaging;

7. Iodine-131 as labeled rose bengal for liver imaging;

8. Iodine-131 as iodopyracet, sodium iodohippurate, sodium diatrizoate, diatrizoate methyglucamine, sodium diprotrizoate or sodium acetrizoate for kidney imaging;

9. Iodine-131 as sodium iodipamide for cardiac imaging;

10. Iodine-131 as iodinated human serum albumin (IHSA) for placenta localization;

11. Indium-113m as choride for blood pool imaging, including placenta localization.

12. Chromium-51 as sodium chromate for spleen imaging;

13. Chromium-51 as labeled human serum albumin for placenta localization;

14. Gallium-67 as gallium citrate to demonstrate the presence and extent of Hodgken's disease, lymphomas and bronchogenic carcinoma.

15. Gold-198 in colloidal form for liver imaging;

16. Mercury-197 as labeled chlormerodrin for kidney and brain imaging;

17. Mercury-203 as labeled chlormerodrin for brain imaging;

18. Selenium-75 as labeled selenomethionine for pancreas imaging;

19. Strontium-85 as nitrate or chloride for bone imaging in patients with suspected or diagnosed cancer;

20. Technetium-99m as pertechnetate for brain imaging;

21. Technetium-99m as pertechnetate for thyroid imaging;

22. Technetium-99m as pertechnetate for salivary gland imaging;

23. Technetium-99m as pertechnetate for blood pool imaging, including placenta localization;

24. Technetium-99m as labeled sulfur colloid for liver, spleen, and bone marrow imaging;

25. Technetium-99m as labeled macroaggregated human serum albumin for lung imaging;

26. Thallium-201 as thallous chloride for myocardial perfusion imaging for the diagnosis and localization of myocardial infarction.

27. Fluorine-18 in solution for bone imaging;

28. Strontium-87m for bone imaging;

29. Ytterbium-169 as labeled diethylenetriaminepentaacetic acid (DTPA) for cisternography;

30. Iodine-123 a sodium iodide (Na^{123} I) for thyroid imaging;

31. Any radioactive material in a radiopharmaceutical prepared from a reagent kit listed in Section (3) of Group III;

32. Any radioactive material in a radiopharmaceutical and for a diagnostic use involving imaging for which a "Notice of Claimed Investigational Exemption for a New Drug" (IND) has been accepted by the Food and Drug Administration (FDA) or for which an NDA is in effect.

Group III. Use of generators and reagent kits for the preparation and use of radiopharmaceuticals containing radioactive material for certain diagnostic uses.

1) Molybdenum-99/technetium-99m generators for the elution of technetium-99m as pertechnetate for:

(i) Brain imaging;

(ii) Thyroid imaging;

(iii) Salivary gland imaging;

(iv) Blood pool imaging including placenta localization;

(v) Blood flow studies;

(vi) Use with reagent kits for preparation and use of radiopharmaceuticals containing technetium-99m as provided in Sections (3) and (4) of this Group.

2) Technetium-99m as pertechnetate for use with reagent kits for preparation and use of radiopharmaceuticals containing technetium-99m as provided in Sections (3) and (4) of this Group.

3) Reagent kits for preparation of technetium-99m labeled:

(i) Sulfur colloid for liver and spleen imaging;

(ii) Iron-ascorbate-diethylenetriamine pentaacetic acid complex for kidney imaging;

(iii) Diethylenetriamine pentaacetic acid (Sn) for kidney imaging and kidney function studies;

(iv) Diethylenetriamine pentaacetic acid (Sn) for brain imaging;

(v) Human serum albumin microspheres for lung imaging;

(vi) Polyphosphates for bone imaging;

(vii) Maroaggregated human serum albumin for lung imaging;

(viii) Distannous etidronate complex for bone imaging;

(ix) Stannous pyrophosphate for bone imaging;

(x) Human serum albumin for heart blood pool imaging;

(xi) Medronate sodium for bone imaging;

(xii) Gluceptate sodium for brain and renal perfusion imaging;

(xiii) Oxidronate sodium for skeletal imaging;

(xiv) Disofenin for hepatobiliary imaging;

(xv) Succimer (DMSA) for renal imaging;

(xvi) Pentetate as an aerosol for lung function studies;

(xvii) Sulphur colloid for gastroesophageal imaging;

(xviii) Sulphur colloid for Le Veen shunt imaging;

(xix) Pertechnetate for Le Veen shunt imaging;

(xx) Macroaggregated human serum albumin for Le Veen shunt imaging;

(xxi) Pertechnetate for cystography.

(xxii) Pertechnetate for dacryocystography.

4) Tin-113/Indium-113m generators for the elution of Indium-113m as chloride for:

(i) Blood pool imaging including placenta localization.

5) Yttrium-87/Strontium-87m generators for the elution of Strontium-87m for bone imaging.

6) Any generator or reagent kit for preparation and diagnostic use of a radiopharmaceutical containing radioactive material for which generator or reagent kit a "Notice of Claimed Investiga-

tional Exemption for a New Drug" (IND) has been accepted by the Food and Drug Administration (FDA) or for which an NDA is in effect.

Group IV. Use of prepared radiopharmaceuticals for certain therapeutic uses that do not normally require hospitalization for purposes of radiation safety:

(1) Iodine-131 as iodide for treatment of hyperthyroidism and cardiac dysfunction;

(2) Phosphorus-32 as soluble phosphorus for treatment of polycythemia vera, leukemia, and bone metastases;

(3) Phosphorus-32 as colloidal chromic phosphate for intracavitary treatment of malignant effusions;

(4) Any radioactive material in a radiopharmaceutical and for a therapeutic use not normally requiring hospitalization for purposes of radiation safety for which a "Notice of Claimed Investigational Exemption for a New Drug." (IND) has been accepted by the Food and Drug Administration (FDA) or for which an NDA is in effect.

Group V. Use of prepared radiopharmaceuticals for certain therapeutic uses that normally require hospitalization for purposes of radiation safety:

(1) Gold-198 as colloid for intracavitary treatment of malignant effusions;

(2) Iodine-131 as iodide for treatment of thyroid carcinoma;

(3) Any radioactive material in a radiopharmaceutical and for a therapeutic use normally requiring hospitalization for radiation safety reasons for which a "Notice of Claimed Investigational Exemption for a New Drug" (IND) has been accepted by the Food and Drug Administration (FDA) or for which an NDA is in effect.

Group VI. Use of sources and devices containing radioactive material for certain medical uses.

1. Americium-241 as a sealed source in a device for bone mineral analysis;

2. Cesium-137 encased in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;

3. Cobalt-60 encased in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;

4. Gold-198 as seeds for interstitial treatment of cancer;

5. Iodine-125 as a sealed source in a device for bone mineral analysis;

6. Iridium-192 as seeds encased in nylon ribbon for interstitial treatment of cancer;

7. Strontium-90 sealed in an applicator for treatment of superficial eye conditions.

8. Iodine-125 as seeds for interstitial treatment of cancer.

9. Radium-226 encased in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer.

10. Radon-222 as seeds for interstitial treatment of cancer.

RHA 2.27. Requirements for License to Manufacture and Distribute Industrial Products Containing Depleted Uranium for Mass–Volume Applications.

2.27.1 An application for a specific license to manufacture industrial products and devices containing depleted uranium for use pursuant to RHA 2.3.4 or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State will be approved if:

2.27.1.1 The applicant satisfies the requirements specified in RHA 2.6.

2.27.1.2 The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling and marking, proposed uses, and potential hazards of the industrial product or service to provide reasonable assurance that possession, use, and transfer of the depleted uranium in the product or device is not likely to cause any individual to receive in any period of one calendar quarter a radiation dose in excess of 10 percent of the limits specified in the table in RHA 3.2.1.

2.27.1.3 The applicant submits sufficient information regarding the industrial product or device and the presence of depleted uranium for a mass-volume application in the product or device to

provide reasonable assurance that unique benefits will accrue to the public because of the usefulness of the product or device.

2.27.2 In the case of an industrial product or device whose unique benefits are questionable, the Department will approve an application for a specific license under RHA 2.27 only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.

2.27.3 The Department may deny any application for a specific license under RHA 2.27 if the end use of the industrial product or device cannot be reasonably foreseen.

2.27.4 Each person licensed pursuant to RHA 2.27.1 shall:

2.27.4.1 Maintain the level of quality control required by the license in the manufacture of the industrial product or device, and in the installation of the depleted uranium into the product or device;

2.27.4.2 Label or mark each unit to: (a) identify the manufacturer of the product or device and the number of the license under which the product or device was manufactured, the fact that the product or device contains depleted uranium, and the quantity of depleted uranium in each product or device; and (b) state the receipt, possession, use, and transfer of the product or device are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or of an Agreement State;

2.27.4.3 Assure that the depleted uranium before being installed in each product or device has been impressed with the following legend clearly legible through any plating or other covering: "DEPLETED URANIUM";

2.27.4.4 (a) Furnish a copy of the general license contained in RHA 2.3.4 and a copy of Department Form RHA-100-2 to each person to whom he transfers depleted uranium in a product or device for use pursuant to the general license contained in RHA 2.3.4; or (b) furnish a copy of the general license contained in the U.S. Nuclear Regulatory Commission's or Agreement State's regulation equivalent to RHA 2.3.4 and a copy of the U.S. Nuclear Regulatory Commission's or Agreement State's certificate, or alternatively, furnish a copy of the general license contained in RHA 2.3.4 and a copy of Department Form RHA-100-2 to each person to whom he transfers depleted uranium in a product or device for use pursuant to the general license of the U.S. Nuclear Regulatory Commission or an Agreement State, with a note explaining the use of the product or device is regulated by the U.S. Regulatory Commission or an Agreement State under requirements substantially the same as those in RHA 2.3.4.

2.27.4.5 Report to the Department all transfers of industrial products or devices to persons for use under the general license in RHA 2.3.4. Such reports shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the Department and the general licensee, the type and model number of device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such a product or device is transferred to the generally licensed person. If no transfers have been made to persons generally licensed under RHA 2.3.4 during the reporting period, the report shall so indicate;

2.27.4.6 Report to the U.S. Nuclear Regulatory Commission all transfers of industrial products or devices to persons for use under the U.S. Nuclear Regulatory Commission general license in Section 40.25 of 10 CFR Part 40. Report to the responsible agreement state agency all transfers of devices manufactured and distributed pursuant to RHA 2.27 for use under a general license in that state's regulations equivalent to RHA 2.3.4. Such reports shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the Department and the general licensee, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such product or device is transferred to the generally licensed person. If no transfers have been made to the U.S. Nuclear Regulatory Commission licensee during the reporting period, this information shall be reported to the U.S. Nuclear Regulatory Commission. If no transfers have been made to the general licensees within a particular agreement state during the reporting period, this information shall be reported to the responsible agreement state agency.

2.27.4.7 Keep records showing the name, address, and point of contact for each general licensee to whom he transfers depleted uranium in industrial products or devices for use pursuant to the general licenses provided in RHA 2.3.4 or equivalent regulations of the U.S. Nuclear Regulatory Commission or of an Agreement State. The records shall show the date of each transfer, the quantity of depleted uranium in each product or device transferred, and compliance with the report requirements of this section.

RHA 2.28. Requirements for Specific License to Manufacture, Assemble, Repair, or Distribute Commodities, Products or Devices Which Contain Naturally Occurring or Accelerator–Produced Radioactive Material (NARM)

2.28.1 Licensing the Distribution of NARM in Exempt Quantities.[12] An application for a specific license to distribute NARM in exempt quantities to persons exempted from these regulations pursuant to 2.20.2.5 will be approved if:

2.28.1.1 the radioactive material is not contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being;

2.28.1.2 the radioactive material is in the form of processed chemical elements, compounds, or mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources, or similar substances, identified as radioactive and to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution; and

2.28.1.3 the applicant submits copies of prototype labels and brochures and the Department approves such labels and brochures.

2.28.2 The license issued under 2.28.1 is subject to the following conditions:

2.28.2.1 no more that 10 exempt quantities shall be sold or transferred in any single transaction. However, an exempt quantity may be composed of fractional parts of one or more of the exempt quantities provided the sum of the fractions shall not exceed unity.

2.28.2.2 each exempt quantity shall be separately and individually packaged. No more than 10 such packaged exempt quantities shall be contained in any outer package for transfer to persons exempt pursuant to 2.20.2.5. The outer package shall be such that the dose rate at the external surface of the package does not exceed 0.5 millirem per hour.

2.28.2.3 the immediate container of each quantity or separately packaged fractional quantity of radioactive material shall bear a durable, legible label which:

2.28.2.3.1 identifies the radionuclide and the quantity of radioactivity, and

2.28.2.3.2 bears the words "Radioactive Material"

2.28.2.4 in addition to the labeling information required by 2.28.2.3, the label affixed to the immediate container, or an accompanying brochure, shall:

2.28.2.4.1 state that the contents are exempt from Licensing State requirements,

2.28.2.4.2 bear the words "Radioactive Material—Not for Human Use—Introduction into Foods, Beverages, Cosmetics, Drugs, or Medicinals, or into Products Manufactured for Commercial Distribution is Prohibited—Exempt Quantities Should Not Be Combined", and,

2.28.2.4.3 set forth appropriate additional radiation safety precautions and instructions relating to the handling, use, storage, and disposal of the radioactive material.

2.28.3 Each person licensed under 2.28.1 shall maintain records identifying, by name and address, each person to whom radioactive material is transferred for use under 2.20.2.5 or the equivalent regulations of a Licensing State, and stating the kinds and quantities of radioactive material transferred. An annual summary report stating the total quantity of each radionuclide transferred under the specific license shall be filed with the Department. Each report shall cover the year ending June 30, and shall be filed within 30 days thereafter. If no transfers of radioactive material have been made pursuant to 2.28.1 during the reporting period, the report shall so indicate.

[12] Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing radioactive material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Wash., D.C. 20555.

2.28.4 Licensing the Incorporation of Naturally Occurring and Accelerator-Produced Radioactive Material into Gas and Aerosol Detectors. An application for a specific license authorizing the incorporation of NARM into gas and aerosol detectors to be distributed to persons exempt under 2.20.2.3 will be approved if the application satisfies requirements equivalent to those contained in Section 32.26 of 10 CFR Part 32. The maximum quantity of radium 226 in each device shall not exceed 0.1 microcurie.

2.28.5 Special Requirements for License to Manufacture Calibration Sources Containing Americium 241, Plutonium or Radium 226 for Distribution to Persons Generally Licensed Under 2.4.5. An application for a specific license to manufacture calibration and reference sources containing americium 241, plutonium or radium 226 to persons generally licensed under 2.4.5 will be approved if:

2.28.5.1 the applicant satisfies the general requirements of 2.6, and

2.28.5.2 the applicant satisfies the requirements of Sections 32.57, 32.58, 32.59, and 32.102 of 10 CFR Part 32 and Section 70.39 of 10 CFR Part 70 or their equivalent.

Editor's Note

Scrivener errors corrected in 2012.

RHA 2.29. Registration of Sealed Sources and Devices Containing Sealed Sources

2.29.1 Any manufacturer or initial distributor of a sealed source or device containing a sealed source may submit a request to the Department for evaluation of radiation safety information about its product and for its registration.

2.29.2 The request for review must be sent to the Department. The request for a review of a sealed source or a device must include sufficient information about the design, manufacture, prototype testing, quality control program, labeling, proposed uses and leak testing and for a device, the request must also include sufficient information about installation, service and maintenance, operating and safety instructions, and its potential hazards, to provide reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property.

2.29.3 The Department normally evaluates a sealed source or a device using radiation safety criteria in accepted industry standards. If these standards and criteria do not readily apply to a particular case, the Department formulates reasonable standards and criteria with the help of the manufacturer or distributor. The Department shall use criteria and standards sufficient to ensure that the radiation safety properties of the device or sealed source are adequate to protect health and minimize danger to life and property. RHA 2.20 of this part includes specific criteria that apply to certain exempt products and RHA 2.4 includes specific criteria applicable to certain generally licensed devices. RHA 2.7 includes specific provisions that apply to certain specifically licensed items.

2.29.4 After completion of the evaluation, the Department issues a certificate of registration to the person making the request. The certificate of registration acknowledges the availability of the submitted information for inclusion in an application for a specific license proposing use of the product, or concerning use under an exemption from licensing or general license as applicable for the category of certificate.

2.29.5 The person submitting the request for evaluation and registration of safety information about the product shall manufacture and distribute the product in accordance with:

2.29.5.1 The statements and representations, including quality control program, contained in the request; and

2.29.5.2 The provisions of the registration certificate.

2.29.6 Authority to manufacture or initially distribute a sealed source or device to specific licensees may be provided in the license without the issuance of a certificate of registration in the following cases:

2.29.6.1 Calibration and reference sources containing no more than:

2.29.6.1.1 37 MBq (1 mCi), for beta and/or gamma emitting radionuclides; or

2.29.6.1.2 0.37 MBq (10 μCi), for alpha emitting radionuclides; or

2.29.6.2 The intended recipients are qualified by training and experience and have sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material in

any form in the case of unregistered sources or, for registered sealed sources contained in unregistered devices, are qualified by training and experience and have sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material in unshielded form, as specified in their licenses; and

2.29.6.2.1 The intended recipients are licensed under RHA 2.8, or comparable regulation; or

2.29.6.2.2 The recipients are authorized for research and development; or

2.29.6.2.3 The sources and devices are to be built to the unique specifications of the particular recipient and contain no more than 740 GBq (20 Ci) of tritium or 7.4 GBq (200 mCi) of any other radionuclide.

2.29.7 After the certificate is issued, the Department may conduct an additional review as it determines is necessary to ensure compliance with current regulatory standards. In conducting its review, the Department will complete its evaluation in accordance with criteria specified in this section. The Department may request such additional information as it considers necessary to conduct its review and the certificate holder shall provide the information as requested.

2.29.8 Inactivation of certificates of registration of sealed sources and devices.

2.29.8.1 A certificate holder who no longer manufactures or initially transfers any of the sealed source(s) or device(s) covered by a particular certificate issued by the Department shall request inactivation of the registration certificate. Such a request must be made to the Department and must normally be made no later than two years after initial distribution of all of the source(s) or device(s) covered by the certificate has ceased. However, if the certificate holder determines that an initial transfer was in fact the last initial transfer more than two years after that transfer, the certificate holder shall request inactivation of the certificate within 90 days of this determination and briefly describe the circumstances of the delay.

2.29.8.2 If a distribution license is to be terminated in accordance with RHA 2.11, the licensee shall request inactivation of its registration certificates associated with that distribution license before the Department will terminate the license. Such a request for inactivation of certificate(s) must indicate that the license is being terminated and include the associated specific license number.

2.29.8.3 A specific license to manufacture or initially transfer a source or device covered only by an inactivated certificate no longer authorizes the licensee to initially transfer such sources or devices for use. Servicing of devices must be in accordance with any conditions in the certificate, including in the case of an inactive certificate.

HISTORY: Amended by State Register Volume 38, Issue No. 10, Doc. No. 4462, eff October 24, 2014.

RHA 2.30. Emergency Plan for Large Quantity Users.

2.30.1 Each application to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in RHA 2.31 "Schedule E - Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release," must contain either:

2.30.1.1 An evaluation showing that the maximum dose to a person offsite due to a release of radioactive materials would not exceed 1 rem effective dose equivalent or 5 rems to the thyroid; or

2.30.1.2 An emergency plan for responding to a release of radioactive material.

2.30.2 One or more of the following factors may be used to support an evaluation submitted under RHA 2.30.1.1 of this section:

2.30.2.1 The radioactive material is physically separated so that only a portion could be involved in an accident;

2.30.2.2 All or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged;

2.30.2.3 The release fraction in the respirable size range would be lower than the release fraction shown in RHA 2.31 due to the chemical or physical form of the material;

2.30.2.4 The solubility of the radioactive material would reduce the dose received;

2.30.2.5 Facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in RHA 2.31, Schedule E.

2.30.2.6 Operating restrictions or procedures would prevent a release fraction as large as that shown in RHA 2.31, Schedule E; or

2.30.2.7 Other factors appropriate for the specific facility.

2.30.3 An emergency plan for responding to a release of radioactive material submitted under RHA 2.30.1.2 of this section must include the following information.

2.30.3.1 Facility description. A brief description of the licensee's facility and area near the site.

2.30.3.2 Types of accidents. An identification of each type of radioactive materials accident for which protective actions may be needed.

2.30.3.3 Classification of accidents. A classification system for classifying accidents as alerts or site area emergencies.

2.30.3.4 Detection of accidents. Identification of the means of detecting each type of accident in a timely manner.

2.30.3.5 Mitigation of consequences. A brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers on site, and a description of the program for maintaining the equipment.

2.30.3.6 Assessment of releases. A brief description of the methods and equipment to assess releases of radioactive materials.

2.30.3.7 Responsibilities. A brief description of the responsibilities of licensee personnel should an accident occur, including identification of personnel responsible for promptly notifying offsite response organizations and the Department; also responsibilities for developing, maintaining, and updating the plan.

2.30.3.8 Notification and coordination. A commitment to and a brief description of the means to promptly notify offsite response organizations and request offsite assistance, including medical assistance for the treatment of contaminated injured onsite workers when appropriate. A control point must be established. The notification and coordination must be planned so that unavailability of some personnel, parts of the facility, and some equipment will not prevent the notification and coordination. The licensee shall also commit to notify the Department immediately after notification of the appropriate offsite response organizations and not later than one hour after the licensee declares an emergency.[1]

2.30.3.9 Information to be communicated. A brief description of the types of information on facility status, radioactive releases, and recommended protective actions, if necessary, to be given to offsite response organizations and to the Department.

2.30.3.10 Training. A brief description of the frequency, performance objectives and plans for the training that the licensee will provide workers on how to respond to an emergency including any special instruction and orientation tours the licensee would offer to fire, police, medical and other emergency personnel. The training shall familiarize personnel with site-specific emergency procedures. Also, the training shall thoroughly prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site, including the use of team training for such scenarios.

2.30.3.11 Safe shutdown. A brief description of the means of restoring the facility to safe condition after an accident.

2.30.3.12 Exercises. Provision for conducting quarterly communications checks with offsite response organizations and biennial onsite exercises to test response to simulated emergencies. Quarterly communications checks with offsite response organizations must include the check and update of all necessary telephone numbers. The licensee shall invite offsite response organizations to participate in the biennial exercises. Participation of offsite response organizations in biennial exercises although recommended is not required.

Exercises must use accident scenarios postulated as most probable for the specific site and the scenarios shall not be known to most exercise participants. The licensee shall critique each exercise using individuals not having direct implementation responsibility for the plan. Critiques of exercises

1 These requirements do not supersede or release licensees of complying with the requirements under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Pub.L. 99–499 or other state or federal reporting requirements.

must evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response. Deficiencies found by the critiques must be corrected.

2.30.3.13 Hazardous chemicals. A certification that the applicant has met its responsibilities under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Pub. L.99-499, if applicable to the applicant's activities at the proposed place of use of the byproduct material.

2.30.4 The licensee shall allow the offsite response organizations expected to respond in case of an accident 60 days to comment on the licensee's emergency plan before submitting it to the Department. The licensee shall provide any comments received within the 60 days to the Department with the emergency plan.

History: Amended by SCSR 44–11, eff November 27, 2020 (errata).

Editor's Note

Scrivener errors corrected in 2012.

RHA 2.31. Schedule E – Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release.

Radioactive Material	Release fraction	Quantity (curies)
Actinium-228	0.001	4,000
Americium-241	.001	2
Americium-242	.001	2
Americium-243	.001	2
Antimony-124	.01	4,000
Antimony-126	.01	6,000
Barium-133	.01	10,000
Barium-140	.01	30,000
Bismuth-207	.01	5,000
Bismuth-210	.01	600
Cadmium-109	.01	1,000
Cadmium-113	.01	80
Calcium-45	.01	20,000
Californium-252	.001	9(20 mg)
Carbon-14	.01	50,000
	Non CO	
Cerium-141	.01	10,000
Cerium-144	.01	300
Cesium-134	.01	2,000
Cesium-137	.01	3,000
Chlorine-36	.5	100
Chromium-51	.01	300,000
Cobalt-60	.001	5,000
Copper-64	.01	20,000
Curium-242	.001	60
Curium-243	.001	3
Curium-244	.001	4
Curium-245	.001	2
Europium-152	.01	500
Europium-154	.01	400
Europium-155	.01	3,000
Germanium-68	.01	2,000
Gadolinium-153	.01	5,000
Gold-198	.01	30,000
Hafnium-172	.01	400
Holmium-166m	.01	7,000
Hydrogen-3	.5	100
Iodine-125	.5	20,000
Iodine-131	.5	10
Indium-114m	.01	1,000
Iridium-192	.001	40,000

Radioactive Material	Release fraction	Quantity (curies)
Iron-55	.01	40,000
Iron-59	.01	7,000
Krypton-85	1.0	6,000,000
Lead-210	.01	8
Manganese-56	.01	60,000
Mercury-203	.01	10,000
Molybdenum-99	.01	30,000
Neptunium-237	.001	2
Nickel-63	.01	20,000
Niobium-94	.01	300
Phosphorus-32	.5	100
Phosphorus-33	.5	1,000
Polonium-32	.01	10
Potassium-42	.01	9,000
Promethium-145	.01	4,000
Promethium-147	.01	4,000
Radium-226	0.001	100
Ruthenium-106	.01	200
Samarium-151	.01	4,000
Scandium-46	.01	3,000
Selenium-75	.01	10,000
Silver-110m	.01	1,000
Sodium-22	.01	9,000
Sodium-24	.01	10,000
Strontium-89	.01	3,000
Strontium-90	.01	90
Sulfur-35	.5	900
Technetium-99	.01	10,000
Technetium-99m	.01	400,000
Tellurium-127m	.01	5,000
Tellurium-129m	.01	5,000
Terbium-160	.01	4,000
Thulium-170	.01	4,000
Tin-13	.01	10,000
Tin-123	.01	3,000
Tin-126	.01	1,000
Titanium-44	.01	100
Vanadium-48	.01	7,000
Xenon-133	1.0	900,000
Yttrium-91	.01	2,000
Zinc-65	.01	5,000
Zirconium-93	.01	400
Zirconium-95	.01	5,000
Any other beta-gamma emitter	.01	10,000
Mixed fission products	.01	1,000
Contaminated equipment beta gamma	.001	10,000
Irradiated material, any form other than solid noncombustible	.01	1,000
Mixed radioactive waste, beta gamma	.01	1,000
Packaged mixed waste, beta gamma [2]	.001	10,000
Any other alpha emitter	.001	2
Contaminated equipment, alpha	.0001	20
Packaged waste, alpha [2]	.0001	20
Combinations of radioactive materials listed above [1]		

[1] For combinations of radioactive materials, consideration of the need for an emergency plan, is required, if the sum of the ratios of the quantity of each radioactive material authorized to the quantity listed for that material in Schedule E exceeds one.

[2] Waste packaged in Type B containers does not require an emergency plan.

RHA 2.32. Reporting Requirements.

2.32.1 Immediate report. Each licensee shall notify the Department as soon as possible but not later than 4 hours after the discovery of an event that prevents immediate protective actions necessary to

avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of licensed material that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, etc.).

2.32.2 Twenty-four hour report. Each licensee shall notify the Department within 24 hours after the discovery of any of the following events involving licensed material:

2.32.2.1 An unplanned contamination event that:

2.32.2.1.1 Requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area;

2.32.2.1.2 Involves a quantity of material greater than five times the lowest annual limit on intake specified in RHA 3.53, appendix b for the material; and

2.32.2.1.3 Has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination.

2.32.2.2 An event in which equipment is disabled or fails to function as designed when:

2.32.2.2.1 The equipment is required by regulation or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident;

2.32.2.2.2 The equipment is required to be available and operable when it is disabled or fails to function; and

2.32.2.2.3 No redundant equipment is available and operable to perform the required safety function.

2.32.2.3 An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body.

2.32.2.4 An unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when:

2.32.2.4.1 The quantity of material involved is greater than five times the lowest annual limit on intake specified in RHA 3.53 appendix B for the material; and

2.32.2.4.2 The damage affects the integrity of the licensed material or its container.

2.32.3 Preparation and submission of reports. Reports made by licensees in response to the requirements of this section must be made as follows:

2.32.3.1 Licensees shall make reports required by RHA 2.32.1 & 2.32.2 of this section by telephone to the Bureau of Radiological Health. to the extent that the information is available at the time of notification, the information provided in these reports must include:

2.32.3.1.1 The caller's name and call back telephone number;

2.32.3.1.2 A description of the event, including date and time;

2.32.3.1.3 The exact location of the event;

2.32.3.1.4 The isotopes, quantities, and chemical and physical form of the licensed material involved; and

2.32.3.1.5 Any personnel radiation exposure data available.

2.32.3.2 Written report. Each licensee who makes a report required by RHA 2.32.1. or 2.32.2 of this section shall submit a written follow-up report within 30 days of the initial report. Written reports prepared pursuant to other regulations may be submitted to fulfill this requirement if the reports contain all of the necessary information and appropriate distribution is made. These written reports must be sent to the S.C. Department of Health & Environmental Control, Bureau of Radiological Health, 2600 Bull Street, Columbia, S.C. 29201. The reports must include the following.

2.32.3.2.1 A description of the event, including the probable cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;

2.32.3.2.2 The exact location of the event;

2.32.3.2.3 The isotopes, quantities, and chemical and physical form of the licensed material involved;

2.32.3.2.4 Date and time of the event;

2.32.3.2.5 Corrective actions taken or planned and the results of any evaluations or assessments; and;

2.32.3.2.6 The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

History: Amended by SCSR 44–11, eff November 27, 2020 (errata).

PART III
STANDARDS FOR PROTECTION AGAINST RADIATION

RHA 3.1. Purpose and Scope.

It is the purpose of the regulations in this part to control the receipt, possession, use, transfer, and disposal of licensed material by any licensee in such a manner that the total dose to an individual (including doses resulting from licensed and unlicensed radioactive material and from radiation sources other than background radiation) does not exceed the standards for protection against radiation prescribed in the regulations in this part. However, nothing in this part shall be construed as limiting actions that may be necessary to protect health and safety.

The regulations in this part apply to persons licensed by the Department to receive, possess, use, transfer, or dispose of radioactive material. The limits in this part do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, to exposure from individuals administered radioactive material and released under RHA 4.32, or to exposure from voluntary participation in medical research programs.

RHA 3.2. Definitions.

As used in this part:

3.2.1 "Absorbed dose" means the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the rad and the gray (Gy).

3.2.2 "Activity" is the rate of disintegration (transformation) or decay of radioactive material. The units of activity are the curie (Ci) and the becquerel (Bq).

3.2.3 "Adult" means an individual 18 or more years of age.

3.2.4 "Airborne radioactivity" area means a room, enclosure, or area in which airborne radioactive materials, composed wholly or partly of licensed material, exist in concentrations—

i) In excess of the derived air concentrations (DACs) specified in Appendix B, RHA 3.53, or

ii) To such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6 percent of the annual limit on intake (ALI) or 12 DAC-hours.

3.2.5 "Air-purifying respirator" means a respirator with an air-purifying filter, cartridge, or canister that removes specific air contaminants by passing ambient air through the air-purifying element.

3.2.6 "ALARA" (acronym for "as low as is reasonably achievable") means making every reasonable effort to maintain exposures to radiation as far below the dose limits in this part as is practical consistent with the purpose for which the licensed activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed materials in the public interest.

3.2.7 "Annual limit on intake" (ALI) means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent of 5 rems (0.05 Sv) or a committed dose equivalent of 50 rems

(0.5 Sv) to any individual organ or tissue. (ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Table 1, Columns 1 and 2, of Appendix B, RHA 3.53).

3.2.8 "Assigned protection factor" (APF) means the expected workplace level of respiratory protection that would be provided by a properly functioning respirator or a class of respirators to properly fitted and trained users. Operationally, the inhaled concentration can be estimated by dividing the ambient airborne concentration by the APF.

3.2.9 "Atmosphere-supplying respirator" means a respirator that supplies the respirator user with breathing air from a source independent of the ambient atmosphere, and includes supplied-air respirators (SARs) and self-contained breathing apparatus (SCBA) units.

3.2.10 "Background radiation" means radiation from cosmic sources; naturally occurring radioactive materials, including radon (except as a decay product of source or special nuclear material) and global fallout as it exists in the environment from the testing of nuclear explosive devices. "Background radiation" does not include radiation from source, byproduct, or special nuclear materials regulated by the Department.

3.2.11 "Bioassay" (radiobioassay) means the determination of kinds, quantities or concentrations, and, in some cases, the locations of radioactive material in the human body, whether by direct measurement (in vivo counting) or by analysis and evaluation of materials excreted or removed from the human body.

3.2.12 "Chelating agent" means amine polycarboxylic acids, hydrocarboxylic, gluconic acid, and polycarboxylic acids.

3.2.13 "Chemical description" means a description of the principal chemical characteristics of a low-level radioactive waste.

3.2.14 "Class" (or lung class or inhalation class) means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or Y, which applies to a range of clearance half-times: for Class D (Days) of less than 10 days, for Class W (Weeks) from 10 to 100 days, and for Class Y (Years) of greater than 100 days.

3.2.15 "Collective dose" is the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

3.2.16 "Committed dose equivalent" (H) means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50–year period following the intake.

3.2.17 "Committed effective dose equivalent" ($H_{E,50}$) is the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to these organs or tissues ($H_{E,50} = \Sigma W_T H_{T,50}$).

3.2.18 "Computer-readable medium" means a medium selected from the available technologies, as authorized by the Department, that can be used to transfer the information to the Department's computer.

3.2.19 "Consignee" means the designated receiver of the shipment of low-level radioactive waste.

3.2.20 "Constraint (dose constraint)" means a value above which specified licensee actions are required.

3.2.21 "Controlled area" means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason.

3.2.22 "Critical Group" means the group of individuals reasonably expected to receive the greatest exposure to residual radiation for any applicable set of circumstances.

3.2.23 "Declared pregnant woman" means a woman who has voluntarily informed the licensee, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant.

3.2.24 "Decommission" means to remove a facility or site safely from service and reduce residual radioactivity to level that permits 1) release of the property for unrestricted use and termination of the license; or 2) release of the property under restricted conditions and termination of the license.

3.2.25 "Decontamination facility" means a facility operating under a license whose principal purpose is decontamination of equipment or materials to accomplish recycle, reuse, or other waste management objectives, and, for purposes of this part, is not considered to be a consignee for LLW shipments.

3.2.26 "Deep-dose equivalent" (H_d), which applies to external whole-body exposure, is the dose equivalent at a tissue depth of 1 cm (1000 mg/cm^2).

3.2.27 "Demand respirator" means an atmosphere-supplying respirator that admits breathing air to the facepiece only when a negative pressure is created inside the facepiece by inhalation.

3.2.28 "Derived air concentration" (DAC) means the concentration of a given radionuclide in air which, if breathed by the reference man for a working year of 2,000 hours under conditions of light work (inhalation rate 1.2 cubic meters of air per hour), results in an intake of one ALI. DAC values are given in Table 1, Column 3, of Appendix B, RHA 3.53.

3.2.29 "Derived air concentration-hour" (DAC-hour) is the product of the concentration of radioactive material in air (expressed as a fraction or multiple of the derived air concentration for each radionuclide) and the time of exposure to that radionuclide, in hours. A licensee may take 2,000 DAC-hours to represent one ALI, equivalent to a committed effective dose equivalent of 5 rems (0.05 Sv).

3.2.30 "Disposal container" means a container principally used to confine low-level radioactive waste during disposal operations at a land disposal facility (also see "high integrity container"). Note that for some shipments, the disposal container may be the transport package.

3.2.31 "Disposable respirator" means a respirator for which maintenance is not intended and that is designed to be discarded after excessive breathing resistance, sorbent exhaustion, physical damage, or end-of-service-life renders it unsuitable for use. Examples of this type of respirator are a disposable half-mask respirator or a disposable escape-only self-contained breathing apparatus (SCBA).

3.2.32 "Distinguishable from Background" means that the detectable concentration of a radionuclide is statistically different from the background concentration of that radionuclide in the vicinity of the site or, in the case of structures, in similar materials using adequate measurement technology, survey, and statistical techniques.

3.2.33 "Dose or radiation dose" is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent, as defined in other paragraphs of this section.

3.2.34 "Dose equivalent" (H_T) means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the rem and sievert (Sv).

3.2.35 "Effective dose equivalent" (H_E) is the sum of the products of the dose equivalent to the organ or tissue (H_T) and the weighting factors (W_T) applicable to each of the body organs or tissues that are irradiated ($H_E = \Sigma W_T H_T$).

3.2.36 "Embryo/fetus" means the developing human organism from conception until the time of birth.

3.2.37 "Entrance or access point" means any location through which an individual could gain access to radiation areas or to radioactive materials. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

3.2.38 "EPA identification number" means the number received by a transporter following application to the administrator of EPA as required by 40 CFR Part 263.

3.2.39 "Exposure" means being exposed to ionizing radiation or to radioactive material.

3.2.40 "External dose" means that portion of the dose equivalent received from radiation sources outside the body.

3.2.41 "Extremity" means hand, elbow, arm below the elbow, foot, knee, and leg below the knee.

3.2.42 "Filtering facepiece" (dust mask) means a negative pressure particulate respirator with a filter as an integral part of the facepiece or with the entire facepiece composed of the filtering medium, not equipped with elastomeric sealing surfaces and adjustable straps.

3.2.43 "Fit factor" means a quantitative estimate of the fit of a particular respirator to a specific individual, and typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn.

3.2.44 "Fit test" means the use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator on an individual.

3.2.45 "Generally applicable environmental radiation standards" means standards issued by the Environmental Protection Agency (EPA) under the authority of the Atomic Energy Act of 1954, as amended, that impose limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.

3.2.46 "Generator" means a licensee operating under a Commission or Agreement State license who (1) is a radioactive waste generator as defined in this part, or (2) is the licensee to whom waste can be attributed within the context of the Low–Level Radioactive Waste Policy Amendments Act of 1985 (e.g. waste generated as a result of decontamination or recycle activities).

3.2.47 "Helmet" means a rigid respiratory inlet covering that also provides head protection against impact and penetration.

3.2.48 "High Integrity Container (HIC)" means a container commonly designed to meet the structural stability requirements of Appendix E, RHA 3.56.2.2, and to meet Department of Transportation requirements for a Type A package.

3.2.49 "High radiation area" means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving a dose equivalent in excess of 0.1 rem (1 mSv) in 1 hour at 30 centimeters from the radiation source or 30 centimeters from any surface that the radiation penetrates.

3.2.50 "Hood" means a respiratory inlet covering that completely covers the head and neck and may also cover portions of the shoulders and torso.

3.2.51 "Individual monitoring" means:

(1) The assessment of dose equivalent by the use of devices designed to be worn by an individual;

(2) The assessment of committed effective dose equivalent by bioassay (see Bioassay) or by determination of the time-weighted air concentrations to which an individual has been exposed, i.e., DAC-hours; or

(3) The assessment of dose equivalent by the use of survey data.

3.2.52 "Individual monitoring devices (individual monitoring equipment)" means devices designed to be worn by a single individual for the assessment of dose equivalent such as film badges, thermoluminescence dosimeters (TLDs), pocket ionization chambers, and personal (lapel) air sampling devices.

3.2.53 "Internal dose" means that portion of the dose equivalent received from radioactive material taken into the body.

3.2.54 "Land disposal facility" means the land buildings and structures, and equipment which are intended to be used for the disposal of radioactive wastes.

3.2.55 "Lens dose equivalent (LDE)" applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm^2).

3.2.56 "Licensed material" means source material, special nuclear material, or byproduct material received, possessed, used, transferred or disposed of under a general or specific license issued by the Department.

3.2.57 "Limits (dose limits)" means the permissible upper bounds of radiation doses.

3.2.58 "Loose-fitting facepiece" means a respiratory inlet covering that is designed to form a partial seal with the face.

3.2.59 "Lost or missing licensed material" means licensed material whose location is unknown. It includes material that has been shipped but has not reached its destination and whose location cannot be readily traced in the transportation system.

3.2.60 ''Member of the public'' means any individual except when that individual is receiving an occupational dose.

3.2.61 ''Minor'' means an individual less than 18 years of age.

3.2.62 ''Monitoring'' (radiation monitoring, radiation protection monitoring) means the measurement of radiation levels, concentrations, surface area concentrations or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses.

3.2.63 ''Nationally tracked source'' means a sealed source containing a quantity equal to or greater than Category 1 or 2 levels of any radioactive material listed in Appendix G to Part 3 of these Regulations. In this context a sealed source is defined as radioactive material that is sealed in a capsule or closely bonded, in a solid form and which is not exempt from regulatory control. It does not mean material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet. Category 1 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 1 threshold. Category 2 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 2 threshold but less than the Category 1 threshold.

3.2.64 ''Negative pressure respirator'' (tight fitting) means a respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside the respirator.

3.2.65 ''Nonstochastic effect'' means health effects, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect (also called a deterministic effect).

3.2.66 ''NRC Forms 540, 540A, 541, 541A, 542, and 542A'' are official NRC forms referenced in this regulation. Licensees need not use originals of these NRC Forms as long as any substitute forms are equivalent to the original documentation in respect to content, clarity, size, and location of information. Upon agreement between the shipper and consignee, NRC Forms 541 (and 541A) and NRC Forms 542 (and 542A) may be completed, transmitted, and stored in electronic media. The electronic media must have the capability for producing legible, accurate, and complete records in the format of the uniform manifest.

3.2.67 ''Occupational dose'' means the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation or to radioactive material from licensed and unlicensed sources of radiation, whether in the possession of the licensee or other person. Occupational dose does not include doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released under RHA 4.32, or from voluntary participation in medical research programs, or as a member of the public.

3.2.68 ''Package'' means the assembly of components necessary to ensure compliance with the packaging requirements of DOT regulations, together with its radioactive contents, as presented for transport.

3.2.69 ''Physical description'' means the items called for on NRC Form 541 to describe a low-level radioactive waste.

3.2.70 ''Planned special exposure'' means an infrequent exposure to radiation, separate from and in addition to the annual dose limits.

3.2.71 ''Positive pressure respirator'' means a respirator in which the pressure inside the respiratory inlet covering exceeds the ambient air pressure outside the respirator.

3.2.72 ''Powered air-purifying respirator'' (PAPR) means an air-purifying respirator that uses a blower to force the ambient air through air-purifying elements to the inlet covering.

3.2.73 ''Pressure demand respirator'' means a positive pressure atmosphere-supplying respirator that admits breathing air to the facepiece when the positive pressure is reduced inside the facepiece by inhalation.

3.2.74 ''Public dose'' means the dose received by a member of the public from exposure to radiation or to radioactive material released by a licensee, or to any other source of radiation under the control of the licensee. Public dose does not include occupational dose or doses received from background radiation, from any medical administration the individual had received, from exposure

to individuals administered radioactive material and released under RHA 4.32, or from voluntary participation in medical research programs.

3.2.75 "Qualitative fit test" (QLFT) means a pass/fail fit test to assess the adequacy of respirator fit that relies on the individual's response to the test agent.

3.2.76 "Quality Factor" (Q) means the modifying factor (listed in tables 1 and 2 of RHA 3.3) that is used to derive dose equivalent from absorbed dose.

3.2.77 "Quantitative fit test" (QNFT) means an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

3.2.78 "Reference man" means a hypothetical aggregation of human physical and physiological characteristics arrived at by international consensus. These characteristics may be used by researchers and public health workers to standardize results of experiments and to relate biological insult to a common base.

3.2.79 "Residual Radioactivity" means radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee's control. This includes radioactivity from all licensed and unlicensed sources used by the licensee but excludes background radiation. It also includes radioactive materials remaining at the site as a result of routine or accidental releases of radioactive material at the site and previous burials at the site, even if those burials were made in accordance with this Regulation.

3.2.80 "Residual waste" means low-level radioactive waste resulting from processing or decontamination activities that cannot be easily separated into distinct batches attributable to specific waste generators. This waste is attributable to the processor or decontamination facility, as applicable.

3.2.81 "Respiratory protective device" means an apparatus, such as a respirator, used to reduce the individual's intake of airborne radioactive materials.

3.2.82 "Sanitary sewerage" means a system of public sewers for carrying off waste water and refuse, but excluding sewage treatment facilities, septic tanks, and leach fields owned or operated by the licensee.

3.2.83 "Self-contained breathing apparatus" (SCBA) means an atmosphere-supplying respirator for which the breathing air source is designed to be carried by the user.

3.2.84 "Shallow-dose equivalent" (H^S), which applies to the external exposure of the skin of the whole body or the skin of an extremity, is taken as the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm^2).

3.2.85 "Shipper" means the licensed entity (i.e. the waste generator, waste collector, or waste processor) who offers low-level radioactive waste for transportation, typically consigning this type of waste to a licensed waste collector, waste processor, or land disposal facility operator.

3.2.86 "Shipping paper" means NRC Form 540 and if required, NRC Form 540A which includes the information required by DOT in 49 CFR Part 172.

3.2.87 "Source material" means (1) uranium or thorium, or any combination thereof, in any physical or chemical form, or (2) ores which contain by weight one-twentieth of one percent (0.05 percent) or more of (a) uranium, (b) thorium, or (c) any combination thereof. Source material does not include special nuclear material (SNM).

3.2.88 "Special nuclear material" means (1) plutonium, uranium–233, uranium-enriched in the isotope–233 or the isotope–235, or (2) any material artificially enriched by any of the foregoing. This definition does not include source material.

3.2.89 "Stochastic effects" means health effects that occur randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects.

3.2.90 "Supplied-air respirator" (SAR) or airline respirator means an atmosphere-supplying respirator for which the source of breathing air is not designed to be carried by the user.

3.2.91 "Tight-fitting facepiece" means a respiratory inlet covering that forms a complete seal with the face.

3.2.92 "Total Effective Dose Equivalent" (TEDE) means the sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

3.2.93 "Type A quantity" means a quantity of radioactive material, the aggregate radioactivity of which does not exceed A_1 for special form radioactive material or A_2 for normal form radioactive material, where A_1 and A_2 are given in Appendix A 10 CFR Part 71 or may be determined by procedures described in Appendix A 10 CFR Part 71.

3.2.94 "Uniform Low–Level Radioactive Waste Manifest or uniform manifest" means the combination of NRC Forms 540, 541, and, if necessary, 542, and their respective continuation sheets as needed, or equivalent.

3.2.95 "User seal check" (fit check) means an action conducted by the respirator user to determine if the respirator is properly seated to the face. Examples include negative pressure check, positive pressure check, irritant smoke check, or isoamyl acetate check.

3.2.96 "Very high radiation area" means an area, accessible to individuals, in which radiation levels could result in an individual receiving an absorbed dose in excess of 500 rads (5 grays) in 1 hour at 1 meter from a radiation source or from any surface that the radiation penetrates.

[Note: At very high doses received at high dose rates, units of absorbed dose (e.g., rads and grays) are appropriate, rather than units of dose equivalent (e.g., rems and sieverts).]

3.2.97 "Waste collector" means an entity, operating under a license issued by the Department, the U.S. Nuclear Regulatory Commission, or another Agreement State, whose principal purpose is to collect and consolidate waste generated by others, and to transfer this waste, without processing or repackaging the collected waste, to another licensed waste collector, licensed waste processor, or licensed land disposal facility.

3.2.98 "Waste description" means the physical, chemical and radiological description of a low-level radioactive waste as called for on NRC Form 541.

3.2.99 "Waste generator" means an entity, operating under a license issued by the Department, the U.S. Nuclear Regulatory Commission, or another Agreement State, who possesses any material or component that contains radioactivity or is radioactively contaminated for which the licensee foresees no further use, and transfers this material or component to a licensed land disposal facility or to a licensed waste collector or processor for handling or treatment prior to disposal. A licensee performing processing or decontamination services may be a "waste generator" if the transfer of low-level radioactive waste from its facility is defined as "residual waste."

3.2.100 "Waste processor" means an entity, operating under a license issued by the Department, the U.S. Nuclear Regulatory Commission, or another Agreement State, whose principal purpose is to process, repackage, or otherwise treat low-level radioactive material or waste generated by others prior to eventual transfer of waste to a licensed low-level radioactive waste land disposal facility.

3.2.101 "Waste type" means a waste within a disposal container having a unique physical description (i.e., a specific waste descriptor code or description; or a waste solidified in a specifically defined media).

3.2.102 "Weighting factor, W_T," for an organ or tissue (T) is the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of W_T are:

ORGAN DOSE WEIGHTING FACTORS

Organ or Tissue	W_T
Gonads	0.25
Breast	0.15
Red bone marrow	0.12
Lung	0.12
Thyroid	0.03
Bone surfaces	0.03
Remainder	[1] 0.30
Whole Body	[2] 1.00

[1] 0.30 results from 0.06 for each of 5 "remainder" organs (excluding the skin and the lens of the eye) that receive the highest doses.

[2] For the purpose of weighting the external whole body dose (for adding it to the internal dose), a single weighting factor, $W_T = 1.0$, has been specified. The use of other weighting factors for external exposure will be approved on a case-by-case basis until such time as specific guidance is issued.

3.2.103 "Working level" (WL) is any combination of short-lived radon daughters (for radon–222: polonium–218, lead–214, bismuth–214, and polonium–214; and for radon–220: polonium–216, lead–212, bismuth–212, and polonium–212) in 1 liter of air that will result in the ultimate emission of 1.3 x 10^5 MeV of potential alpha particle energy.

3.2.104 "Working level month" (WLM) means an exposure to 1 working level for 170 hours (2,000 working hours per year/12 months per year = approximately 170 hours per month).

3.2.105 "Year" means the period of time beginning in January used to determine compliance with the provisions of this part. The licensee may change the starting date of the year used to determine compliance by the licensee provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

History: Amended by SCSR 44–11, eff November 27, 2020 (errata).

RHA 3.3. Units of Radiation Dose.

3.3.1 Definitions. As used in this part, the units of radiation dose are:

3.3.1.1 Gray (Gy) is the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 Joule/kilogram (100 rads).

3.3.1.2 Rad is the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 ergs/gram or 0.01 joule/kilogram (0.01 gray).

3.3.1.3 Rem is the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rems is equal to the absorbed dose in rads multiplied by the quality factor (1 rem = 0.01 sievert).

3.3.1.4 Sievert is the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sieverts is equal to the absorbed dose in grays multiplied by the quality factor (1 Sv = 100 rems).

3.3.2 As used in this part, the quality factors for converting absorbed dose to dose equivalent are shown in Table 1.

TABLE 1: QUALITY FACTORS AND ABSORBED DOSE EQUIVALENCIES

TYPE OF RADIATION	Quality Factor (Q)	Absorbed dose equal to a unit dose equivalent [2]
X-, gamma, or beta radiation	1	1
Alpha particles, multiple-charged particles, fission fragments and heavy particles of unknown charge	20	0.05
Neutrons of unknown energy	10	0.1
High-energy protons	10	0.1

[2] Absorbed dose in rad equal to 1 rem or the absorbed dose in gray equal to 1 sievert.

3.3.3 If it is more convenient to measure the neutron fluence rate than to determine the neutron dose equivalent rate in rems per hour or sieverts per hour, as provided in paragraph 3.3.2 of this section, 1 rem (0.01 Sv) of neutron radiation of unknown energies may, for purposes of the regulations in this part, be assumed to result from a total fluence of 25 million neutrons per square centimeter incident upon the body. If sufficient information exists to estimate the approximate energy distribution of the neutrons, the licensee may use the fluence rate per unit dose equivalent or the appropriate Q value from Table 2 to convert a measured tissue dose in rads to dose equivalent in rems.

TABLE 2: MEAN QUALITY FACTORS, Q, AND FLUENCE PER UNIT DOSE EQUIVALENT FOR MONOENERGETIC NEUTRONS

	Neutron Energy (MeV)	Quality Factor [a] (Q)	Fluence per Unit Dose Equivalent [b] (neutrons cm^{-2} rem^{-1})
(thermal)	2.5×10^{-8}	2	980×10^6
	1×10^{-7}	2	980×10^6
	1×10^{-6}	2	810×10^6

Neutron Energy (MeV)	Quality Factor [a] (Q)	Fluence per Unit Dose Equivalent [b] (neutrons cm^{-2} rem^{-1})
1×10^{-5}	2	810×10^{6}
1×10^{-4}	2	840×10^{6}
1×10^{-3}	2	980×10^{6}
1×10^{-2}	2.5	1010×10^{6}
1×10^{-1}	7.5	170×10^{6}
5×10^{-1}	11	39×10^{6}
1	11	27×10^{6}
2.5	9	29×10^{6}
5	8	23×10^{6}
7	7	24×10^{6}
10	6.5	24×10^{6}
14	7.5	17×10^{6}
20	8	16×10^{6}
40	7	14×10^{6}
60	5.5	16×10^{6}
1×10^{2}	4	20×10^{6}
2×10^{2}	3.5	19×10^{6}
3×10^{2}	3.5	16×10^{6}
4×10^{2}	3.5	14×10^{6}

[a] Value of quality factor (Q) at the point where the dose equivalent is maximum in a 30-cm diameter cylinder tissue-equivalent phantom.
[b] Monoenergetic neutrons incident normally on a 30-cm diameter cylinder tissue-equivalent phantom.

RHA 3.4. Radiation Protection Programs.

3.4.1 Each licensee shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of this part. (See RHA 3.35 for recordkeeping requirements relating to these programs.)

3.4.2 The licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).

3.4.3 The licensee shall periodically (at least annually) review the radiation protection program content and implementation.

3.4.4 To implement the ALARA requirements of RHA 3.4.2, and notwithstanding the requirements in RHA 3.13, a constraint on air emissions of radioactive material to the environment, excluding Radon-222 and its daughters, shall be established by licensees, such that the individual member of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent in excess of 10 mrem (0.1 mSv) per year from these emissions. If a licensee subject to this requirement exceeds this dose constraint, the licensee shall report the exceedance as provided in RHA 3.46 and promptly take appropriate corrective action to ensure against recurrence.

RHA 3.5. Occupational Dose Limits for Adults.

3.5.1 The licensee shall control the occupational dose to individual adults, except for planned special exposures under RHA 3.10 to the following dose limits.

3.5.1.1 An annual limit, which is the more limiting of—

3.5.1.1.1 The total effective dose equivalent being equal to 5 rems (0.05 Sv); or

3.5.1.1.2 The sum of the deep-dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 50 rems (0.5 Sv).

3.5.1.2 The annual limits to the lens of the eye, to the skin of the whole body, and to the skin of the extremities, which are:

3.5.1.2.1 A lens dose equivalent of 15 rems (0.15 Sv), and

3.5.1.2.2 A shallow-dose equivalent of 50 rems (0.50 Sv) to the skin of the whole body or to the skin of any extremity.

3.5.2 Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, must be subtracted from the limits for planned special exposures that the individual may receive during the current year (see 3.10.5.1) and during the individual's lifetime (see 3.10.5.2).

3.5.3 When the external exposure is determined by measurement with an external personal monitoring device, the deep-dose equivalent must be used in place of the effective dose equivalent, unless the effective dose equivalent is determined by a dosimetry method approved by the Department. The assigned deep-dose equivalent must be for the part of the body receiving the highest exposure. The assigned shallow-dose equivalent must be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure. The deep-dose equivalent, lens dose equivalent and shallow-dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable.

3.5.4 Derived air concentration (DAC) and annual limit on intake (ALI) values are presented in table 1 of appendix B, RHA 3.53 and may be used to determine the individual's dose (see RHA 3.39) and to demonstrate compliance with the occupational dose limits.

3.5.5 In addition to the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to 10 milligrams in a week in consideration of chemical toxicity (see footnote 3 of Appendix B, RHA 3.53).

3.5.6 The licensee shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person (see 3.37.2.5).

RHA 3.6. Compliance with Requirements for Summation of External and Internal Doses.

3.6.1 If the licensee is required to monitor under both 3.17.1 and 3.17.2, the licensee shall demonstrate compliance with the dose limits by summing external and internal doses. If the licensee is required to monitor only under 3.17.1 or only under 3.17.2, then summation is not required to demonstrate compliance with the dose limits. The licensee may demonstrate compliance with the requirements for summation of external and internal doses by meeting one of the conditions specified in paragraph 3.6.1.1 of this section and the conditions in paragraphs 3.6.1.2 and 3.6.1.3 of this section.

(Note: The dose equivalents for the lens of the eye, the skin, and the extremities are not included in the summation, but are subject to separate limits.)

3.6.1.1 Intake by inhalation. If the only intake of radionuclides is by inhalation, the total effective dose equivalent limit is not exceeded if the sum of the deep-dose equivalent divided by the total effective dose equivalent limit, and one of the following, does not exceed unity:

3.6.1.1.1 The sum of the fractions of the inhalation ALI for each radionuclide, or

3.6.1.1.2 The total number of derived air concentration-hours (DAC-hours) for all radionuclides divided by 2,000, or

3.6.1.1.3 The sum of the calculated committed effective dose equivalents to all significantly irradiated[1] organs or tissues (T) calculated from bioassay data using appropriate biological models and expressed as a fraction of the annual limit.

3.6.1.2 Intake by oral ingestion. If the occupationally exposed individual also receives an intake of radionuclides by oral ingestion greater than 10 percent of the applicable oral ALI, the licensee shall account for this intake and include it in demonstrating compliance with the limits.

3.6.1.3 Intake through wounds or absorption through skin. The licensee shall evaluate and, to the extent practical, account for intakes through wounds or skin absorption. (NOTE: The intake through intact skin has been included in the calculation of DAC for hydrogen-3 and does not need to be further evaluated.)

[1] An organ or tissue is deemed to be significantly irradiated if, for that organ or tissue, the product of the weighting factors, W_T, and the committed dose equivalent, H_{50}, per unit intake is greater than 10 percent of the maximum weighted value of $H_{5,0}$ (i.e., $W_T H_{50,T}$) per unit intake for any organ or tissue.

RHA 3.7. Determination of External Dose from Airborne Radioactive Material.

3.7.1 Licensees shall, when determining the dose from airborne radioactive material, include the contribution to the deep-dose equivalent, lens dose equivalent, and shallow-dose equivalent from external exposure to the radioactive cloud (see Appendix B, RHA 3.53 footnotes 1 and 2).

NOTE: Airborne radioactivity measurements and DAC values should not be used as the primary means to assess the deep-dose equivalent when the airborne radioactive material includes radionuclides other than noble gases or if the cloud of airborne radioactive material is not relatively uniform. The determination of the deep-dose equivalent to an individual should be based upon measurements using instruments or individual monitoring devices.

RHA 3.8. Determination of Internal Exposure.

3.8.1 For purposes of assessing dose used to determine compliance with occupational dose equivalent limits, the licensee shall, when required under RHA 3.17, take suitable and timely measurements of—

3.8.1.1 Concentrations of radioactive materials in air in work areas;

3.8.1.2 Quantities of radionuclides in the body; or

3.8.1.3 Quantities of radionuclides excreted from the body; or

3.8.1.4 Combinations of these measurements.

3.8.2 Unless respiratory protective equipment is used, as provided in 3.19.3, or the assessment of intake is based on bioassays, the licensee shall assume that an individual inhales radioactive material at the airborne concentration in which the individual is present.

3.8.3 When specific information on the physical and biochemical properties of the radionuclides taken into the body or the behavior or the material in an individual is known, the licensee may—

3.8.3.1 Use that information to calculate the committed effective dose equivalent, and, if used, the licensee shall document that information in the individual's record; and

3.8.3.2 Upon prior approval of the Department, adjust the DAC or ALI values to reflect the actual physical and chemical characteristics of airborne radioactive material (e.g., aerosol size distribution or density); and

3.8.3.3 Separately assess the contribution of fractional intakes of Class D, W, or Y compounds of a given radionuclide (see Appendix B, RHA 3.53) to the committed effective dose equivalent.

3.8.4 If the licensee chooses to assess intakes of Class Y material using the measurements given in 3.8.1.2 or 3.8.1.3, the licensee may delay the recording and reporting of the assessments for periods up to 7 months, unless otherwise required by RHA 3.45 or RHA 3.46, in order to permit the licensee to make additional measurements basic to the assessments.

3.8.5 If the identity and concentration of each radionuclide in a mixture are known, the fraction of the DAC applicable to the mixture for use in calculating DAC-hours must be either—

3.8.5.1 The sum of the ratios of the concentration to the appropriate DAC value (e.g., D, W, Y) from Appendix B, RHA 3.53 for each radionuclide in the mixture; or

3.8.5.2 The ratio of the total concentration for all radionuclides in the mixture to the most restrictive DAC value for any radionuclide in the mixture.

3.8.6 If the identity of each radionuclide in a mixture is known, but the concentration of one or more of the radionuclides in the mixture is not known, the DAC for the mixture must be the most restrictive DAC of any radionuclide in the mixture.

3.8.7 When a mixture of radionuclides in air exists, licensees may disregard certain radionuclides in the mixture if—

3.8.7.1 The licensee uses the total activity of the mixture in demonstrating compliance with the dose limits in RHA 3.5 and in complying with the monitoring requirements in 3.17.2, and

3.8.7.2 The concentration of any radionuclide disregarded is less than 10 percent of its DAC, and

3.8.7.3 The sum of these percentages for all of the radionuclides disregarded in the mixture does not exceed 30 percent.

3.8.8 In order to calculate the committed effective dose equivalent, the licensee may assume that the inhalation of one ALI, or an exposure of 2,000 DAC-hours, results in a committed effective dose equivalent of 5 rems (0.05 Sv) for radionuclides that have their ALIs or DACs based on the committed effective dose equivalent.

3.8.9 When the ALI (and the associated DAC) is determined by the nonstochastic organ dose limit of 50 rems (0.5 Sv), the intake of radionuclides that would result in a committed effective dose equivalent of 5 rems (0.05 Sv) (the stochastic ALI) is listed in parentheses in Table 1 of Appendix B, RHA 3.53. In this case, the licensee may, as a simplifying assumption, use the stochastic ALIs to determine committed effective dose equivalent. However, if the licensee uses the stochastic ALIs, the licensee must also demonstrate that the limit in 3.5.1.1.2 is met.

RHA 3.10. Planned Special Exposures.

A licensee may authorize an adult worker to receive doses in addition to and accounted for separately from the doses received under the limits specified in RHA 3.5 provided that each of the following conditions is satisfied—

3.10.1 The licensee authorizes a planned special exposure only in an exceptional situation when alternatives that might avoid the dose estimated to result from the planned special exposure are unavailable or impractical.

3.10.2 The licensee (and employer if the employer is not the licensee) specifically authorizes the planned special exposure, in writing, before the exposure occurs.

3.10.3 Before a planned special exposure, the licensee ensures that the individuals involved are–

3.10.3.1 Informed of the purpose of the planned operation;

3.10.3.2 Informed of the estimated doses and associated potential risks and specific radiation levels or other conditions that might be involved in performing the task; and

3.10.3.3 Instructed in the measures to be taken to keep the dose ALARA considering other risks that may be present.

3.10.4 Prior to permitting an individual to participate in a planned special exposure, the licensee ascertains prior doses as required by RHA 3.37.2 during the lifetime of the individual for each individual involved.

3.10.5 Subject to RHA 3.5.2, the licensee does not authorize a planned special exposure that would cause an individual to receive a dose from all planned special exposures and all doses in excess of the limits to exceed—

3.10.5.1 The numerical values of any of the dose limits in RHA 3.5.1 in any year; and

3.10.5.2 Five times the annual dose limits in RHA 3.5.1 during the individual's lifetime.

3.10.6 The licensee maintains records of the conduct of a planned special exposure in accordance with RHA 3.38 and submits a written report in accordance with RHA 3.47.

3.10.7 The licensee records the best estimate of the dose resulting from the planned special exposure in the individual's record and informs the individual, in writing, of the dose within 30 days from the date of the planned special exposure. The dose from planned special exposures is not to be considered in controlling future occupational dose of the individual under RHA 3.5.1 but is to be included in evaluations required by RHA 3.10.4 and 3.10.5.

RHA 3.11. Occupational Dose Limits for Minors.

The annual occupational dose limits for minors are 10 percent of the annual dose limits specified for adult workers in RHA 3.5.

RHA 3.12. Dose to an Embryo/Fetus.

3.12.1 The licensee shall ensure that the dose equivalent to the embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 0.5 rem (5 mSv). (For recordkeeping requirements, see RHA 3.39)

3.12.2 The licensee shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in paragraph 3.12.1 of this section.

3.12.3 The dose equivalent to the embryo/fetus is the sum of—

3.12.3.1 The deep-dose equivalent to the declared pregnant woman; and

3.12.3.2 The dose equivalent to the embryo/fetus resulting from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.

3.12.4 If the dose equivalent to the embryo/fetus is found to have exceeded 0.5 rem (5 mSv), or is within 0.05 rem (0.5 mSv) of this dose, by the time the woman declares the pregnancy to the licensee, the licensee shall be deemed to be in compliance with paragraph 3.12.1 of this section if the additional dose equivalent to the embryo/fetus does not exceed 0.05 rem (0.5 mSv) during the remainder of the pregnancy.

RHA 3.13. Dose Limits for Individual Members of the Public.

3.13.1 Each licensee shall conduct operations so that—

3.13.1.1 The total effective dose equivalent to individual members of the public from the licensed operation does not exceed 0.1 rem (1 mSv) in a year, exclusive of the dose contribution from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released, under RHA 4.32, from voluntary participation in medical research programs, and from the licensee's disposal of radioactive material into sanitary sewerage in accordance with RHA 3.29, and

3.13.1.2 The dose in any unrestricted area from external sources, exclusive of the dose contributions from patients administered radioactive material and released in accordance with RHA 4.8.12, does not exceed 0.002 rem (0.02 mSv) in any one hour.

3.13.2 If the licensee permits members of the public to have access to controlled areas, the limits for members of the public continue to apply to those individuals.

3.13.3 Notwithstanding paragraph 3.13.1.1 of this section, a licensee may permit visitors to an individual who cannot be released, under RHA 4.32, to receive a radiation dose greater than 0.1 rem (1 mSv) if—

3.13.3.1 The radiation dose received does not exceed 0.5 rem (5 mSv); and

3.13.3.2 The authorized user, as defined in Part IV of these regulations, has determined before the visit that it is appropriate.

3.13.4 A licensee or license applicant may apply for prior Department authorization to operate up to an annual dose limit for an individual member of the public of 0.5 rem (5 mSv). The licensee or license applicant shall include the following information in this application:

3.13.4.1 Demonstration of the need for and the expected duration of operations in excess of the limit in paragraph 3.13.1 of this section;

3.13.4.2 The licensee's program to assess and control dose within the 0.5 rem (5 mSv) annual limit; and

3.13.4.3 The procedures to be followed to maintain the dose as low as is reasonably achievable.

3.13.5 In addition to the requirements of this part, a licensee subject to the provisions of EPA's generally applicable environmental radiation standards in 40 CFR Part 190 shall comply with those standards.

3.13.6 The Department may impose additional restrictions on radiation levels in unrestricted areas and on the total quantity of radionuclides that a licensee may release in effluents in order to restrict the collective dose.

RHA 3.14. Compliance with Dose Limits for Individual Members of the Public.

3.14.1 The licensee shall make or cause to be made, as appropriate, surveys of radiation levels in unrestricted and controlled areas and radioactive materials in effluents released to unrestricted and controlled areas to demonstrate compliance with the dose limits for individual members of the public in RHA 3.13.

3.14.2 A licensee shall show compliance with the annual dose limit in RHA 3.13 by—

3.14.2.1 Demonstrating by measurement or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the annual dose limit; or

3.14.2.2 Demonstrating that—

3.14.2.2.1 The annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in Table 2 of Appendix B, RHA 3.53 and

3.14.2.2.2 If an individual were continually present in an unrestricted area, the dose from external sources would not exceed 0.002 rem (0.02 mSv) in an hour and 0.05 rem (0.5 mSv) in a year.

3.14.3 Upon approval from the Department, the licensee may adjust the effluent concentration values in Appendix B, RHA 3.53 Table 2, for members of the public, to take into account the actual physical and chemical characteristics of the effluents (e.g., aerosol size distribution, solubility, density, radioactive decay equilibrium, chemical form).

RHA 3.16. Surveys and Monitoring.

3.16.1 Each licensee shall make or cause to be made, surveys of areas, including the subsurface, that—

3.16.1.1 May be necessary for the licensee to comply with the regulations in this part; and

3.16.1.2 Are reasonable under the circumstances to evaluate—

3.16.1.2.1 The magnitude and extent of radiation levels; and

3.16.1.2.2 Concentrations or quantities of residual radioactivity; and

3.16.1.2.3 The potential radiological hazards of the radiation levels and residual radioactivity detected.

3.16.2 Notwithstanding RHA 3.36.1, records from surveys describing the location and amount of subsurface residual radioactivity identified at the site must be kept with records important for decommissioning, and such records must be retained in accordance with RHA 1.15.13.

3.16.3 The licensee shall ensure that instruments and equipment used for quantitative radiation measurements (e.g., dose rate and effluent monitoring) are calibrated at least annually for the radiation measured.

3.16.4 All personnel dosimeters (except for direct and indirect reading pocket dosimeters and those dosimeters used to measure the dose to the extremities) that require processing to determine the radiation dose and that are used by licensees to comply with RHA 3.5, with other applicable provisions of this chapter, or with conditions specified in a license must be processed and evaluated by a dosimetry processor—

3.16.4.1 Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and

3.16.4.2 Approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

HISTORY: Amended by State Register Volume 38, Issue No. 10, Doc. No. 4462, eff October 24, 2014.

RHA 3.17. Conditions Requiring Individual Monitoring of External and Internal Occupational Dose.

Each licensee shall monitor exposures to radiation and radioactive material at levels sufficient to demonstrate compliance with the occupational dose limits of this part. As a minimum—

3.17.1 Each licensee shall monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee and shall supply and require the use of individual monitoring devices by—

3.17.1.1 Adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in RHA 3.5.1,

3.17.1.2 Minors likely to receive, in 1 year from radiation sources external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv), a lens dose equivalent in excess of 0.15 rem (1.5 mSv), or a shallow dose equivalent to the skin or to the extremities in excess of 0.5 rem (5 mSv);

3.17.1.3 Declared pregnant women likely to receive during the entire pregnancy, from radiation sources external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv). (Note: All of the occupational doses in RHA 3.5 continue to be applicable to the declared pregnant worker as long as the embryo/fetus dose limit is not exceeded.)

3.17.1.4 Individuals entering a high or very high radiation area.

3.17.2 Each licensee shall monitor (see RHA 3.8) the occupational intake of radioactive material by and assess the committed effective dose equivalent to—

3.17.2.1 Adults likely to receive, in 1 year, an intake in excess of 10 percent of the applicable ALI(s) in Table 1, Columns 1 and 2, of Appendix B, RHA 3.53;

3.17.2.2 Minors likely to receive, in 1 year, a committed effective dose equivalent in excess of 0.1 rem (1 mSv); and

3.17.2.3 Declared pregnant women likely to receive, during the entire pregnancy, a committed effective dose equivalent in excess of 0.1 rem (1 mSv).

RHA 3.18. Control of Exposure from External Sources in Restricted Areas.

3.18.1 CONTROL OF ACCESS TO HIGH RADIATION AREAS.

3.18.1.1 The licensee shall ensure that each entrance or access point to a high radiation area has one or more of the following features—

3.18.1.1.1 A control device that, upon entry into the area, causes the level of radiation to be reduced below that level at which an individual might receive a deep-dose equivalent of 0.1 rem (1 mSv) in 1 hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates;

3.18.1.1.2 A control device that energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry; or

3.18.1.1.3 Entryways that are locked, except during periods when access to the areas is required, with positive control over each individual entry.

3.18.1.2 In place of the controls required by paragraph 3.18.1.1 of this section for a high radiation area, the licensee may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry.

3.18.1.3 A licensee may apply to the Department for approval of alternative methods for controlling access to high radiation areas.

3.18.1.4 The licensee shall establish the controls required by paragraphs 3.18.1.1 and 3.18.1.3 of this section in a way that does not prevent individuals from leaving a high radiation area.

3.18.1.5 Control is not required for each entrance or access point to a room or other area that is a high radiation area solely because of the presence of radioactive materials prepared for transport and packaged and labeled in accordance with the regulations of the Department of Transportation provided that—

3.18.1.5.1 The packages do not remain in the area longer than 3 days; and

3.18.1.5.2 The dose rate at 1 meter from the external surface of any package does not exceed 0.01 rem (0.1 mSv) per hour.

3.18.1.6 Control of entrance or access to rooms or other areas in hospitals is not required solely because of the presence of patients containing radioactive material, provided that there are personnel in attendance who will take the necessary precautions to prevent the exposure of individuals to radiation or radioactive material in excess of the limits established in this part and to operate within the ALARA provisions of the licensee's radiation protection program.

3.18.2 CONTROL OF ACCESS TO VERY HIGH RADIATION AREAS.

In addition to the requirements in 3.18.1, the licensee shall institute additional measures to ensure that an individual is not able to gain unauthorized or inadvertent access to areas in which radiation

levels could be encountered at 500 rads (5 grays) or more in 1 hour at 1 meter from a radiation source or any surface through which the radiation penetrates.

3.18.3 [3.18.3–3.18.3.3 Reserved]

RHA 3.19. Respiratory Protection and Controls to Restrict Internal Exposure in Restricted Areas.

3.19.1 USE OF PROCESS OR OTHER ENGINEERING CONTROLS.

3.19.1.1 The licensee shall use, to the extent practical, process or other engineering controls (e.g., containment, decontamination or ventilation) to control the concentrations of radioactive material in air.

3.19.2 USE OF OTHER CONTROLS.

When it is not practical to apply process or other engineering controls to control the concentrations of radioactive material in air to values below those that define an airborne radioactivity area, the licensee shall, consistent with maintaining the total effective dose equivalent ALARA, increase monitoring and limit intakes by one or more of the following means:

3.19.2.1 Control of access;

3.19.2.2 Limitation of exposure times;

3.19.2.3 Use of respiratory protection equipment; or

3.19.2.4 Other controls.

If the licensee performs an ALARA analysis to determine whether or not respirators should be used, the licensee may consider safety factors other than radiological factors. The licensee should also consider the impact of respirator use on workers' industrial health and safety.

3.19.3 USE OF INDIVIDUAL RESPIRATORY PROTECTION EQUIPMENT.

3.19.3.1 If the licensee uses respiratory protection equipment to limit intakes pursuant to 3.19.2—

3.19.3.1.1 The licensee shall use only respiratory protection equipment that is tested and certified by the National Institute for Occupational Safety and Health (NIOSH), except as otherwise noted in this regulation.

3.19.3.1.2 If the licensee wishes to use equipment that has not been tested or certified by NIOSH or for which there is no schedule for testing or certification, the licensee shall submit an application for authorized use of that equipment, except as provided in this regulation, including a demonstration by testing, or a demonstration on the basis of reliable test information, that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use.

3.19.3.1.3 The licensee shall implement and maintain a respiratory protection program that includes—

3.19.3.1.3.1 Air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate doses;

3.19.3.1.3.2 Surveys and bioassays, as appropriate, to evaluate actual intakes;

3.19.3.1.3.3 Testing of respirators for operability (user seal check for face sealing devices and functional check for others) immediately prior to each use;

3.19.3.1.3.4 Written procedures regarding selection, fitting, issuance, maintenance, and testing of respirators, including testing for operability immediately prior to each use; supervision and training of personnel; breathing air quality; storage; inventory and control; repair; quality assurance of respiratory protection equipment; limitations on periods of respirator use and relief from respirator use; monitoring, including air sampling and bioassays; and recordkeeping; and

3.19.3.1.3.5 Determination by a physician prior to initial fitting of face sealing respirators or before the first field use of non-face sealing respirators, and either every 12 months thereafter or periodically at a frequency determined by a physician, that the individual user is medically fit to use the respiratory protection equipment.

3.19.3.1.3.6 Fit testing, with fit factor ⩾ 10 times the APF for negative pressure devices, and a fit factor ⩾ 500 for any positive pressure, continuous flow, and pressure-demand devices, before the first field use of tight fitting, face-sealing respirators and periodically thereafter at a frequency not to exceed 1 year. Fit testing must be performed with the facepiece operating in the negative pressure mode.

3.19.3.1.4 The licensee shall advise each respirator user that the user may leave the area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other conditions that might require such relief.

3.19.3.1.5 The licensee shall use equipment within limitations for type and mode of use and shall provide proper visual, communication, and other special capabilities (such as low temperature work environments) when needed. The licensee shall also provide for the concurrent use of other safety or radiological protection equipment. The licensee shall use equipment in such a way as not to interfere with the proper operation of the respirator.

3.19.3.1.6 Standby rescue persons are required whenever one-piece atmosphere-supplying suits, or any combination of supplied air respiratory protection device and personnel protective equipment are used from which an unaided individual would have difficulty extricating himself or herself. The standby persons must be equipped with respiratory protection devices or other apparatus appropriate for the potential hazards. The standby rescue persons shall observe or otherwise maintain continuous communication with the workers (visual, voice, signal line, telephone, radio, or other suitable means), and be immediately available to assist them in case of a failure of the air supply or for any other reason that requires relief from distress. A sufficient number of standby rescue persons must be immediately available to assist all users of this type of equipment and to provide effective emergency rescue if needed.

3.19.3.1.7 Atmosphere-supplying respirators must be supplied with respirable air of grade D quality or better as defined by the Compressed Gas Association in publication G–7.1, "Commodity Specification for Air," 1997 and included in the regulations of the Occupational Safety and Health Administration (29 CFR 1910.134 (i) (1) (ii) (A) through (E)). Grade D quality air criteria include:

(1) Oxygen content (v/v) of 19.5–23.5%;

(2) Hydrocarbon (condensed) content of 5 milligrams per cubic meter of air or less;

(3) Carbon monoxide (CO) content of 10 ppm or less;

(4) Carbon dioxide content of 1,000 ppm or less; and

(5) Lack of noticeable odor.

3.19.3.1.8 The licensee shall ensure that no objects, materials or substances, such as facial hair, or any conditions that interfere with the face—facepiece seal or valve function, and that are under the control of the respirator wearer, are present between the skin of the wearer's face and the sealing surface of a tight-fitting respirator facepiece.

3.19.3.2 In estimating the dose to individuals from intake of airborne radioactive materials, the concentration of radioactive material in the air that is inhaled when respirators are worn is initially assumed to be the ambient concentration in air without respiratory protection, divided by the assigned protection factor. If the dose is later found to be greater than the estimated dose, the corrected value must be used. If the dose is later found to be less than the estimated dose, the corrected value may be used.

3.19.4 Further restrictions on the use of respiratory protection equipment.

The Department may impose restrictions in addition to those in 3.19.2, 3.19.3 and Appendix A, RHA 3.52 to—

3.19.4.1 Ensure that the respiratory protection program of the licensee is adequate to limit doses to individuals from intakes of airborne radioactive materials consistent with maintaining total effective dose equivalent ALARA; and

3.19.4.2 Limit the extent to which a licensee may use respiratory protection equipment instead of process or other engineering controls.

3.19.5 Application for use of higher assigned protection factors.

The licensee shall obtain authorization from the Department before using assigned protection factors in excess of those specified in Appendix A, RHA 3.52. The Department may authorize a licensee to use higher assigned protection factors on receipt of an application that—

3.19.5.1 Describes the situation for which a need exists for higher protection factors; and

3.19.5.2 Demonstrates that the respiratory protection equipment provides these higher protection factors under the proposed conditions of use.

RHA 3.20. Storage and Control of Licensed Material.

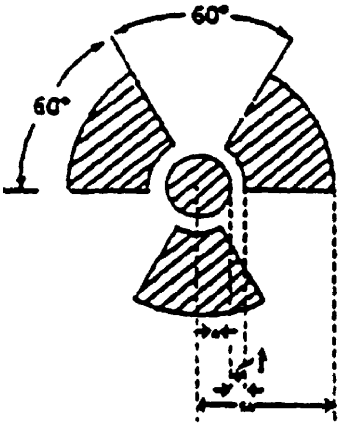
3.20.1 Security of stored material. The licensee shall secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas.

3.20.2 Control of material not in storage. The licensee shall control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage.

RHA 3.21. Caution Signs.

3.21.1 Standard radiation symbol. Unless otherwise authorized by the Department, the symbol prescribed by this part shall use the colors magenta, or purple, or black on yellow background. The symbol prescribed by this part is the three-bladed design:

RADIATION SYMBOL



3.21.1.1 Cross-hatched area is to be magenta, or purple, or black, and

3.21.1.2 The background is to be yellow.

3.21.1.2.1 Exception to color requirements for standard radiation symbol. Notwithstanding the requirements of paragraph 3.21.1 of this section, licensees are authorized to label sources, source holders, or device components containing sources of licensed materials that are subjected to high temperatures, with conspicuously etched or stamped radiation caution symbols and without a color requirement.

3.21.1.2.2 Additional information on signs and labels. In addition to the contents of signs and labels prescribed in this part, the licensee may provide, on or near the required signs and labels, additional information, as appropriate, to make individuals aware of potential radiation exposures and to minimize the exposures.

RHA 3.22. Posting Requirements.

3.22.1 Posting of radiation areas. The licensee shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIATION AREA."

3.22.2 Posting of high radiation areas. The licensee shall post each high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, HIGH RADIATION AREA" or "DANGER, HIGH RADIATION AREA."

3.22.3 Posting of very high radiation areas. The licensee shall post each very high radiation area with a conspicuous sign or signs bearing the radiation symbol and words "GRAVE DANGER, VERY HIGH RADIATION AREA."

3.22.4 Posting of airborne radioactivity areas. The licensee shall post each airborne radioactivity area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, AIRBORNE RADIOACTIVITY AREA" or "DANGER, AIRBORNE RADIOACTIVITY AREA."

3.22.5 Posting of areas or rooms in which licensed material is used or stored. The licensee shall post each area or room in which there is used or stored an amount of licensed material exceeding 10 times the quantity of such material specified in Appendix C, RHA 3.54 with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)."

RHA 3.23. Exceptions to Posting Requirements.

3.23.1 A licensee is not required to post caution signs in areas or rooms containing radioactive materials for periods of less than 8 hours, if each of the following conditions is met:

3.23.1.1 The materials are constantly attended during these periods by an individual who takes the precautions necessary to prevent the exposure of individuals to radiation or radioactive materials in excess of the limits established in this part; and

3.23.1.2 The area or room is subject to the licensee's control.

3.23.2 Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs pursuant to RHA 3.22 provided that the patient could be released from licensee control pursuant to RHA 4.8.12.

3.23.3 A room or area is not required to be posted with a caution sign because of the presence of a sealed source provided the radiation level at 30 centimeters from the surface of the source container or housing does not exceed 0.005 rem (0.05 mSv) per hour.

3.23.4 Rooms in hospitals or clinics that are used for teletherapy are exempt from the requirement to post caution signs under RHA 3.22 if—

3.23.4.1 Access to the room is controlled pursuant to RHA 4.14.6; and

3.23.4.2 Personnel in attendance take necessary precautions to prevent the inadvertent exposure of workers, other patients, and members of the public to radiation in excess of the limits established in this part.

RHA 3.24. Labeling Containers.

3.24.1 The licensee shall ensure that each container of licensed material bears a durable, clearly visible label bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL." The label must also provide sufficient information (such as the radionuclide(s) present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, kinds of materials, and mass enrichment) to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures.

3.24.2 Each licensee shall, prior to removal or disposal of empty uncontaminated containers to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials.

RHA 3.25. Exemptions to Labeling Requirements.

A licensee is not required to label—

3.25.1 Containers holding licensed material in quantities less than the quantities listed in Appendix C, RHA 3.54; or

3.25.2 Containers holding licensed material in concentrations less than those specified in Table 3 of Appendix B, RHA 3.53 or

3.25.3 Containers attended by an individual who takes the precautions necessary to prevent the exposure of individuals in excess of the limits established by this part; or

3.25.4 Containers when they are in transport and packaged and labeled in accordance with the regulations of the Department of Transportation [3], or

3.25.5 Containers that are accessible only to individuals authorized to handle or use them, or to work in the vicinity of the containers, if the contents are identified to these individuals by a readily available written record (examples of containers of this type are containers in locations such as water-filled canals, storage vaults, or hot cells). The record must be retained as long as the containers are in use for the purpose indicated on the record; or

3.25.6 Installed manufacturing or process equipment, such as reactor components, piping, and tanks.

Editor's Note

Scrivener errors corrected in 2012.

RHA 3.26. Procedures for Receiving and Opening Packages.

3.26.1 Each licensee who expects to receive a package containing quantities of radioactive material in excess of a Type A quantity, as defined in RHA 3.2.43 and Appendix A, 10 CFR Part 71, shall make arrangements to receive—

3.26.1.1 The package when the carrier offers it for delivery; or

3.26.1.2 Notification of the arrival of the package at the carrier's terminal and to take possession of the package expeditiously.

3.26.2 Each licensee shall—

3.26.2.1 Monitor the external surfaces of a labeled [3a] package for radioactive contamination unless the package contains only radioactive material in the form of a gas or in special form as defined in 10 CFR 71.4;

3.26.2.2 Monitor the external surfaces of a labeled [3a] package for radiation levels unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, as defined in RHA 3.2.43, and Appendix A, 10 CFR Part 71[3b]; and

[3a] Labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in U.S. Department of Transportation regulations, 49 CFR 172.403 and 172.438-440.

[3b] A copy of 10 CFR Part 71 may be obtained from the Superintendent of Documents, Government Printing Office, Washington, DC 20402 (Telephone 202-512-1800).

3.26.2.3 Monitor all packages known to contain radioactive material for radioactive contamination and radiation levels if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.

3.26.3 The licensee shall perform the monitoring required by paragraph 3.26.2 of this section as soon as practicable after receipt of the package, but not later than 3 hours after the package is received at the licensee's facility if it is received during the licensee's normal working hours, or not later than 3 hours from the beginning of the next working day if it is received after working hours.

3.26.4 The licensee shall immediately notify the final delivery carrier and the S.C. Department of Health & Environmental Control, Bureau of Radiological Health, (803–545–4400 or 803–690–8286), by telephone, when:

3.26.4.1 Removable radioactive surface contamination exceeds the limits of 10 CFR 71.87(i) or

3.26.4.2 External radiation levels exceed the limits of 10 CFR 71.47.

3.26.5 Each licensee shall—

3.26.5.1 Establish, maintain, and retain written procedures for safely opening packages in which radioactive material is received; and

3.26.5.2 Ensure that the procedures are followed and that due consideration is given to special instructions for the type of package being opened.

3.26.6 Licensees transferring special form sources in licensee-owned or licensee-operated vehicles to and from a work site are exempt from the contamination monitoring requirements of paragraph

[3] Labeling of packages containing radioactive materials is required by the Department of Transportation (DOT) if the amount and type of radioactive material exceeds the limits for an excepted quantity or article as defined and limited by DOT regulations 49 CFR 173.403 (m) and (w) and 173.421-424.

3.26.2 of this section, but are not exempt from the survey requirement in paragraph 3.26.2 of this section for measuring radiation levels that is required to ensure that the source is still properly lodged in its shield.

RHA 3.27. Waste Disposal – General Requirements.

3.27.1 A licensee shall dispose of licensed material only—

3.27.1.1 By transfer to an authorized recipient as provided in RHA 3.32 or in the regulations in Parts II and VII; or

3.27.1.2 By decay in storage; or

3.27.1.3 By release in effluents within the limits in RHA 3.13 or

3.27.1.4 As authorized under RHA 3.28, 3.29, 3.30, or 3.31.

3.27.2 A person must be specifically licensed to receive waste containing licensed material from other persons for:

3.27.2.1 Treatment prior to disposal; or

3.27.2.2 Treatment or disposal by incineration; or

3.27.2.3 Decay in storage; or

3.27.2.4 Disposal at a land disposal facility licensed under Part VII of these regulations.

RHA 3.28. Method for Obtaining Approval of Proposed Disposal Procedures.

A licensee or applicant for a license may apply to the Department for approval of proposed procedures, not otherwise authorized in the regulations in this chapter, to dispose of licensed material generated in the licensee's activities. Each application shall include:

3.28.1 A description of the waste containing licensed material to be disposed of, including the physical and chemical properties important to risk evaluation, and the proposed manner and conditions of waste disposal; and

3.28.2 An analysis and evaluation of pertinent information on the nature of the environment; and

3.28.3 The nature and location of other potentially affected licensed and unlicensed facilities; and

3.28.4 Analyses and procedures to ensure that doses are maintained ALARA and within the dose limits in this part.

RHA 3.29. Disposal by Release into Sanitary Sewerage.

3.29.1 A licensee may discharge licensed material into sanitary sewerage if each of the following conditions is satisfied:

3.29.1.1 The material is readily soluble (or is readily dispersible biological material) in water; and

3.29.1.2 The quantity of licensed or other radioactive material that the licensee releases into the sewer in 1 month divided by the average monthly volume of water released into the sewer by the licensee does not exceed the concentration listed in Table 3 of Appendix B, RHA 3.53 and

3.29.1.3 If more than one radionuclide is released, the following conditions must also be satisfied:

3.29.1.3.1 The licensee shall determine the fraction of the limit in Table 3 of Appendix B, RHA 3.53 represented by discharges into sanitary sewerage by dividing the actual monthly average concentration of each radionuclide released by the licensee into the sewer by the concentration of that radionuclide listed in Table 3 of Appendix B, RHA 3.53 and

3.29.1.3.2 The sum of the fractions for each radionuclide required by paragraph 3.29.1.3.1 of this section does not exceed unity; and

3.29.1.4 The total quantity of licensed and other radioactive material that the licensee releases into the sanitary sewerage system in a year does not exceed 5 curies (185 GBq) of hydrogen-3, 1 curie (37 GBq) of carbon-14, and 1 curie (37 GBq) of all other radioactive materials combined.

3.29.2 Excreta from individuals undergoing medical diagnosis or therapy with radioactive material is not subject to the limitations contained in paragraph 3.29.1 of this section.

RHA 3.30. Treatment or Disposal by Incineration.

A licensee may treat or dispose of licensed material by incineration only in the amounts and forms specified in RHA 3.31 or as specifically approved by the Department pursuant to RHA 3.28.

RHA 3.31. Disposal of Specific Wastes and Certain Byproduct Material.

3.31.1 A licensee may dispose of the following licensed material as if it were not radioactive:

3.31.1.1 0.05 microcurie (1.85 kBq), or less, of hydrogen-3 or carbon-14 per gram of medium used for liquid scintillation counting; and

3.31.1.2 0.05 microcurie (1.85 kBq), or less, of hydrogen-3 or carbon-14 per gram of animal tissue, averaged over the weight of the entire animal.

3.31.2 A licensee may not dispose of tissue under paragraph 3.31.1.2 of this section in a manner that would permit its use either as food for humans or as animal feed.

3.31.3 Licensed material as defined in paragraphs (3) and (4) of the definition of byproduct material set forth in RHA 1.2.6 may be disposed of in accordance with Part 3 of this Regulation, even though it is not defined as low-level radioactive waste. Therefore, any licensed byproduct material being disposed of at a facility, or transferred for ultimate disposal at a facility authorized to dispose of such material, must meet the requirements of RHA 3.32.

3.31.4 A licensee may dispose of byproduct material, as defined in paragraphs (3) and (4) of the definition of byproduct material set forth in RHA 1.2.6, at a disposal facility authorized to dispose of such material in accordance with any Federal or State solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005.

3.31.5 The licensee shall maintain records in accordance with RHA 3.41.

RHA 3.32. Transfer for Disposal and Manifests.

3.32.1 The requirements of this section and Appendix D, RHA 3.55 are designed to control transfers of low-level radioactive waste by any waste generator, waste collector, or waste processor, as defined in this part, who ship low-level waste either directly, or indirectly through a waste collector or waste processor, to a low-level waste land disposal facility (as defined in Part VII of these regulations), establish a manifest tracking system, and supplement existing requirements concerning transfers and recordkeeping for those wastes.

3.32.2 Any licensee shipping radioactive waste intended for ultimate disposal at a licensed land disposal facility must document the information required on NRC's Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with Section 3.55.1 of Appendix D, RHA 3.55.

3.32.3 Each shipment manifest must include a certification by the waste generator as specified in Section 3.55.2 of Appendix D, RHA 3.55.

3.32.4 Each person involved in the transfer for disposal and disposal of waste, including the waste generator, waste collector, waste processor, and disposal facility operator, shall comply with the requirements specified in Section 3.55.3 of Appendix D, RHA 3.55.

3.32.5 Any licensee shipping byproduct material as defined in paragraphs 3 and 4 of the definition of byproduct material set forth in RHA 1.2.6 intended for ultimate disposal at a land disposal facility licensed under Part 7 of this Regulation must document the information required on the NRC's Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with Appendix D to this part.

RHA 3.33. Compliance with Environmental and Health Protection Regulations.

Nothing in this subpart relieves the licensee from complying with other applicable Federal, State, and local regulations governing any other toxic or hazardous properties of materials that may be disposed of under this subpart.

RHA 3.34. Records – General Provisions.

3.34.1 Each licensee shall use the units: curie, rad, rem, including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by this part.

3.34.2 In the records required by this part, the licensee may record quantities in SI units in parentheses following each of the units specified in RHA 3.34.1. However, all quantities must be recorded as stated in RHA 3.34.1.

3.34.3 Not withstanding the requirements of 3.34.1 of this section, when recording information on shipment manifests, as required in 3.32.2 information must be recorded in the International System of Units(SI) or in SI and units as specified in 3.34.1 of this section.

3.34.4 The licensee shall make a clear distinction among the quantities entered on the records required by this part (e.g., total effective dose equivalent, shallow-dose equivalent, lens dose equivalent, deep-dose equivalent, committed effective dose equivalent).

3.34.5 Prior to license termination, each licensee authorized to possess radioactive material with a half-life greater than 120 days or source material, in an unsealed form, shall forward the following records to the Department:

3.34.5.1 Records of disposal of licensed material made under RHA 3.28 thru 3.31; and

3.34.5.2 Records required by RHA 3.36.2.4.

3.34.6 If licensed activities are transferred or assigned in accordance with RHA 2.10.2, each licensee authorized to possess radioactive material with a half-life greater than 120 days or source material, in an unsealed form, shall transfer the following records to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated:

3.34.6.1 Records of disposal of licensed material made under RHA 3.28 thru 3.31; and

3.34.6.2 Records required by RHA 3.36.2.4.

3.34.7 Prior to license termination, each licensee shall forward the records required by RHA 1.15.13 to the Department.

RHA 3.35. Records of Radiation Protection Programs.

3.35.1 Each licensee shall maintain records of the radiation protection program, including:

3.35.1.1 The provisions of the program; and

3.35.1.2 Audits and other reviews of program content and implementation.

3.35.2 The licensee shall retain the records required by paragraph 3.35.1.1 of this section until the Department terminates each pertinent license requiring the record. The licensee shall retain the records required by paragraph 3.35.1.2 of this section for 3 years after the record is made.

RHA 3.36. Records of Surveys.

3.36.1 Each licensee shall maintain records showing the results of surveys and calibrations required by RHA 3.16 and 3.26.2. The licensee shall retain these records for 3 years after the record is made.

3.36.2 The licensee shall retain each of the following records until the Department terminates each pertinent license requiring the record:

3.36.2.1 Records of the results of surveys to determine the dose from external sources and used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents; and

3.36.2.2 Records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose; and

3.36.2.3 Records showing the results of air sampling, surveys, and bioassays required pursuant to RHA 3.19.3.1.3.1 and 3.19.3.1.3.2; and

3.36.2.4 Records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment.

RHA 3.37. Determination of Prior Occupational Dose.

3.37.1 For each individual who is likely to receive in a year, an occupational dose requiring monitoring pursuant to RHA 3.17, the licensee shall—

3.37.1.1 Determine the occupational radiation dose received during the current year; and

3.37.1.2 Attempt to obtain the records of lifetime cumulative occupational radiation dose.

3.37.2 Prior to permitting an individual to participate in a planned special exposure, the licensee shall determine—

3.37.2.1 The internal and external doses from all previous planned special exposures; and

3.37.2.2 All doses in excess of the limits (including doses received during accidents and emergencies) received during the lifetime of the individual.

3.37.3 In complying with the requirements of paragraph 3.37.1 of this section, a licensee may—

3.37.3.1 Accept, as a record of the occupational dose that the individual received during the current year, a written signed statement from the individual, or from the individual's most recent employer for work involving radiation exposure, that discloses the nature and the amount of any occupational dose that the individual may have received during the current year;

3.37.3.2 Accept, as the record of lifetime cumulative radiation dose, an up-to-date S.C. Form 4, or equivalent, signed by the individual and counter-signed by an appropriate official of the most recent employer for work involving radiation exposure, or the individual's current employer (if the individual is not employed by the licensee); and

3.37.3.3 Obtain reports of the individual's dose equivalent(s) from the most recent employer for work involving radiation exposure, or the individual's current employer (if the individual is not employed by the licensee) by telephone, telegram, electronic media, or letter. The licensee shall request a written verification of the dose data if the authenticity of the transmitted report cannot be established.

3.37.4 The licensee shall record the exposure history, as required by paragraph 3.37.1 of this section, on S.C. Form 4, or other clear and legible record, of all the information required on that form.[4] The form or record must show each period in which the individual received occupational exposure to radiation or radioactive material and must be signed by the individual who received the exposure. For each period for which the licensee obtains reports, the licensee shall use the dose shown in the report in preparing S.C. Form 4. For any period in which the licensee does not obtain a report, the licensee shall place a notation on S.C. Form 4 indicating the periods of time for which data is not available.

3.37.5 If the licensee is unable to obtain a complete record of an individual's current and previously accumulated occupational dose, the licensee shall assume—

3.37.5.1 In establishing administrative controls under 3.5.6 for the current year, that the allowable dose limit for the individual is reduced by 1.25 rems (12.5 mSv) for each quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure; and

3.37.5.2 That the individual is not available for planned special exposures.

3.37.6 The licensee shall retain the records on S.C. Form 4 or equivalent until the Department terminates each pertinent license requiring this record. The licensee shall retain records used in preparing S.C. Form 4 for 3 years after the record is made.

Editor's Note

Scrivener errors corrected in 2012.

RHA 3.38. Records of Planned Special Exposures.

3.38.1 For each use of the provisions of RHA 3.10 for planned special exposures, the licensee shall maintain records that describe—

[4] Licensees are not required to reevaluate the separate external dose equivalents and internal committed dose equivalents or intakes of radionuclides assessed under the regulations in Part III in effect before January 1, 1994. Further, occupational exposure histories obtained and recorded on S.C. Form 4 before January 1, 1994, would not have included effective dose equivalent but may be used in the absence of specific information on the intake of radionuclides by the individual.

3.38.1.1 The exceptional circumstances requiring the use of a planned special exposure; and

3.38.1.2 The name of the management official who authorized the planned special exposure and a copy of the signed authorization; and

3.38.1.3 What actions were necessary; and

3.38.1.4 Why the actions were necessary; and

3.38.1.5 How doses were maintained ALARA; and

3.38.1.6 What individual and collective doses were expected to result, and the doses actually received in the planned special exposure.

3.38.2 The licensee shall retain the records until the Department terminates each pertinent license requiring these records.

RHA 3.39. Records of Individual Monitoring Results.

3.39.1 Recordkeeping requirement. Each licensee shall maintain records of doses received by all individuals for whom monitoring was required pursuant to RHA 3.17, and records of doses received during planned special exposures, accidents, and emergency conditions. These records must include, when applicable—

3.39.1.1 The deep-dose equivalent to the whole body, lens dose equivalent, shallow-dose equivalent to the skin, and shallow-dose equivalent to the extremities; and

3.39.1.2 The estimated intake of radionuclides (see RHA 3.6); and

3.39.1.3 The committed effective dose equivalent assigned to the intake of radionuclides; and

3.39.1.4 The specific information used to assess the committed effective dose equivalent pursuant to RHA 3.8.1 and RHA 3.8.3, and when required by RHA 3.17, and

3.39.1.5 The total effective dose equivalent when required by RHA 3.6 and

3.39.1.6 The total of the deep-dose equivalent and the committed dose to the organ receiving the highest total dose.

3.39.2 Recordkeeping frequency. The licensee shall make entries of the records specified in paragraph 3.39.1 of this section at least annually.

3.39.3 Recordkeeping format. The licensee shall maintain the records specified in paragraph 3.39.1 of this section on S.C. Form 5, in accordance with the instructions for S.C. Form 5, or in clear and legible records containing all the information required by S.C. Form 5.

3.39.4 Privacy protection. The records required under this section should be protected from public disclosure because of their personal privacy nature. These records are protected by most State privacy laws.

3.39.5 The licensee shall maintain the records of dose to an embryo/fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy shall also be kept on file, but may be maintained separately from the dose records.

3.39.6 The licensee shall retain each required form or record until the Department terminates each pertinent license requiring the record.

RHA 3.40. Records of Dose to Individual Members of the Public.

3.40.1 Each licensee shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public (see RHA 3.13).

3.40.2 The licensee shall retain the records required by paragraph 3.40.1 of this section until the Department terminates each pertinent license requiring the record.

RHA 3.41. Records of Waste Disposal.

3.41.1 Each licensee shall maintain records of the disposal of licensed materials made under RHA 3.28, 3.29, 3.30, 3.31 and disposal by burial in soil.

3.41.2 The licensee shall retain the records required by paragraph RHA 3.41.1 of this section until the Department terminates each pertinent license requiring the record. Requirements for disposition

of these records, prior to license termination, are located in Section 3.34 for activities licensed under these parts.

RHA 3.42. Vacating Premises.

Before a licensee vacates any location which may have been contaminated by radioactive material as a result of the licensee's activities the licensee shall, not less than 30 days prior to such vacating, notify the Department in writing of intent to vacate. The licensee shall decontaminate or have decontaminated the location to a degree consistent with subsequent use as an unrestricted area, in accordance with Appendix F, RHA 3.57.

RHA 3.43. Form of Records.

Each record required by this part must be legible throughout the specified retention period. The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, must include all pertinent information, such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

RHA 3.44. Reports of Theft or Loss of Licensed Material.

3.44.1 Telephone reports. Each licensee shall report by telephone to the S.C. Department of Health and Environmental Control, Bureau of Radiological Health, 2600 Bull Street, Columbia, S.C. 29201, as follows:

3.44.1.1 Immediately after its occurrence becomes known to the licensee, any lost, stolen, or missing licensed material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in Appendix C RHA 3.55 under such circumstances that it appears to the licensee that an exposure could result to persons in unrestricted areas; or

3.44.1.2 Within 30 days after the occurrence of any lost, stolen, or missing licensed material becomes known to the licensee, all licensed material in a quantity greater than 10 times the quantity specified in Appendix C RHA 3.55 that is still missing at this time.

3.44.2 Reports must be made as follows:

3.44.2.1 Written reports. Each licensee required to make a report under paragraph 3.44.1 of this section shall, within 30 days after making the telephone report, make a written report setting forth the following information:

3.44.2.1.1 A description of the licensed material involved, including kind, quantity, and chemical and physical form; and

3.44.2.1.2 A description of the circumstances under which the loss or theft occurred; and

3.44.2.1.3 A statement of disposition, or probable disposition, of the licensed material involved; and

3.44.2.1.4 Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas; and

3.44.2.1.5 Actions that have been taken, or will be taken, to recover the material; and

3.44.2.1.6 Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed material.

3.44.3 Subsequent to filing the written report, the licensee shall also report any additional substantive information on the loss or theft within 30 days after the licensee learns of such information.

3.44.4 The licensee shall prepare any report filed with the Department pursuant to this section so that names of individuals who may have received exposure to radiation are stated in a separate and detachable part of the report.

RHA 3.45. Notification of Incidents.

3.45.1 Immediate notification. Notwithstanding any other requirements for notification, each licensee shall immediately notify the S.C. Department of Health & Environmental Control, Bureau of Radiological Health, 2600 Bull Street, Columbia, SC 29201, by telephone (803–545–4400) and confirming letter of any event involving radioactive material possessed by the licensee that may have caused or threatens to cause any of the following conditions—

3.45.1.1 An individual to receive—

3.45.1.1.1 A total effective dose equivalent of 25 rems (0.25 Sv) or more; or

3.45.1.1.2 A lens dose equivalent of 75 rems (0.75 Sv) or more;

3.45.1.1.3 A shallow-dose equivalent to the skin or extremities of 250 rads (2.5 Gy) or more; or

3.45.1.2 The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake five times the occupational annual limit on intake (the provisions of this paragraph do not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures); or

3.45.1.3 A loss of 1 working week or more of the operation of any facilities affected; or

3.45.1.4 Damage to property in excess of $200,000.

3.45.2 Twenty-four hour notification. Each licensee shall, within 24 hours of discovery of the event, report any event involving loss of control of licensed material possessed by the licensee that may have caused, or threatens to cause, any of the following conditions:

3.45.2.1 An individual to receive, in a period of 24 hours—

3.45.2.1.1 A total effective dose equivalent exceeding 5 rems (0.05 Sv); or

3.45.2.1.2 A lens dose equivalent exceeding 15 rems (0.15 Sv);

3.45.2.1.3 A shallow-dose equivalent to the skin or extremities exceeding 50 rems (0.5 Sv); or

3.45.2.2 The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake in excess of one occupational annual limit on intake (the provisions of this paragraph do not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures); or

3.45.2.3 A loss of 1 day or more of the operation of any facilities affected; or

3.45.2.4 Damage to property in excess of $2,000.

3.45.3 The licensee shall prepare any report filed with the Department pursuant to this section so that names of individuals who have received exposure to radiation or radioactive material are stated in a separate and detachable part of the report.

3.45.4 The provisions of this section do not include doses that result from planned special exposures, that are within the limits for planned special exposures, and that are reported under RHA 3.47.

RHA 3.46. Reports of Exposures, Radiation Levels, and Concentrations of Radioactive Material Exceeding the Limits.

3.46.1 Reportable events. In addition to the notification required by RHA 3.45, each licensee shall submit a written report within 30 days after learning of any of the following occurrences:

3.46.1.1 Any incident for which notification is required by RHA 3.45; or

3.46.1.2 Doses in excess of any of the following:

3.46.1.2.1 The occupational dose limits for adults in RHA 3.5; or

3.46.1.2.2 The occupational dose limits for a minor in RHA 3.11; or

3.46.1.2.3 The limits for an embryo/fetus of a declared pregnant woman in RHA 3.12; or

3.46.1.2.4 The limits for an individual member of the public in RHA 3.13; or

3.46.1.2.5 Any applicable limit in the license; or

3.46.1.2.6 The ALARA constraints for air emissions established under RHA 3.4.4; or

3.46.1.3 Levels of radiation or concentrations of radioactive material in—

3.46.1.3.1 A restricted area in excess of any applicable limit in the license; or

3.46.1.3.2 An unrestricted area in excess of 10 times any applicable limit set forth in this part or in the license (whether or not involving exposure of any individual in excess of the limits in RHA 3.13);

3.46.2 Contents of reports. Each report required by paragraph 3.46.1 of this section must describe the extent of exposure of individuals to radiation and radioactive material, including, as appropriate:

3.46.2.1 Estimates of each individual's dose; and

3.46.2.2 The levels of radiation and concentrations of radioactive material involved; and

3.46.2.3 The cause of the elevated exposures, dose rates, or concentrations; and

3.46.2.4 Corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, ALARA constraints, generally applicable environmental standards, and associated license conditions.

3.46.3 Each report filed pursuant to paragraph RHA 3.46.1 of this section must include for each occupationally overexposed [5] individual: the name, Social Security account number, and date of birth. The report must be prepared so that this information is stated in a separate and detachable part of the report.

3.46.4 All licensees, who make reports under paragraph 3.46.1 of this section shall submit the report in writing to the S.C. Department of Health & Environmental Control, Bureau of Radiological Health, 2600 Bull Street, Columbia, SC.

Editor's Note

Scrivener errors corrected in 2012.

RHA 3.47. Reports of Planned Special Exposures.

The licensee shall submit a written report to S.C. Department of Health & Environmental Control, Bureau of Radiological Health, 2600 Bull Street, Columbia, SC 29201 within 30 days following any planned special exposure conducted in accordance with RHA 3.10, informing the Department that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by RHA 3.38.

RHA 3.48. Reports to Individuals of Exceeding Dose Limits.

When a licensee is required, pursuant to the provisions of RHA 3.46, 3.47, and 3.49, to report to the Department any exposure of an identified occupationally exposed individual, or an identified member of the public, to radiation or radioactive material, the licensee shall also provide the individual a report on his or her exposure data included in the report to the Department. This report must be transmitted at a time no later than the transmittal to the Department.

RHA 3.49. Reports of Individual Monitoring.

3.49.1 This section applies to each person licensed by the Department to—

3.49.1.1 Possess or use radioactive material for purposes of industrial radiography pursuant to Part V of these regulation; or

3.49.1.2 Receive radioactive waste from other persons for disposal under Part VII of these regulations; or

3.49.1.3 Possess or use at any time, for processing or manufacturing for distribution pursuant to Parts II or IV, of these regulations, radioactive material in quantities exceeding any one of the following quantities:

Radionuclide	Quantity of Radionuclide [1] in curies
Cesium-137	1

[5] With respect to the limit for the embryo-fetus (RHA 3.12), the identifiers should be those of the declared pregnant woman.

Radionuclide	Quantity of Radionuclide [1] in curies
Cobalt-60	1
Gold-198	100
Iodine-131	1
Iridium-192	10
Krypton-85	1,000
Promethium-147	10
Technetium-99m	1,000

[1] The Department may require as a license condition, or by rule, regulation, or order pursuant to RHA 3.52, reports from licensees who are licensed to use radionuclides not on this list, in quantities sufficient to cause comparable radiation levels.

3.49.2 Each licensee in a category listed in paragraph 3.49.1 of this section shall submit an annual report of the results of individual monitoring carried out by the licensee for each individual for whom monitoring was required by RHA 3.17 during that year. The licensee may include additional data for individuals for whom monitoring was provided but not required. The licensee shall use S.C. Form 5 or electronic media containing all the information required by Form S.C. Form 5.

3.49.3 The licensee shall file the report required by 3.49.2, covering the preceding year, on or before April 30 of each year. The licensee shall submit the report to S.C. Department of Health & Environmental Control, Bureau of Radiological Health, 2600 Bull Street, Columbia, SC, 29201.

RHA 3.50. Applications for Exemptions.

The Department may, upon application by a licensee or upon its own initiative, grant an exemption from the requirements of the regulations in this part if it determines the exemption is authorized by law and would not result in undue hazard to life or property.

RHA 3.51. Additional Requirements.

The Department may, by rule, regulation, or order, impose requirements on a licensee, in addition to those established in the regulations in this part, as it deems appropriate or necessary to protect health or to minimize danger to life or property.

RHA 3.52. [Appendix A] Protection Factors for Respirators.

APPENDIX A-RHA 3.52 PROTECTION FACTORS FOR RESPIRATORS[a]

		Operating Mode	Assigned Protection Factors
I.	Air Purifying Respirators (Particulate[b] only)[c]		
	Filtering facepiece disposable[d]	Negative Pressure	([d])
	Facepiece, half[e]	Negative Pressure	10
	Facepiece, full	Negative Pressure	100
	Facepiece, half	Powered air-purifying respirators	50
	Facepiece, full	Powered air-purifying respirators	1000
	Helmet/hood	Powered air-purifying respirators	1000
	Facepiece, loose-fitting	Powered air-purifying respirators	25
II.	Atmosphere supplying respirators (particulate, gases and vapors[f])		
	1. Air-line respirator:		
	Facepiece, half	Demand	10
	Facepiece, half	Continuous Flow	50
	Facepiece, half	Pressure Demand	50
	Facepiece, full	Demand	100
	Facepiece, full	Continuous Flow	1000
	Facepiece, full	Pressure Demand	1000
	Helmet/hood	Continuous Flow	1000
	Facepiece, loose-fitting	Continuous Flow	25
	Suit	Continuous Flow	([g])
	2. Self-contained breathing Apparatus (SCBA):		

Facepiece, full	Demand	[h]100
Facepiece, full	Pressure Demand	[i]10,000
Facepiece, full Demand,	Recirculating	[h]100
Facepiece, full	Positive Pressure Recirculating	[i]10,000
III. Combination Respirators		
Any combination of air-purifying and atmosphere-supplying respirators	(1) Assigned protection factor for type and mode of operation as listed above.	

[a] These assigned protection factors apply only in a respiratory protection program that meets the requirements of this Part. They are applicable only to airborne radiological hazards and may not be appropriate to circumstances when chemical or other respiratory hazards exist instead of, or in addition to, radioactive hazards. Selection and use of respirators for such circumstances must also comply with Department of Labor regulations.

Radioactive contaminants for which the concentration values in Table 1, Column 3 of Appendix B, RHA 3.53 are based on internal dose due to inhalation may, in addition, present external exposure hazards at higher concentrations. Under these circumstances, limitations on occupancy may have to be governed by external dose limits.

b Air purifying respirators with APF <100 must be equipped with particulate filters that are at least 95 percent efficient. Air purifying respirator's with APF = 100 must be equipped with particulate filters that are at least 99 percent efficient. Air purifying respirators with APFs <100 must be equipped with particulate filters that are at least 99.97 percent efficient.

[c] The licensee may apply to the Department for the use of an APF greater than 1 for sorbent cartridges as protection against airborne radioactive gases and vapors (e.g., radioiodine).

[d] Licensees may permit individuals to use this type of respirator who have not been medically screened or fit tested on the device provided that no credit be taken for their use in estimating intake or dose. It is also recognized that it is difficult to perform an effective positive or negative pressure pre-use user seal check on this type of device. All other respiratory protection program requirements listed in RHA 3.19.3 apply. An assigned protection factor has not been assigned for these devices. However, an APF equal to 10 may be used if the licensee can demonstrate a fit factor of at least 100 by use of a validated or evaluated, qualitative or quantitative fit test.

[e] Under-chin type only. No distinction is made in this Appendix between elastomeric half-masks with replaceable cartridges and those designed with the filter medium as an integral part of the facepiece (e.g., disposable or reusable disposable). Both types are acceptable so long as the seal area of the latter contains some substantial type of seal-enhancing material such as rubber or plastic, the two or more suspension straps are adjustable, the filter medium is at least 95 percent efficient and all other requirements of this Part are met.

[f] The assigned protection factors for gases and vapors are not applicable to radioactive contaminants that present an absorption or submersion hazard. For tritium oxide vapor, approximately one-third of the intake occurs by absorption through the skin so that an overall protection factor of 3 is appropriate when atmosphere-supplying respirators are used to protect against tritium oxide. Exposure to radioactive noble gases is not considered a significant respiratory hazard, and protective actions for these contaminants should be based on external (submersion) dose considerations.

[g] No NIOSH approval schedule is currently available for atmosphere supplying suits. This equipment may be used in an acceptable respiratory protection program as long as all the other minimum program requirements, with the exception of fit testing, are met (i.e., RHA 3.19.3).

[h] The licensee should implement institutional controls to assure that these devices are not used in areas immediately dangerous to life or health (IDLH).

[i] This type of respirator may be used as an emergency device in unknown concentrations for protection against inhalation hazards. External radiation hazards and other limitations to permitted exposure such as skin absorption shall be taken into account in these circumstances. This device may not be used by any individual who experiences perceptible outward leakage of breathing gas while wearing the device.

History: Amended by SCSR 44–11, eff November 27, 2020 (errata).

RHA 3.53. [Appendix B] Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage.

Introduction

For each radionuclide, Table 1 indicates the chemical form which is to be used for selecting the appropriate ALI or DAC value. The ALIs and DACs for inhalation are given for an aerosol with an

activity median aerodynamic diameter (AMAD) of 1 micron and for three classes (D,W,Y) of radioactive material, which refer to their retention (approximately days, weeks or years) in the pulmonary region of the lung. This classification applies to a range of clearance halftimes for 0 of less than 10 days, for W from 10 to 100 days, and for Y greater than 100 days. Table 2 provides concentration limits for airborne and liquid effluents released to the general environment. Table 3 provides concentration limits for discharges to sanitary sewer systems.

Note:

The values in Tables 1, 2, and 3 are presented in the computer "E" notation. In this notation a value of 6E-02 represents a value of 6×10^{-2} or 0.06, 6E+2 represents $6 \times 1O^{2}$ or 600, and 6E+0 represents 6×10^{0} or 6.

Table 1 "Occupational Values"

Note that the columns in Table 1 of this appendix captioned "Oral Ingestion ALI," "Inhalation ALI," and "DAC," are applicable to occupational exposure to radioactive material.

The ALIs in this appendix are the annual intakes of given radionuclide by "Reference Man" which would result in either (1) a committed effective dose equivalent of 5 rems (stochastic ALI) or (2) a committed dose equivalent of 50 rems to an organ or tissue (non-stochastic ALI). The stochastic ALIs were derived to result in a risk, due to irradiation of organs and tissues, comparable to the risk associated with deep dose equivalent to the whole body of 5 rems. The derivation includes multiplying the committed dose equivalent to an organ or tissue by a weighting factor, wT. This weighting factor is the proportion of the risk of stochastic effects resulting from irradiation of the organ or tissue, T, to the total risk of stochastic effects when the whole body is irradiated uniformly. The values of wT are listed under the definition of weighting factor in RHA 3.2. The non-stochastic ALIs were derived to avoid non-stochastic effects, such as prompt damage to tissue or reduction in organ function.

A value of wT = 0.06 is applicable to each of the five organs or tissues in the "remainder" category receiving the highest dose equivalents, and the dose equivalents of all other remaining tissues may be disregarded. The following parts of the GI tract –stomach, small intestine, upper large intestine, and lower large intestine –are to be treated as four separate organs.

Note that the dose equivalents for extremities (hands and forearms, feet and lower legs), skin, and lens of the eye are not considered in computing the committed effective dose equivalent, but are subject to limits that must be met separately.

When an ALI is defined by the stochastic dose limit, this value alone, is given. When an ALI is determined by the non-stochastic dose limit to an organ, the organ or tissue to which the limit applies is shown, and the ALI for the stochastic limit is shown in parentheses. (Abbreviated organ or tissue designations are used: LLI wall = lower large intestine wall; St. wall = stomach wall; Blad wall = bladder wall; and Bone surf = bone surface.)

The use of the ALIs listed first, the more limiting of the stochastic and non-stochastic ALIs, will ensure that non-stochastic effects are avoided and that the risk of stochastic effects is limited to an acceptably low value. If, in a particular situation involving a radionuclide for which the non-stochastic ALI is limiting, use of that non-stochastic ALI is considered unduly conservative, the licensee may use the stochastic ALI to determine the committed effective dose equivalent. However, the licensee shall also ensure that the 50-rem dose equivalent limit for any organ or tissue is not exceeded by the sum of the external deep dose equivalent plus the internal committed dose to that organ (not the effective dose). For the case where there is no external dose contribution, this would be demonstrated if the sum of the fractions of the nonstochastic ALIs (ALIns) that contribute to the committed dose equivalent to the organ receiving the highest dose does not exceed unity (i.e., (intake (in Ci) of each radionuclide/ALIins) 1.0). If there is an external deep dose equivalent contribution of Hd then this sum must be less than 1 -(Hd/50) instead of being 1.0.

Note that the dose equivalents for extremities (hand and forearms, feet and lower legs), skin, and lens of the are are not considered in computing the committed effective dose equivalent, but are subject to limits that must be met separately.

The derived air concentration (DAC) values are derived limits intended to control chronic occupational exposures. The relationship between the DAC and the ALI is given by: DAC = ALI(in Ci)/(2000 hours per working year $\times$ 60 minutes/hour $\times$ 2 $\times$ 10 ml per minute) = [ALI/2.4 $\times$ 10]

Ci/ml, where 2 × 10 ml per minute is the volume of air breathed per minute at work by "Reference Man" under working conditions of "light work."

The DAC values relate to one of two modes of exposure: either external submersion or the internal committed dose equivalents resulting from inhalation of radioactive materials. Derived air concentrations based upon submersion are for immersion in a semi-infinite cloud of uniform concentration and apply to each radionuclide separately.

The ALI and DAC values relate to exposure to the single radionuclide named, but also include contributions from the in-growth of any daughter radionuclide produced in the body by the decay of the parent. However, intakes that include both the parent and daughter radionuclides should be treated by the general method appropriate for mixtures.

The value of ALI and DAC do not apply directly when the individual both ingests and inhales a radionuclide, when the individual is exposed to a mixture of radionuclides by either inhalation or ingestion or both, or when the individual is exposed to both internal and external irradiation (see RHA 3.6). When an individual is exposed to radioactive materials which fall under several of the translocation classifications (i.e., Class D, Class W, or Class Y) of the same radionuclide, the exposure may be evaluated as if it were a mixture of different radionuclides.

It should be noted that the classification of a compound as Class D, W, or Y is based on the chemical form of the compound and does not take into account the radiological half-life of different radioisotopes. For this reason, values are given for Class D, W, and Y compounds, even for very short-lived radionuclides.

Table 2 "Effluent Concentrations"

The columns in Table 2 of this appendix captioned "Effluents," "Air," and "Water," are applicable to the assessment and control of dose to the public, particularly in the implementation of the provisions of RHA 3.14. The concentration values given in Columns 1 and 2 of Table 2 are equivalent to the radionuclide concentrations which, if inhaled or ingested continuously over the course of a year, would produce a total effective dose equivalent of 0.05 rem (50 millirem or 0.5 millisieverts).

Consideration of non-stochastic limits has not been included in deriving the air and water effluent concentration limits because non-stochastic effects are presumed not to occur at the dose levels established for individual members of the public. For radionuclides, where the non-stochastic limit was governing in deriving the occupational DAC, the stochastic ALI was used in deriving the corresponding airborne effluent limit in Table 2. For this reason, the DAC and airborne effluent limits are not always proportional as was the case in Appendix A of Part III of the July 1990 edition of Radioactive Materials Regulation 61-63, Title A.

The air concentration values listed in Table 2, Column 1, were derived by one of two methods. For those radionuclides for which the stochastic limit is governing, the occupational stochastic inhalation ALI was divided by 2.4 × 10, relating the inhalation ALI to the DAC, as explained above, and then divided by a factor of 300. The factor of 300 includes the following components: a factor of 50 to relate the 5-rem annual occupational dose limit to the 0.1-rem limit for members of the public, a factor of 3 to adjust for the difference in exposure time and the inhalation rate for a worker and that for members of the public; and a factor of 2 to adjust the occupational values (derived for adults) so that they are applicable to other age groups.

For those radionuclides for which submersion (external dose) is limiting, the occupational DAC in Table 1, Column 3, was divided by 219. The factor of 219 is composed of a factor of 50, as described above, and a factor of 4.38 relating occupational exposure for 2,000 hours per year to full-time exposure (8,760 hours per year). Note that an additional factor of 2 for age considerations is not warranted in the submersion case.

The water concentrations were derived by taking the most restrictive occupational stochastic oral ingestion ALI and dividing by 7.3 × 10. The factor of 7.3 × 10 (ml) includes the following components: the factors of 50 and 2 described above and a factor of 7.3 × 10 (ml) which is the annual water intake of "Reference Man."

Note 2 of this appendix provides groupings of radionuclides which are applicable to unknown mixtures of radionuclides. These groupings (including occupational inhalation ALIs and DACs, air and water effluent concentrations and sewerage) require demonstrating that the most limiting

radionuclides in successive classes are absent. The limit for the unknown mixture is defined when the presence of the one of the listed radionuclides cannot be definitely excluded as being present either from knowledge of the radionuclide composition of the source or from actual measurements.

Table 3 "Releases to Sewers"

The monthly average concentrations for release to sanitary sewers are applicable to the provisions in RHA 3.29. The concentration values were derived by taking the most restrictive occupational stochastic oral ingestion ALI and dividing by 7.3 × 10(ml). The factor of 7.3 × 10(ml) is composed of a factor of 7.3 × 10(ml), the annual water intake by "Reference Man," and a factor of 10, such that the concentrations, if the sewage released by the licensee were the only source of water ingested by a reference man during a year, would result in a committed effective dose equivalent of 0.5 rem.

List of Elements

Name	Symbol	Atomic No.
Actinium	Ac	89
Aluminium	Al	13
Americium	Am	95
Antimony	Sb	51
Argon	Ar	18
Arsenic	As	33
Astatine	At	85
Barium	Ba	56
Berkelium	Bk	97
Beryllium	Be	4
Bismuth	Bi	83
Bromine	Br	35
Cadmium	Cd	48
Calcium	Ca	20
Californium	Cf	98
Carbon	C	6
Cerium	Ce	58
Cesium	Cs	55
Chlorine	Cl	17
Chromium	Cr	24
Cobalt	Co	27
Copper	Cu	29
Curium	Cm	96
Dysprosium	Dy	66
Einsteinium	Es	99
Erbium	Er	68
Europium	Eu	63
Fermium	Fm	100
Fluorine	F	9
Francium	Fr	87
Gadolinium	Gd	64
Gallium	Ga	31
Germanium	Ge	32
Gold	Au	79
Hafnium	Hf	72
Holmium	Ho	67
Hydrogen	H	1
Indium	In	49
Iodine	I	53
Iridium	Ir	77
Iron	Fe	26
Krypton	Kr	36
Lanthanum	La	57
Lead	Pb	82
Lutetium	Lu	71
Magnesium	Mg	12
Manganese	Mn	25
Mendelevium	Md	101

Name	Symbol	Atomic No.
Mercury	Hg	80
Molybdenum	Mo	42
Neodymium	Nd	60
Neptunium	Np	93
Nickel	Ni	28
Niobium	Nb	41
Nitrogen	N	7
Osmium	Os	76
Oxygen	O	8
Palladium	Pd	46
Phosphorus	P	15
Platinum	Pt	78
Plutonium	Pu	94
Polonium	Po	84
Potassium	K	19
Praseodymium	Pr	59
Promethium	Pm	61
Protactinium	Pa	91
Radium	Ra	88
Radon	Rn	86
Rhenium	Re	75
Rhodium	Rh	45
Rubidium	Rb	37
Ruthenium	Ru	44
Samarium	Sm	62
Scandium	Sc	21
Selenium	Se	34
Silicon	Si	14
Silver	Ag	47
Sodium	Na	11
Strontium	Sr	38
Sulfur	S	16
Tantalum	Ta	73
Technetium	Tc	43
Tellurium	Te	52
Terbium	Tb	65
Thullium	Tl	81
Thorium	Th	90
Thulium	Tm	69
Tin	Sn	50
Titanium	Ti	22
Tungsten	W	74
Uranium	U	92
Vanadium	V	23
Xenon	Xe	54
Ytterbium	Yb	70
Yttrium	Y	39
Zinc	Zn	30
Zirconium	Zr	40

RHA 3.53 [Appendix B] Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage.

		Table 1 Occupational Values			Table 2 Effluent Concentrations		Table 3 Releases to Sewers
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
		Oral Ingestion	Inhalation				Monthly Average
Atomic Radionuclide No.	Class	ALI (uCi)	ALI (uCi)	DAC (uCi/ml)	Air (uCi/ml)	Water (uCi/ml)	Conc. (uCi/ml)
1 Hydrogen-3	Water, DAC includes skin absorption	8E+4	8E+4	2E-5	1E-7	1E-3	1E-2
	Gas (HT or T_2)Submersion[1]: Use above values as HT and T_2 oxidize in air and in the body to HTO.						
4 Beryllium-7	W, all compounds except those given for Y	4E+4	2E+4	9E-6	3E-8	6E-4	6E-3
	Y, oxides, halides, and nitrates -	-	2E+4	8E-6	3E-8	-	-
4 Beryllium-10	W, see ^{7}Be	1E+3	2E+2	6E-8	2E-10	-	-
		LLI wall (1E+3)	-	-	-	2E-5	2E-4
	Y, see ^{7}Be	-	1E+1	6E-9	2E-11	-	-
6 Carbon-11[2]	Monoxide	-	1E+6	5E-4	2E-6	-	-
	Dioxide	-	6E+5	3E-4	9E-7	-	-
	Compounds	4E+5	4E+5	2E-4	6E-7	6E-3	6E-2
6 Carbon-14	Monoxide	-	2E+6	7E-4	2E-6	-	-
	Dioxide	-	2E+5	9E-5	3E-7	-	-
	Compounds	2E+3	2E+3	1E-6	3E-9	3E-5	3E-4
7 Nitrogen-13[2]	Submersion[1]			4E-6	2E-8		
8 Oxygen-15[2]	Submersion[1]			4E-6	2E-8		
9 Fluorine-18[2]	D, fluorides of H, Li, Na, K, Rb, Cs, and Fr	5E+4	7E+4	3E-5	1E-7	-	-
		St. wall (5E+4)	-	-	-	7E-4	7E-3

	W, fluorides of Be, Mg, Ca, Sr, Ba, Ra, Al, Ga, In, Tl, As, Sb, Bi, Fe, Ru, Os, Co, Ni, Pd, Pt, Cu, Ag, Au, Zn, Cd, Hg, Sc, Y, Ti, Zr, V, Nb, Ta, Mn, Tc, and Re	-	9E+4	4E-5	1E-7	-	-
	Y, lanthanum fluoride	-	8E+4	3E-5	1E-7	-	-
11 Sodium-22	D, all compounds	4E+2	6E+2	3E-7	9E-10	6E-6	6E-5
11 Sodium-24	D, all compounds	4E+3	5E+3	2E-6	7E-9	5E-5	5E-4
12 Magnesium-28	D, all compounds except those given for W	7E+2	2E+3	7E-7	2E-9	9E-6	9E-5
	W, oxides, hydroxides, carbides, halides, & nitrates	-	1E+3	5E-7	2E-9	-	-
13 Aluminum-26	D, all compounds except those given for W	4E+2	6E+1	3E-8	9E-11	6E-6	6E-5
	W, oxides, hydroxides, carbides, halides,& nitrates	-	9E+1	4E-8	1E-10	-	-
14 Silicon-31	D, all compounds except those given for W and Y	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3
	W, oxides, hydroxides, carbides, & nitrates	-	3E+4	1E-5	5E-8	-	-
	Y, aluminosilicate glass	-	3E+4	1E-5	4E-8	-	-
14 Silicon-32	D, see ^{31}Si	2E+3	2E+2	1E-7	3E-10	-	-
	LLI wall (3E+3)	-	-	-	4E-5	-	4E-4
	W, see ^{31}Si	-	1E+2	5E-8	2E-10	-	-
	Y, see ^{31}Si	-	5E+0	2E-9	7E-12	-	-

15 Phosphorus-32	D, all compounds except phosphates given for W	6E+2	9E+2	4E-7	1E-9	9E-6	9E-5
	W, phosphates of Zn^{2+}, $S^{3}+$, $Mg^{2}+$, $Fe^{3}+$, $Bi^{3}+$, and lanthanides	-	4E+2	2E-7	5E-10	-	-
15 Phosphorus-33	D, see ^{32}p	6E+3	8E+3	4E-6	1E-8	8E-5	8E-4
	W, see ^{32}p	-	3E+3	1E-6	4E-9	-	-
16 Sulfur-35	Vapor	-	1E+4	6E-6	2E-8	-	-
	D, sulfides and sulfates except those given for W	1E+4	2E+4	7E-6	2E-8	-	-
		LLI wall (8E+3)	-	-	-	1E-4	1E-3
	W, elemental sulfur, sulfides of Sr, Ba, Ge, Sn, Pb, As, Sb, Bi, Cu, Ag, Au, Zn, Cd, Hg, W, and Mo. Sulfates of Ca, Sr, Ba, Ra, As, Sb, and Bi	6E+3 -	2E+3	9E-7	3E-9	-	-
17 Chlorine-36	D, chlorides of H, Li, Na, K, Rb, Cs, and Fr	2E+3	2E+3	1E-6	3E-9	2E-5	2E-4
	W, chlorides of lanthanides, Be, Mg, Ca, Sr, Ba, Ra, Al, Ga, In, Tl, Ge, Sn, Pb, As, Sb, Bi, Fe, Ru, Os, Co, Rh, Ir, Ni, Pd, Pt, Cu, Ag, Au, Zn, Cd, Hg, Sc, Y, Ti, Zr, Hf, V, Nb, Ta, Cr, Mo, W, Mn, Tc, and Re	-	2E+2	1E-7	3E-10	-	-
17 Chlorine-38[2]	D, see ^{36}Cl	2E+4	4E+4	2E-5	6E-8	-	-
		St. wall (3E+4)	-	-	-	3E-4	3E-3
	W, see ^{36}Cl	-	5E+4	2E-5	6E-8	-	-

17 Chlorine-39[2]	D, see ^{36}Cl	2E+4	5E+4	2E-5	7E-8	-	-
		St. wall (4E+4)	-	-	-	5E-4	5E-3
	W, see ^{36}Cl	-	6E+4	2E-5	8E-8	-	-
18 Argon-37	Submersion[1]	-	-	1E+0	6E-3	-	-
18 Argon-39	Submersion[1]	-	-	2E-4	8E-7	-	-
18 Argon-41	Submersion[1]	-	-	3E-6	1E-8	-	-
19 Potassium-40	D, all compounds	3E+2	4E+2	2E-7	6E-10	4E-6	4E-5
19 Potassium-42	D, all compounds	5E+3	5E+3	2E-6	7E-9	6E-5	6E-4
19 Potassium-43	D, all compounds	6E+3	9E+3	4E-6	1E-8	9E-5	9E-4
19 Potassium-44[2]	D, all compounds	2E+4	7E+4	3E-5	9E-8	-	-
		St. wall (4E+4)	-	-	-	5E-4	5E-3
19 Potassium-45[2]	D, all compounds	3E+4	1E+5	5E-5	2E-7	-	-
		St. wall (5E+4)	-	-	-	7E-4	7E-3
20 Calcium-41	W, all compounds	3E+3	4E+3	2E-6	-	-	-
		Bone surf (4E+3)	Bone surf (4E+3)	-	5E-9	6E-5	6E-4
20 Calcium-45	W, all compounds	2E+3	8E+2	4E-7	1E-9	2E-5	2E-4
20 Calcium-47	W, all compounds	8E+2	9E+2	4E-7	1E-9	1E-5	1E-4
21 Scandium-43	Y, all compounds	7E+3	2E+4	9E-6	3E-8	1E-4	1E-3
21 Scandium-44m	Y, all compounds	5E+2	7E+2	3E-7	1E-9	7E-6	7E-5
21 Scandium-44	Y, all compounds	4E+3	1E+4	5E-6	2E-8	5E-5	5E-4
21 Scandium-46	Y, all compounds	9E+2	2E+2	1E-7	3E-10	1E-5	1E-4
21 Scandium-47	Y, all compounds	2E+3	3E+3	1E-6	4E-9	-	-
		LLI wall (3E+3)	-	-	-	4E-5	4E-4
21 Scandium-48	Y, all compounds	8E+2	1E+3	6E-7	2E-9	1E-5	1E-4
21 Scandium-49[2]	Y, all compounds	2E+4	5E+4	2E-5	8E-8	3E-4	3E-3

22 Titanium-44	D, all compounds except those given for W and Y	3E+2	1E+1	5E-9	2E-11	4E-6	4E-5
	W, oxides, hydroxides, carbides, halides, & nitrates	-	3E+1	1E-8	4E-11	-	-
	Y, $SrTi0_3$	-	6E+0	2E-9	8E-12	-	-
22 Titanium-45	D, see ^{44}Ti	9E+3	3E+4	1E-5	3E-8	1E-4	1E-3
	W, see ^{44}Ti	-	4E+4	1E-5	5E-8	-	-
	Y, see ^{44}Ti	-	3E+4	1E-5	4E-8	-	-
23 Vanadium-47[2]	D, all compounds except those given for W	3E+4	8E+4	3E-5	1E-7	-	-
		St. wall (3E+4)	-	-	-	4E-4	4E-3
	W, oxides, hydroxides, carbides, and halides	-	1E+5	4E-5	1E-7	-	-
23 Vanadium-48	D, see ^{47}V	6E+2	1E+3	5E-7	2E-9	9E-6	9E-5
	W, see ^{47}V	-	6E+2	3E-7	9E-10	-	-
23 Vanadium-49	D, see ^{47}V	7E+4	3E+4	1E-5	-	-	-
		LLI wall (9E+4)	Bone surf (3E+4)	-	5E-8	1E-3	1E-2
	W, see ^{47}V	-	2E+4	8E-6	2E-8	-	-
24 Chromium-48	D, all compounds except those given for W and Y	6E+3	1E+4	5E-6	2E-8	8E-5	8E-4
	W, halides and nitrates	-	7E+3	3E-6	1E-8	-	-
	Y, oxides and hydroxides	-	7E+3	3E-6	1E-8	-	-
24 Chromium-49[2]	D, see ^{48}Cr	3E+4	8E+4	4E-5	1E-7	4E-4	4E-3
	W, see ^{48}Cr	-	1E+5	4E-5	1E-7	-	-
	Y, see ^{48}Cr	-	9E+4	4E-5	1E-7	-	-
24 Chromium-51	D, see ^{48}Cr	4E+4	5E+4	2E-5	6E-8	5E-4	5E-3

	W, see ^{48}Cr	-	2E+4	1E-5	3E-8	-	-
	Y, see ^{48}Cr	-	2E+4	8E-6	3E-8	-	-
25 Manganese-51[2]	D, all compounds except those given for W,	2E+4	5E+4	2E-5	7E-8	3E-4	3E-3
	W, oxides, hydroxides, halides, & nitrates	-	6E+4	3E-5	8E-8	-	-
25 Manganese-52m[2]	D, see ^{51}Mn	3E+4	9E+4	4E-5	1E-7	-	-
		St. wall (4E+4)	-	-	-	5E-4	5E-3
	W, see ^{51}Mn	-	1E+5	4E-5	1E-7	-	-
25 Manganese-52	D, see ^{51}Mn	7E+2	1E+3	5E-7	2E-9	1E-5	1E-4
	W, see ^{51}Mn	-	9E+2	4E-7	1E-9	-	-
25 Manganese-53	D, see ^{51}Mn	5E+4	1E+4	5E-6	-	7E-4	7E-3
		-	Bone surf (2E+4)	-	3E-8	-	-
	W, see ^{51}Mn	-	1E+4	5E-6	2E-8	-	-
25 Manganese-54	D, see ^{51}Mn	2E+3	9E+2	4E-7	1E-9	3E-5	3E-4
	W, see ^{51}Mn	-	8E+2	3E-7	1E-9	-	-
25 Manganese-56	D, see ^{51}Mn	5E+3	2E+4	6E-6	2E-8	7E-5	7E-4
	W, see ^{51}Mn	-	2E+4	9E-6	3E-8	-	-
26 Iron-52	D, all compounds except those given for W	9E+2	3E+3	1E-6	4E-9	1E-5	1E-4
	W, oxides, hydroxides, and halides	-	2E+3	1E-6	3E-9	-	-
26 Iron-55	D, see ^{52}Fe	9E+3	2E+3	8E-7	3E-9	1E-4	1E-3
	W, see ^{52}Fe	-	4E+3	2E-6	6E-9	-	-
26 Iron-59	D, see ^{52}Fe	8E+2	3E+2	1E-7	5E-10	1E-5	1E-4
	W, see ^{52}Fe	-	5E+2	2E-7	7E-10	-	-
26 Iron-60	D, see ^{52}Fe	3E+1	6E+0	3E-9	9E-12	4E-7	4E-6
	W, see ^{52}Fe	-	2E+1	8E-9	3E-11	-	-
27 Cobalt-55	W, all compounds except those						

	given for Y	1E+3	3E+3	1E-6	4E-9	2E-5	2E-4
	Y, oxides, hydroxides, halides, and nitrates	-	3E+3	1E-6	4E-9	-	-
27 Cobalt-56	W, see ^{55}Co	5E+2	3E+2	1E-7	4E-10	6E-6	6E-5
	Y, see ^{55}Co	4E+2	2E+2	8E-8	3E-10	-	-
27 Cobalt-57	W, see ^{55}Co	8E+3	3E+3	1E-6	4E-9	6E-5	6E-4
	Y, see ^{55}Co	4E+3	7E+2	3E-7	9E-10	-	-
27 Cobalt-58m	W, see ^{55}Co	6E+4	9E+4	4E-5	1E-7	8E-4	8E-3
	Y, see ^{55}Co	-	6E+4	3E-5	9E-8	-	-
27 Cobalt-58	W, see ^{55}Co	2E+3	1E+3	5E-7	2E-9	2E-5	2E-4
	Y, see ^{55}Co	1E+3	7E+2	3E-7	1E-9	-	-
27 Cobalt-60m[2]	W, see ^{55}Co	1E+6	4E+6	2E-3	6E-6	-	-
		St. wall (1E+6)	-	-	-	2E-2	2E-1
	Y, see ^{55}Co	-	3E+6	1E-3	4E-6	-	-
27 Cobalt-60	W, see ^{55}Co	5E+2	2E+2	7E-8	2E-10	3E-6	3E-5
	Y, see ^{55}Co	2E+2	3E+1	1E-8	5E-11	-	-
27 Cobalt-61[2]	W, see ^{55}Co	2E+4	6E+4	3E-5	9E-8	3E-4	3E-3
	Y, see ^{55}Co	2E+4	6E+4	2E-5	8E-8	-	-
27 Cobalt-62m[2]	W, see ^{55}Co	4E+4	2E+5	7E-5	2E-7	-	-
		St. wall (5E+4)	-	-	-	7E-4	7E-3
	Y, see ^{55}Co	-	2E+5	6E-5	2E-7	-	-
28 Nickel-56	D, all compounds except those given for W	1E+3	2E+3	8E-7	3E-9	2E-5	2E-4
	W, oxides, hydroxides and carbides	-	1E+3	5E-7	2E-9	-	-
	Vapor	-	1E+3	5E-7	2E-9	-	-
28 Nickel-57	D, see ^{56}Ni	2E+3	5E+3	2E-6	7E-9	2E-5	2E-4
	W, see ^{56}Ni	-	3E+3	1E-6	4E-9	-	-
	Vapor	-	6E+3	3E-6	9E-9	-	-
28 Nickel-59	D, see ^{56}Ni	2E+4	4E+3	2E-6	5E-9	3E-4	3E-3
	W, see ^{56}Ni	-	7E+3	3E-6	1E-8	-	-
	Vapor	-	2E+3	8E-7	3E-9	-	-

28 Nickel-63	D, see ^{56}Ni	9E+3	2E+3	7E-7	2E-9	1E-4	1E-3
	W, see ^{56}Ni	-	3E+3	1E-6	4E-9	-	-
	Vapor	-	8E+2	3E-7	1E-9	-	-
28 Nickel-65	D, see ^{56}Ni	8E+3	2E+4	1E-5	3E-8	1E-4	1E-3
	W, see ^{56}Ni	-	3E+4	1E-5	4E-8	-	-
	Vapor	-	2E+4	7E-6	2E-8	-	-
28 Nickel-66	D, see ^{56}Ni	4E+2	2E+3	7E-7	2E-9	-	-
		LLI wall (5E+2)	-	-	-	6E-6	6E-5
	W, see ^{56}Ni	-	6E+2	3E-7	9E-10	-	-
	Vapor	-	3E+3	1E-6	4E-9	-	-
29 Copper-60[2]	D, all compounds except those given for W and Y	3E+4	9E+4	4E-5	1E-7	-	-
		St. wall (3E+4)	-	-	-	4E-4	4E-3
	W, sulfides, halides and nitrates	-	1E+5	5E-5	2E-7	-	-
	Y, oxides and hydroxides	-	1E+5	4E-5	1E-7	-	-
29 Copper-61	D, see ^{60}Cu	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
	W, see ^{60}Cu	-	4E+4	2E-5	6E-8	-	-
	Y, see ^{60}Cu	-	4E+4	1E-5	5E-8	-	-
29 Copper-64	D, see ^{60}Cu	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
	W, see ^{60}Cu	-	2E+4	1E-5	3E-8	-	-
	Y, see ^{60}Cu	-	2E+4	9E-6	3E-8	-	-
29 Copper-67	D, see ^{60}Cu	5E+3	8E+3	3E-6	1E-8	6E-5	6E-4
	W, see ^{60}Cu	-	5E+3	2E-6	7E-9	-	-
	Y, see ^{60}Cu	-	5E+3	2E-6	6E-9	-	-
30 Zinc-62	Y, all compounds	1E+3	3E+3	1E-6	4E-9	2E-5	2E-4
30 Zinc-63[2]	Y, all compounds	2E+4	7E+4	3E-5	9E-8	-	-
		St. wall (3E+4)	-	-	-	3E-4	3E-3
30 Zinc-65	Y, all compounds	4E+2	3E+2	1E-7	4E-10	5E-6	5E-5

30 Zinc-69m	Y, all compounds	4E+3	7E+3	3E-6	1E-8	6E-5	6E-4
30 Zinc-69[2]	Y, all compounds	6E+4	1E+5	6E-5	2E-7	8E-4	8E-3
30 Zinc-71m	Y, all compounds	6E+3	2E+4	7E-6	2E-8	8E-5	8E-4
30 Zinc-72	Y, all compounds	1E+3	1E+3	5E-7	2E-9	1E-5	1E-4
31 Gallium-65[2]	D, all compounds except those given for W	5E+4	2E+5	7E-5	2E-7	-	-
		St. wall (6E+4)	-	-	-	9E-4	9E-3
	W, oxides, hydroxides, carbides, halides, and nitrates	-	2E+5	8E-5	3E-7	-	-
31 Gallium-66	D, see ^{65}Ga	1E+3	4E+3	1E-6	5E-9	1E-5	1E-4
	W, see ^{65}Ga	-	3E+3	1E-6	4E-9	-	-
31 Gallium-67	D, see ^{65}Ga	7E+3	1E+4	6E-6	2E-8	1E-4	1E-3
	W, see ^{65}Ga	-	1E+4	4E-6	1E-8	-	-
31 Gallium-68[2]	D, see ^{65}Ga	2E+4	4E+4	2E-5	6E-8	2E-4	2E-3
	W, see ^{65}Ga	-	5E+4	2E-5	7E-8	-	-
31 Gallium-70[2]	D, see ^{65}Ga	5E+4	2E+5	7E-5	2E-7	-	-
		St. wall (7E+4)	-	-	-	1E-3	1E-2
	W, see ^{65}Ga	-	2E+5	8E-5	3E-7	-	-
31 Gallium-72	D, see ^{65}Ga	1E+3	4E+3	1E-6	5E-9	2E-5	2E-4
	W, see ^{65}Ga	-	3E+3	1E-6	4E-9	-	-
31 Gallium-73	D, see ^{65}Ga	5E+3	2E+4	6E-6	2E-8	7E-5	7E-4
	W, see ^{65}Ga	-	2E+4	6E-6	2E-8	-	-
32 Germanium-66	D, all compounds except those given for W	2E+4	3E+4	1E-5	4E-8	3E-4	3E-3
	W, oxides, sulfides, and halides	-	2E+4	8E-6	3E-8	-	-
32 Germanium-67[2]	D, see ^{66}Ge	3E+4	9E+4	4E-5	1E-7	-	-
		St. wall (4E+4)	-	-	-	6E-4	6E-3

	W, see ^{66}Ge	-	1E+5	4E-5	1E-7	-	-
32 Germanium-68	D, see ^{66}Ge	5E+3	4E+3	2E-6	5E-9	6E-5	6E-4
	W, see ^{66}Ge	-	1E+2	4E-8	1E-10	-	-
32 Germanium-69	D, see ^{66}Ge	1E+4	2E+4	6E-6	2E-8	2E-4	2E-3
	W, see ^{66}Ge	-	8E+3	3E-6	1E-8	-	-
32 Germanium-71	D, see ^{66}Ge	5E+5	4E+5	2E-4	6E-7	7E-3	7E-2
	W, see ^{66}Ge	-	4E+4	2E-5	6E-8	-	-
32 Germanium-75[2]	D, see ^{66}Ge	4E+4	8E+4	3E-5	1E-7	-	-
		St. wall (7E+4)	-	-	-	9E-4	9E-3
	W, see ^{66}Ge	-	8E+4	4E-5	1E-7	-	-
32 Germanium-77	D, see ^{66}Ge	9E+3	1E+4	4E-6	1E-8	1E-4	1E-3
	W, see ^{66}Ge	-	6E+3	2E-6	8E-9	-	-
32 Germanium-78[2]	D, see ^{66}Ge	2E+4	2E+4	9E-6	3E-8	-	-
		St. wall (2E+4)	-	-	-	3E-4	3E-3
	W, see ^{66}Ge	-	2E+4	9E-6	3E-8	-	-
33 Arsenic-69[2]	W, all compounds	3E+4	1E+5	5E-5	2E-7	-	-
		St. wall (4E+4)	-	-	-	6E-4	6E-3
33 Arsenic-70[2]	W, all compounds	1E+4	5E+4	2E-5	7E-8	2E-4	2E-3
33 Arsenic-71	W, all compounds	4E+3	5E+3	2E-6	6E-9	5E-5	5E-4
33 Arsenic-72	W, all compounds	9E+2	1E+3	6E-7	2E-9	1E-5	1E-4
33 Arsenic-73	W, all compounds	8E+3	2E+3	7E-7	2E-9	1E-4	1E-3
33 Arsenic-74	W, all compounds	1E+3	8E+2	3E-7	1E-9	2E-5	2E-4
33 Arsenic-76	W, all compounds	1E+3	1E+3	6E-7	2E-9	1E-5	1E-4
33 Arsenic-77	W, all compounds	4E+3	5E+3	2E-6	7E-9	-	-
		LLI wall (5E+3)	-	-	-	6E-5	6E-4
33 Arsenic-78[2]	W, all compounds	8E+3	2E+4	9E-6	3E-8	1E-4	1E-3

34 Selenium-70[2]	D, all compounds except those given for W	2E+4	4E+4	2E-5	5E-8	1E-4	1E-3
	W, oxides, hydroxides, carbides, and elemental Se	1E+4	4E+4	2E-5	6E-8	-	-
34 Selenium-73m[2]	D, see ^{70}Se	6E+4	2E+5	6E-5	2E-7	4E-4	4E-3
	W, see ^{70}Se	3E+4	1E+5	6E-5	2E-7	-	-
34 Selenium-73	D, see ^{70}Se	3E+3	1E+4	5E-6	2E-8	4E-5	4E-4
	W, see ^{70}Se	-	2E+4	7E-6	2E-8	-	-
34 Selenium-75	D, see ^{70}Se	5E+2	7E+2	3E-7	1E-9	7E-6	7E-5
	W, see ^{70}Se	-	6E+2	3E-7	8E-10	-	-
34 Selenium-79	D, see ^{70}Se	6E+2	8E+2	3E-7	1E-9	8E-6	8E-5
	W, see ^{70}Se	-	6E+2	2E-7	8E-10	-	-
34 Selenium-81m[2]	D, see ^{70}Se	4E+4	7E+4	3E-5	9E-8	3E-4	3E-3
	W, see ^{70}Se	2E+4	7E+4	3E-5	1E-7	-	-
34 Selenium-81[2]	D, see ^{70}Se	6E+4	2E+5	9E-5	3E-7	-	-
		St. wall (8E+4)	-	-	-	1E-3	1E-2
	W, see ^{70}Se	-	2E+5	1E-4	3E-7	-	-
34 Selenium-83[2]	D, see ^{70}Se	4E+4	1E+5	5E-5	2E-7	4E-4	4E-3
	W, see ^{70}Se	3E+4	1E+5	5E-5	2E-7	-	-
35 Bromine-74m[2]	D, bromides of H, Li, Na, K, Rb, Cs, and Fr	1E+4	4E+4	2E-5	5E-8	-	-
		St. wall (2E+4)	-	-	-	3E-4	3E-3
	W, bromides of lanthanides, Be, Mg, Ca, Sr, Ba, Ra, Al, Ga, In, Tl, Ge, Sn, Pb, As, Sb, Bi, Fe, Ru, Os, Co, Rh, Ir, Ni, Pd, Pt, Cu, Ag, Au, Zn, Cd, Hg, Sc, Y, Ti, Zr, Hf, V, Nb, Ta, Mn, Tc, and Re	-	4E+4	2E-5	6E-8	-	-
35 Bromine-74[2]	D, see ^{74}mBr	2E+4	7E+4	3E-5	1E-7	-	-

		St. wall (4E+4)	-	-	-	5E-4	5E-3
	W, see ^{74}mBr	-	8E+4	4E-5	1E-7	-	-
35 Bromine-75[2]	D, see ^{74}mBr	3E+4	5E+4	2E-5	7E-8	-	-
		St. wall (4E+4)	-	-	-	5E-4	5E-3
	W, see ^{74}mBr	-	5E+4	2E-5	7E-8	-	-
35 Bromine-76	D, see ^{74}mBr	4E+3	5E+3	2E-6	7E-9	5E-5	5E-4
	W, see ^{74}mBr	-	4E+3	2E-6	6E-9	-	-
35 Bromine-77	D, see ^{74}mBr	2E+4	2E+4	1E-5	3E-8	2E-4	2E-3
	W, see ^{74}mBr	-	2E+4	8E-6	3E-8	-	-
35 Bromine-80m	D, see ^{74}mBr	2E+4	2E+4	7E-6	2E-8	3E-4	3E-3
	W, see ^{74}mBr	-	1E+4	6E-6	2E-8	-	-
35 Bromine-80[2]	D, see ^{74}mBr	5E+4	2E+5	8E-5	3E-7	-	-
		St. wall (9E+4)	-	-	-	1E-3	1E-2
	W, see ^{74}mBr	-	2E+5	9E-5	3E-7	-	-
35 Bromine-82	D, see ^{74}mBr	3E+3	4E+3	2E-6	6E-9	4E-5	4E-4
	W, see ^{74}mBr	-	4E+3	2E-6	5E-9	-	-
35 Bromine-83	D, see ^{74}mBr	5E+4	6E+4	3E-5	9E-8	-	-
		St. wall (7E+4)	-	-	-	9E-4	9E-3
	W, see ^{74}mBr	-	6E+4	3E-5	9E-8	-	-
35 Bromine-84[2]	D, see ^{74}mBr	2E+4	6E+4	2E-5	8E-8	-	-
		St. wall (3E+4)	-	-	-	4E-4	4E-3
	W, see ^{74}mBr	-	6E+4	3E-5	9E-8	-	-
36 Krypton-74[2]	Submersion[1]	-	-	3E-6	1E-8	-	-
36 Krypton-76	Submersion[1]	-	-	9E-6	4E-8	-	-
36 Krypton-77[2]	Submersion[1]	-	-	4E-6	2E-8	-	-
36 Krypton-79	Submersion[1]	-	-	2E-5	7E-8	-	-

36 Krypton-81	Submersion[1]	-	-	7E-4	3E-6	-	-
36 Krypton-83m[2]	Submersion[1]	-	-	1E-2	5E-5	-	-
36 Krypton-85m	Submersion[1]	-	-	2E-5	1E-7	-	-
36 Krypton-85	Submersion[1]	-	-	1E-4	7E-7	-	-
36 Krypton-87[2]	Submersion[1]	-	-	5E-6	2E-8	-	-
36 Krypton-88	Submersion[1]	-	-	2E-6	9E-9	-	-
37 Rubidium-79[2]	D, all compounds	4E+4	1E+5	5E-5	2E-7	-	-
		St. wall (6E+4)	-	-	-	8E-4	8E-3
37 Rubidium-81m[2]	D, all compounds	2E+5	3E+5	1E-4	5E-7	-	-
		St. wall (3E+5)	-	-	-	4E-3	4E-2
37 Rubidium-81	D, all compounds	4E+4	5E+4	2E-5	7E-8	5E-4	5E-3
37 Rubidium-82m	D, all compounds	1E+4	2E+4	7E-6	2E-8	2E-4	2E-3
37 Rubidium-83	D, all compounds	6E+2	1E+3	4E-7	1E-9	9E-6	9E-5
37 Rubidium-84	D, all compounds	5E+2	8E+2	3E-7	1E-9	7E-6	7E-5
37 Rubidium-86	D, all compounds	5E+2	8E+2	3E-7	1E-9	7E-6	7E-5
37 Rubidium-87	D, all compounds	1E+3	2E+3	6E-7	2E-9	1E-5	1E-4
37 Rubidium-88[2]	D, all compounds	2E+4	6E+4	3E-5	9E-8	-	-
		St. wall (3E+4)	-	-	-	4E-4	4E-3
37 Rubidium-89[2]	D, all compounds	4E+4	1E+5	6E-5	2E-7	-	-
		St. wall (6E+4)	-	-	-	9E-4	9E-3
38 Strontium-80[2]	D, all soluble compounds except $SrTi0_3$	4E+3	1E+4	5E-6	2E-8	6E-5	6E-4
	Y, all insoluble compounds and $SrTi0_3$	-	1E+4	5E-6	2E-8	-	-
38 Strontium-81[2]	D, see ^{80}Sr	3E+4	8E+4	3E-5	1E-7	3E-4	3E-3
	Y, see ^{80}Sr	2E+4	8E+4	3E-5	1E-7	-	-

38 Strontium-82	D, see ^{80}Sr	3E+2	4E+2	2E-7	6E-10	-	-
		LLI wall (2E+2)	-	-	-	3E-6	3E-5
	Y, see ^{80}Sr	2E+2	9E+1	4E-8	1E-10	-	-
38 Strontium-83	D, see ^{80}Sr	3E+3	7E+3	3E-6	1E-8	3E-5	3E-4
	Y, see ^{80}Sr	2E+3	4E+3	1E-6	5E-9	-	-
38 Strontium-85m[2]	D, see ^{80}Sr	2E+5	6E+5	3E-4	9E-7	3E-3	3E-2
	Y, see ^{80}Sr	-	8E+5	4E-4	1E-6	-	-
38 Strontium-85	D, see ^{80}Sr	3E+3	3E+3	1E-6	4E-9	4E-5	4E-4
	Y, see ^{80}Sr	-	2E+3	6E-7	2E-9	-	-
38 Strontium-87m	D, see ^{80}Sr	5E+4	1E+5	5E-5	2E-7	6E-4	6E-3
	Y, see ^{80}Sr	4E+4	2E+5	6E-5	2E-7	-	-
38 Strontium-89	D, see ^{80}Sr	6E+2	8E+2	4E-7	1E-9	-	-
		LLI wall (6E+2)	-	-	-	8E-6	8E-5
	Y, see ^{80}Sr	5E+2	1E+2	6E-8	2E-10	-	-
38 Strontium-90	D, see ^{80}Sr	3E+1	2E+1	8E-9	-	-	-
		Bone surf (4E+1)	Bone surf (2E+1)	-	3E-11	5E-7	5E-6
	Y, see ^{80}Sr	-	4E+0	2E-9	6E-12	-	-
38 Strontium-91	D, see ^{80}Sr	2E+3	6E+3	2E-6	8E-9	2E-5	2E-4
	Y, see ^{80}Sr	-	4E+3	1E-6	5E-9	-	-
38 Strontium-92	D, see ^{80}Sr	3E+3	9E+3	4E-6	1E-8	4E-5	4E-4
	Y, see ^{80}Sr	-	7E+3	3E-6	9E-9	-	-
39 Yttrium-86m[2]	W, all compounds except those given for Y	2E+4	6E+4	2E-5	8E-8	3E-4	3E-3
	Y, oxides and hydroxides	-	5E+4	2E-5	8E-8	-	-
39 Yttrium-86	W, see ^{86m}Y	1E+3	3E+3	1E-6	5E-9	2E-5	2E-4
	Y, see ^{86m}Y	-	3E+3	1E-6	5E-9	-	-
39 Yttrium-87	W, see ^{86m}Y	2E+3	3E+3	1E-6	5E-9	3E-5	3E-4

	Y, see ^{86m}Y	-	3E+3	1E-6	5E-9	-	-
39 Yttrium-88	W, see ^{86m}Y	1E+3	3E+2	1E-7	3E-10	1E-5	1E-4
	Y, see ^{86m}Y	-	2E+2	1E-7	3E-10	-	-
39 Yttrium-90m	W, see ^{86m}Y	8E+3	1E+4	5E-6	2E-8	1E-4	1E-3
	Y, see ^{86m}Y	-	1E+4	5E-6	2E-8	-	-
39 Yttrium-90	W, see ^{86m}Y	4E+2	7E+2	3E-7	9E-10	-	-
		LLI wall (5E+2)	-	-	-	7E-6	7E-5
	Y, see ^{86m}Y	-	6E+2	3E-7	9E-10	-	-
39 Yttrium-91m[2]	W, see ^{86m}Y	1E+5	2E+5	1E-4	3E-7	2E-3	2E-2
	Y, see ^{86m}Y	-	2E+5	7E-5	2E-7	-	-
39 Yttrium-91	W, see ^{86m}Y	5E+2	2E+2	7E-8	2E-10	-	-
		LLI wall (6E+2)	-	-	-	8E-6	8E-5
	Y, see ^{86m}Y	-	1E+2	5E-8	2E-10	-	-
39 Yttrium-92	W, see ^{86m}Y	3E+3	9E+3	4E-6	1E-8	4E-5	4E-4
	Y, see ^{86m}Y	-	8E+3	3E-6	1E-8	-	-
39 Yttrium-93	W, see ^{86m}Y	1E+3	3E+3	1E-6	4E-9	2E-5	2E-4
	Y, see ^{86m}Y	-	2E+3	1E-6	3E-9	-	-
39 Yttrium-94[2]	W, see ^{86m}Y	2E+4	8E+4	3E-5	1E-7	-	-
		St. wall (3E+4)	-	-	-	4E-4	4E-3
	Y, see ^{86m}Y	-	8E+4	3E-5	1E-7	-	-
39 Yttrium-95[2]	W, see ^{86m}Y	4E+4	2E+5	6E-5	2E-7	-	-
		St. wall (5E+4)	-	-	-	7E-4	7E-3
	Y, see ^{86m}Y	-	1E+5	6E-5	2E-7	-	-
40 Zirconium-86	D, all compounds except those given for W and Y	1E+3	4E+3	2E-6	6E-9	2E-5	2E-4
	W, oxides, hydroxides, halides, and nitrates	-	3E+3	1E-6	4E-9	-	-

	Y, carbide	-	2E+3	1E-6	3E-9	-	-
40 Zirconium-88	D, see ^{86}Zr	4E+3	2E+2	9E-8	3E-10	5E-5	5E-4
	W, see ^{86}Zr	-	5E+2	2E-7	7E-10	-	-
	Y, see ^{86}Zr	-	3E+2	1E-7	4E-10-		-
40 Zirconium-89	D, see ^{86}Zr	2E+3	4E+3	1E-6	5E-9	2E-5	2E-4
	W, see ^{86}Zr	-	2E+3	1E-6	3E-9	-	-
	Y, see ^{86}Zr	-	2E+3	1E-6	3E-9	-	-
40 Zirconium-93	D, see ^{86}Zr	1E+3	6E+0	3E-9	-	-	-
		Bone surf	Bone surf				
		(3E+3)	(2E+1)	-	2E-11	4E-5	4E-4
	W, see ^{86}Zr	-	2E+1	1E-8	-	-	-
			Bone surf				
		-	(6E+1)	-	9E-11	-	-
	Y, see ^{86}Zr	-	6E+1	2E-8	-	-	-
			Bone surf				
		-	(7E+1)	-	9E-11	-	-
40 Zirconium-95	D, see ^{86}Zr	1E+3	1E+2	5E-8	-	2E-5	2E-4
			Bone surf				
		-	(3E+2)	-	4E-10	-	-
	W, see ^{86}Zr	-	4E+2	2E-7	5E-10	-	-
	Y, see ^{86}Zr	-	3E+2	1E-7	4E-10	-	-
40 Zirconium-97	D, see ^{86}Zr	6E+2	2E+3	8E-7	3E-9	9E-6	9E-5
	W, see ^{86}Zr	-	1E+3	6E-7	2E-9	-	-
	Y, see ^{86}Zr	-	1E+3	5E-7	2E-9	-	-
41 Niobium-88[2]	W, all compounds except those given for Y	5E+4	2E+5	9E-5	3E-7	-	-
		St. wall					
		(7E+4)	-	-	-	1E-3	1E-2
	Y, oxides and hydroxides	-	2E+5	9E-5	3E-7	-	-
41 Niobium-89m[2]	W, see ^{88}Nb	1E+4	4E+4	2E-5	6E-8	1E-4	1E-3
(66 min)	Y, see ^{88}Nb	-	4E+4	2E-5	5E-8	-	-

41 Niobium-89	W, see ^{88}Nb	5E+3	2E+4	8E-6	3E-8	7E-5	7E-4
(122 min)	Y, see ^{88}Nb	-	2E+4	6E-6	2E-8	-	-
41 Niobium-90	W, see ^{88}Nb	1E+3	3E+3	1E-6	4E-9	1E-5	1E-4
	Y, see ^{88}Nb	-	2E+3	1E-6	3E-9	-	-
41 Niobium-93m	W, see ^{88}Nb	9E+3	2E+3	8E-7	3E-9	-	-
		LLI wall (1E+4)	-	-	-	2E-4	2E-3
	Y, see ^{88}Nb	-	2E+2	7E-8	2E-10	-	-
41 Niobium-94	W, see ^{88}Nb	9E+2	2E+2	8E-8	3E-10	1E-5	1E-4
	Y, see ^{88}Nb	-	2E+1	6E-9	2E-11	-	-
41 Niobium-95m	W, see ^{88}Nb	2E+3	3E+3	1E-6	4E-9	-	-
		LLI wall (2E+3)	-	-	-	3E-5	3E-4
	Y, see ^{88}Nb	-	2E+3	9E-7	3E-9	-	-
41 Niobium-95	W, see ^{88}Nb	2E+3	1E+3	5E-7	2E-9	3E-5	3E-4
	Y, see ^{88}Nb	-	1E+3	5E-7	2E-9	-	-
41 Niobium-96	W, see ^{88}Nb	1E+3	3E+3	1E-6	4E-9	2E-5	2E-4
	Y, see ^{88}Nb	-	2E+3	1E-6	3E-9	-	-
41 Niobium-97[2]	W, see ^{88}Nb	2E+4	8E+4	3E-5	1E-7	3E-4	3E-3
	Y, see ^{88}Nb	-	7E+4	3E-5	1E-7	-	-
41 Niobium-98[2]	W, see ^{88}Nb	1E+4	5E+4	2E-5	8E-8	2E-4	2E-3
	Y, see ^{88}Nb	-	5E+4	2E-5	7E-8	-	-
42 Molybdenum-90	D all compounds except those given for Y	4E+3	7E+3	3E-6	1E-8	3E-5	3E-4
	Y, oxides, hydroxides, and MoS_2	2E+3	5E+3	2E-6	6E-9	-	-
42 Molybdenum-93m	D, see ^{90}Mo	9E+3	2E+4	7E-6	2E-8	6E-5	6E-4
	Y, see ^{90}Mo	4E+3	1E+4	6E-6	2E-8	-	-
42 Molybdenum-93	D, see ^{90}Mo	4E+3	5E+3	2E-6	8E-9	5E-5	5E-4
	Y, see ^{90}Mo	2E+4	2E+2	8E-8	2E-10	-	-
42 Molybdenum-99	D, see ^{90}Mo	2E+3	3E+3	1E-6	4E-9	-	-

		LLI wall (1E+3)	-	-	-	2E-5	2E-4
	Y, see ^{90}Mo	1E+3	1E+3	6E-7	2E-9	-	-
42 Molybdenum-101[2]	D, see ^{90}Mo	4E+4	1E+5	6E-5	2E-7	-	-
		St. wall (5E+4)	-	-	-	7E-4	7E-3
	Y, see ^{90}Mo	-	1E+5	6E-5	2E-7	-	-
43 Technetium-93m[2]	D, all compounds except those given for W	7E+4	2E+5	6E-5	2E-7	1E-3	1E-2
	W, oxides, hydroxides, halides, and nitrates	-	3E+5	1E-4	4E-7	-	-
43 Technetium-93	D, see ^{93m}Tc	3E+4	7E+4	3E-5	1E-7	4E-4	4E-3
	W, see ^{93m}Tc	-	1E+5	4E-5	1E-7	-	-
43 Technetium-94m[2]	D, see ^{93m}Tc	2E+4	4E+4	2E-5	6E-8	3E-4	3E-3
	W, see ^{93m}Tc	-	6E+4	2E-5	8E-8	-	-
43 Technetium-94	D, see ^{93m}Tc	9E+3	2E+4	8E-6	3E-8	1E-4	1E-3
	W, see ^{93m}Tc	-	2E+4	1E-5	3E-8	-	-
43 Technetium-95m	D, see ^{93m}Tc	4E+3	5E+3	2E-6	8E-9	5E-5	5E-4
	W, see ^{93m}Tc	-	2E+3	8E-7	3E-9	-	-
43 Technetium-95	D, see ^{93m}Tc	1E+4	2E+4	9E-6	3E-8	1E-4	1E-3
	W, see ^{93m}Tc	-	2E+4	8E-6	3E-8	-	-
43 Technetium-96m[2]	D, see ^{93m}Tc	2E+5	3E+5	1E-4	4E-7	2E-3	2E-2
	W, see ^{93m}Tc	-	2E+5	1E-4	3E-7	-	-
43 Technetium-96	D, see ^{93m}Tc	2E+3	3E+3	1E-6	5E-9	3E-5	3E-4
	W, see ^{93m}Tc	-	2E+3	9E-7	3E-9	-	-
43 Technetium-97m	D, see ^{93m}Tc	5E+3	7E+3	3E-6	-	6E-5	6E-4
		-	St. wall (7E+3)	-	1E-8	-	-
	W, see ^{93m}Tc	-	1E+3	5E-7	2E-9	-	-
43 Technetium-97	D, see ^{93m}Tc	4E+4	5E+4	2E-5	7E-8	5E-4	5E-3
	W, see ^{93m}Tc	-	6E+3	2E-6	8E-9	-	-
43 Technetium-98	D, see ^{93m}Tc	1E+3	2E+3	7E-7	2E-9	1E-5	1E-4

	W, see ^{93m}Tc	-	3E+2	1E-7	4E-10	-	-
43 Technetium-99m	D, see ^{93m}Tc	8E+4	2E+5	6E-5	2E-7	1E-3	1E-2
	W, see ^{93m}Tc	-	2E+5	1E-4	3E-7	-	-
43 Technetium-99	D, see ^{93m}Tc	4E+3	5E+3	2E-6	-	6 E-5	6E-4
		-	St. wall (6E+3)	-	8E-9	-	-
	W, see ^{93m}Tc	-	7E+2	3E-7	9E-10	-	-
43 Technetium-101[2]	D, see ^{93m}Tc	9E+4	3E+5	1E-4	5E-7	-	-
		St. wall (1E+5)	-	-	-	2E-3	2E-2
	W, see ^{93m}Tc	-	4E+5	2E-4	5E-7	-	-
43 Technetium-104[2]	D, see ^{93m}Tc	2E+4	7E+4	3E-5	1E-7	-	-
		St. wall (3E+4)	-	-	-	4E-4	4E-3
	W, see ^{93m}Tc	-	9E+4	4E-5	1E-7	-	-
44 Ruthenium-94[2]	D, all compounds except those given for W and Y	2E+4	4E+4	2E-5	6E-8	2E-4	2E-3
	W, halides	-	6E+4	3E-5	9E-8	-	-
	Y, oxides and hydroxides	-	6E+4	2E-5	8E-8	-	-
44 Ruthenium-97	D, see ^{94}Ru	8E+3	2E+4	8E-6	3E-8	1E-4	1E-3
	W, see ^{94}Ru	-	1E+4	5E-6	2E-8	-	-
	Y, see ^{94}Ru	-	1E+4	5E-6	2E-8	-	-
44 Ruthenium-103	D, see ^{94}Ru	2E+3	2E+3	7E-7	2E-9	3E-5	3E-4
	W, see ^{94}Ru	-	1E+3	4E-7	1E-9	-	-
	Y, see ^{94}Ru	-	6E+2	3E-7	9E-10-		-
44 Ruthenium-105	D, see ^{94}Ru	5E+3	1E+4	6E-6	2E-8	7E-5	7E-4
	W, see ^{94}Ru	-	1E+4	6E-6	2E-8	-	-
	Y, see ^{94}Ru	-	1E+4	5E-6	2E-8	-	-
44 Ruthenium-106	D, see ^{94}Ru	2E+2	9E+1	4E-8	1E-10	-	-
		LLI wall (2E+2)	-	-	-	3E-6	3E-5
	W, see ^{94}Ru	-	5E+1	2E-8	8E-11	-	-

	Y, see ^{94}Ru	-	1E+1	5E-9	2E-11	-	-
45 Rhodium-99m	D, all compounds except those given for W and Y	2E+4	6E+4	2E-5	8E-8	2E-4	2E-3
	W, halides	-	8E+4	3E-5	1E-7	-	-
	Y, oxides and hydroxides	-	7E+4	3E-5	9E-8	-	-
45 Rhodium-99	D, see ^{99m}Rh	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
	W, see ^{99m}Rh	-	2E+3	9E-7	3E-9	-	-
	Y, see ^{99m}Rh	-	2E+3	8E-7	3E-9	-	-
45 Rhodium-100	D, see ^{99m}Rh	2E+3	5E+3	2E-6	7E-9	2E-5	2E-4
	W, see ^{99m}Rh	-	4E+3	2E-6	6E-9	-	-
	Y, see ^{99m}Rh	-	4E+3	2E-6	5E-9	-	-
45 Rhodium-101m	D, see ^{99m}Rh	6E+3	1E+4	5E-6	2E-8	8E-5	8E-4
	W, see ^{99m}Rh	-	8E+3	4E-6	1E-8	-	-
	Y, see ^{99m}Rh	-	8E+3	3E-6	1E-8	-	-
45 Rhodium-101	D, see ^{99m}Rh	2E+3	5E+2	2E-7	7E-10	3E-5	3E-4
	W, see ^{99m}Rh	-	8E+2	3E-7	1E-9	-	-
	Y, see ^{99m}Rh	-	2E+2	6E-8	2E-10	-	-
45 Rhodium-102m	D, see ^{99m}Rh	1E+3	5E+2	2E-7	7E-10	-	-
		LLI wall (1E+3)	-	-	-	2E-5	2E-4
	W, see ^{99m}Rh	-	4E+2	2E-7	5E-10	-	-
	Y, see ^{99m}Rh	-	1E+2	5E-8	2E-10	-	-
45 Rhodium-102	D, see ^{99m}Rh	6E+2	9E+1	4E-8	1E-10	8E-6	8E-5
	W, see ^{99m}Rh	-	2E+2	7E-8	2E-10	-	-
	Y, see ^{99m}Rh	-	6E+1	2E-8	8E-11	-	-
45 Rhodium-103m[2]	D, see ^{99m}Rh	4E+5	1E+6	5E-4	2E-6	6E-3	6E-2
	W, see ^{99m}Rh	-	1E+6	5E-4	2E-6	-	-
	Y, see ^{99m}Rh	-	1E+6	5E-4	2E-6	-	-
45 Rhodium-105	D, see ^{99m}Rh	4E+3	1E+4	5E-6	2E-8	-	-
		LLI wall (4E+3)	-	-	-	5E-5	5E-4
	W, see ^{99m}Rh	-	6E+3	3E-6	9E-9	-	-
	Y, see ^{99m}Rh	-	6E+3	2E-6	8E-9	-	-

45 Rhodium-106m	D, see ^{99m}Rh	8E+3	3E+4	1E-5	4E-8	1E-4	1E-3
	W, see ^{99m}Rh	-	4E+4	2E-5	5E-8	-	-
	Y, see ^{99m}Rh	-	4E+4	1E-5	5E-8	-	-
45 Rhodium-107[2]	D, see ^{99m}Rh	7E+4	2E+5	1E-4	3E-7	-	-
		St. wall (9E+4)	-	-	-	1E-3	1E-2
	W, see ^{99m}Rh	-	3E+5	1E-4	4E-7	-	-
	Y, see ^{99m}Rh	-	3E+5	1E-4	3E-7	-	-
46 Palladium-100	D, all compounds except those given for W and Y	1E+3	1E+3	6E-7	2E-9	2E-5	2E-4
	W, nitrates	-	1E+3	5E-7	2E-9	-	-
	Y, oxides and hydroxides	-	1E+3	6E-7	2E-9	-	-
46 Palladium-101	D, see ^{100}Pd	1E+4	3E+4	1E-5	5E-8	2E-4	2E-3
	W, see ^{100}Pd	-	3E+4	1E-5	5E-8	-	-
	Y, see ^{100}Pd	-	3E+4	1E-5	4E-8	-	-
46 Palladium-103	D, see ^{100}Pd	6E+3	6E+3	3E-6	9E-9	-	-
		LLI wall (7E+3)	-	-	-	1E-4	1E-3
	W, see ^{100}Pd	-	4E+3	2E-6	6E-9	-	-
	Y, see ^{100}Pd	-	4E+3	1E-6	5E-9	-	-
46 Palladium-107	D, see ^{100}Pd	3E+4	2E+4	9E-6	-	-	-
		LLI wall (4E+4)	Kidneys (2E+4)	-	3E-8	5E-4	5E-3
	W, see ^{100}Pd	-	7E+3	3E-6	1E-8	-	-
	Y, see ^{100}Pd	-	4E+2	2E-7	6E-10	-	-
46 Palladium-109	D, see ^{100}Pd	2E+3	6E+3	3E-6	9E-9	3E-5	3E-4
	W, see ^{100}Pd	-	5E+3	2E-6	8E-9	-	-
	Y, see ^{100}Pd	-	5E+3	2E-6	6E-9	-	-
47 Silver-102[2]	D, all compounds except those given for W and Y	5E+4	2E+5	8E-5	2E-7	-	-
		St. wall					

		(6E+4)	-	-	-	9E-4	9E-3
	W, nitrates and sulfides	-	2E+5	9E-5	3E-7	-	-
	Y, oxides and hydroxides	-	2E+5	8E-5	3E-7	-	-
47 Silver-103[2]	D, see ^{102}Ag	4E+4	1E+5	4E-5	1E-7	5E-4	5E-3
	W, see ^{102}Ag	-	1E+5	5E-5	2E-7	-	-
	Y, see ^{102}Ag	-	1E+5	5E-5	2E-7	-	-
47 Silver-104m[2]	D, see ^{102}Ag	3E+4	9E+4	4E-5	1E-7	4E-4	4E-3
	W, see ^{102}Ag	-	1E+5	5E-5	2E-7	-	-
	Y, see ^{102}Ag	-	1E+5	5E-5	2E-7	-	-
47 Silver-104[2]	D, see ^{102}Ag	2E+4	7E+4	3E-5	1E-7	3E-4	3E-3
	W, see ^{102}Ag	-	1E+5	6E-5	2E-7	-	-
	Y, see ^{102}Ag	-	1E+5	6E-5	2E-7	-	-
47 Silver-105	D, see ^{102}Ag	3E+3	1E+3	4E-7	1E-9	4E-5	4E-4
	W, see ^{102}Ag	-	2E+3	7E-7	2E-9	-	-
	Y, see ^{102}Ag	-	2E+3	7E-7	2E-9	-	-
47 Silver-106m	D, see ^{102}Ag	8E+2	7E+2	3E-7	1E-9	1E-5	1E-4
	W, see ^{102}Ag	-	9E+2	4E-7	1E-9	-	-
	Y, see ^{102}Ag	-	9E+2	4E-7	1E-9	-	-
47 Silver-106[2]	D, see ^{102}Ag	6E+4	2E+5	8E-5	3E-7	-	-
		St. wall (6E+4)	-	-	-	9E-4	9E-3
	W, see ^{102}Ag	-	2E+5	9E-5	3E-7	-	-
	Y, see ^{102}Ag	-	2E+5	8E-5	3E-7	-	-
47 Silver-108m	D, see ^{102}Ag	6E+2	2E+2	8E-8	3E-10	9E-6	9E-5
	W, see ^{102}Ag	-	3E+2	1E-7	4E-10	-	-
	Y, see ^{102}Ag	-	2E+1	1E-8	3E-11	-	-
47 Silver-110m	D, see ^{102}Ag	5E+2	1E+2	5E-8	2E-10	6E-6	6E-5
	W, see ^{102}Ag	-	2E+2	8E-8	3E-10	-	-
	Y, see ^{102}Ag	-	9E+1	4E-8	1E-10	-	-
47 Silver-111	D, see ^{102}Ag	9E+2	2E+3	6E-7	-	-	-
		LLI wall (1E+3)	Liver (2E+3)	-	2E-9	2E-5	2E-4
	W, see ^{102}Ag	-	9E+2	4E-7	1E-9	-	-

	Y, see ^{102}Ag	-	9E+2	4E-7	1E-9	-	-
47 Silver-112	D, see ^{102}Ag	3E+3	8E+3	3E-6	1E-8	4E-5	4E-4
	W, see ^{102}Ag	-	1E+4	4E-6	1E-8	-	-
	Y, see ^{102}Ag	-	9E+3	4E-6	1E-8	-	-
47 Silver-115[2]	D, see ^{102}Ag	3E+4	9E+4	4E-5	1E-7	-	-
		St. wall (3E+4)	-	-	-	4E-4	4E-3
	W, see ^{102}Ag	-	9E+4	4E-5	1E-7	-	-
	Y, see ^{102}Ag	-	8E+4	3E-5	1E-7	-	-
48 Cadmium-104[2]	D, all compounds except those given for W and Y	2E+4	7E+4	3E-5	9E-8	3E-4	3E-3
	W, sulfides, halides, and nitrates	-	1E+5	5E-5	2E-7	-	-
	Y, oxides and hydroxides	-	1E+5	5E-5	2E-7	-	-
48 Cadmium-107	D, see ^{104}Cd	2E+4	5E+4	2E-5	8E-8	3E-4	3E-3
	W, see ^{104}Cd	-	6E+4	2E-5	8E-8	-	-
	Y, see ^{104}Cd	-	5E+4	2E-5	7E-8	-	-
48 Cadmium-109	D, see ^{104}Cd	3E+2	4E+1	1E-8	-	-	-
		Kidneys (4E+2)	Kidneys (5E+1)	-	7E-11	6E-6	6E-5
	W, see ^{104}Cd	-	1E+2	5E-8	-	-	-
		Kidneys -	(1E+2)	-	2E-10	-	-
	Y, see ^{104}Cd	-	1E+2	5E-8	2E-10	-	-
48 Cadmium-113m	D, see ^{104}Cd	2E+1	2E+0	1E-9	-	-	-
		Kidneys (4E+1)	Kidneys (4E+0)	-	5E-12	5E-7	5E-6
	W, see ^{104}Cd	-	8E+0	4E-9	-	-	-
		-	Kidneys (1E+1)	-	2E-11	-	-
	Y, see ^{104}Cd	-	1E+1	5E-9	2E-11	-	-
48 Cadmium-113	D, see ^{104}Cd	2E+1	2E+0	9E-10	-	-	-
		Kidneys	Kidneys				

		(3E+1)	(3E+0)	-	5E-12	4E-7	4E-6
	W, see ^{104}Cd	-	8E+0	3E-9	-	-	-
		-	Kidneys (1E+1)	-	2E-11	-	-
	Y, see ^{104}Cd	-	1E+1	6E-9	2E-11	-	-
48 Cadmium-115m	D, see ^{104}Cd	3E+2	5E+1	2E-8	-	4E-6	4E-5
		-	Kidneys (8E+1)	-	1E-10	-	-
	W, see ^{104}Cd	-	1E+2	5E-8	2E-10	-	-
	Y, see ^{104}Cd	-	1E+2	6E-8	2E-10	-	-
48 Cadmium-115	D, see ^{104}Cd	9E+2	1E+3	6E-7	2E-9	-	-
		LLI wall (1E+3)	-	-	-	1E-5	1E-4
	W, see ^{104}Cd	-	1E+3	5E-7	2E-9	-	-
	Y, see ^{104}Cd	-	1E+3	6E-7	2E-9	-	-
48 Cadmium-117m	D, see ^{104}Cd	5E+3	1E+4	5E-6	2E-8	6E-5	6E-4
	W, see ^{104}Cd	-	2E+4	7E-6	2E-8	-	-
	Y, see ^{104}Cd	-	1E+4	6E-6	2E-8	-	-
48 Cadmium-117	D, see ^{104}Cd	5E+3	1E+4	5E-6	2E-8	6E-5	6E-4
	W, see ^{104}Cd	-	2E+4	7E-6	2E-8	-	-
	Y, see ^{104}Cd	-	1E+4	6E-6	2E-8	-	-
49 Indium-109	D, all compounds except those given for W	2E+4	4E+4	2E-5	6E-8	3E-4	3E-3
	W, oxides, hydroxides, halides, and nitrates	-	6E+4	3E-5	9E-8	-	-
49 Indium-110[2] (69.1 min)	D, see ^{109}In	2E+4	4E+4	2E-5	6E-8	2E-4	2E-3
	W, see ^{109}In	-	6E+4	2E-5	8E-8	-	-
49 Indium-110 (4.9 h)	D, see ^{109}In	5E+3	2E+4	7E-6	2E-8	7E-5	7E-4
	W, see ^{109}In	-	2E+4	8E-6	3E-8	-	-
49 Indium-111	D, see ^{109}In	4E+3	6E+3	3E-6	9E-9	6E-5	6E-4
	W, see ^{109}In	-	6E+3	3E-6	9E-9	-	-
49 Indium-112[2]	D, see ^{109}In	2E+5	6E+5	3E-4	9E-7	2E-3	2E-2
	W, see ^{109}In	-	7E+5	3E-4	1E-6	-	-

49 Indium-113m[2]	D, see ^{109}In	5E+4	1E+5	6E-5	2E-7	7E-4	7E-3
	W, see ^{109}In	-	2E+5	8E-5	3E-7	-	-
49 Indium-114m	D, see ^{109}In	3E+2	6E+1	3E-8	9E-11	-	-
		LLI wall (4E+2)	-	-	-	5E-6	5E-5
	W, see ^{109}In	-	1E+2	4E-8	1E-10	-	-
49 Indium-115m	D, see ^{109}In	1E+4	4E+4	2E-5	6E-8	2E-4	2E-3
	W, see ^{109}In	-	5E+4	2E-5	7E-8	-	-
49 Indium-115	D, see ^{109}In	4E+1	1E+0	6E-10	2E-12	5E-7	5E-6
	W, see ^{109}In	-	5E+0	2E-9	8E-12	-	-
49 Indium-116m[2]	D, see ^{109}In	2E+4	8E+4	3E-5	1E-7	3E-4	3E-3
	W, see ^{109}In	-	1E+5	5E-5	2E-7	-	-
49 Indium-117m[2]	D, see ^{109}In	1E+4	3E+4	1E-5	5E-8	2E-4	2E-3
	W, see ^{109}In	-	4E+4	2E-5	6E-8	-	-
49 Indium-117[2]	D, see ^{109}In	6E+4	2E+5	7E-5	2E-7	8E-4	8E-3
	W, see ^{109}In	-	2E+5	9E-5	3E-7	-	-
49 Indium-119m[2]	D, see ^{109}In	4E+4	1E+5	5E-5	2E-7	-	-
		St. wall (5E+4)	-	-	-	7E-4	7E-3
	W, see ^{109}In	-	1E+5	6E-5	2E-7	-	-
50 Tin-110	D, all compounds except those given for W	4E+3	1E+4	5E-6	2E-8	5E-5	5E-4
	W, sulfides, oxides, hydroxides, halides, nitrates, and stannic phosphate	-	1E+4	5E-6	2E-8	-	-
50 Tin-111[2]	D, see ^{110}Sn	7E+4	2E+5	9E-5	3E-7	1E-3	1E-2
	W, see ^{110}Sn	-	3E+5	1E-4	4E-7	-	-
50 Tin-113	D, see ^{110}Sn	2E+3	1E+3	5E-7	2E-9	-	-
		LLI wall (2E+3)	-	-	-	3E-5	3E-4
	W, see ^{110}Sn	-	5E+2	2E-7	8E-10	-	-
50 Tin-117m	D, see ^{110}Sn	2E+3	1E+3	5E-7	-	-	-
		LLI wall	Bone surf				

		(2E+3)	(2E+3)	-	3E-9	3E-5	3E-4
	W, see ^{110}Sn	-	1E+3	6E-7	2E-9	-	-
50 Tin-119m	D, see ^{110}Sn	3E+3	2E+3	1E-6	3E-9	-	-
		LLI wall (4E+3)	-	-	-	6E-5	6E-4
	W, see ^{110}Sn	-	1E+3	4E-7	1E-9	-	-
50 Tin-121m	D, see ^{110}Sn	3E+3	9E+2	4E-7	1E-9	-	-
		LLI wall (4E+3)	-	-	-	5E-5	5E-4
	W, see ^{110}Sn	-	5E+2	2E-7	8E-10	-	-
50 Tin-121	D, see ^{110}Sn	6E+3	2E+4	6E-6	2E-8	-	-
		LLI wall (6E+3)	-	-	-	8E-5	8E-4
	W, see ^{110}Sn	-	1E+4	5E-6	2E-8	-	-
50 Tin-123m[2]	D, see ^{110}Sn	5E+4	1E+5	5E-5	2E-7	7E-4	7E-3
	W, see ^{110}Sn	-	1E+5	6E-5	2E-7	-	-
50 Tin-123	D, see ^{110}Sn	5E+2	6E+2	3E-7	9E-10	-	-
		LLI wall (6E+2)	-	-	-	9E-6	9E-5
	W, see ^{110}Sn	-	2E+2	7E-8	2E-10	-	-
50 Tin-125	D, see ^{110}Sn	4E+2	9E+2	4E-7	1E-9	-	-
		LLI wall (5E+2)	-	-	-	6E-6	6E-5
	W, see ^{110}Sn	-	4E+2	1E-7	5E-10	-	-
50 Tin-126	D, see ^{110}Sn	3E+2	6E+1	2E-8	8E-11	4E-6	4E-5
	W, see ^{110}Sn	-	7E+1	3E-8	9E-11	-	-
50 Tin-127	D, see ^{110}Sn	7E+3	2E+4	8E-6	3E-8	9E-5	9E-4
	W, see ^{110}Sn	-	2E+4	8E-6	3E-8	-	-
50 Tin-128[2]	D, see ^{110}Sn	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3
	W, see ^{110}Sn	-	4E+4	1E-5	5E-8	-	-
51 Antimony-115[2]	D, all compounds except those given for W	8E+4	2E+5	1E-4	3E-7	1E-3	1E-2

	W, oxides, hydroxides, halides, sulfides, sulfates, and nitrates	-	3E+5	1E-4	4E-7	-	-
51 Antimony-116m[2]	D, see ^{115}Sb	2E+4	7E+4	3E-5	1E-7	3E-4	3E-3
	W, see ^{115}Sb	-	1E+5	6E-5	2E-7	-	-
51 Antimony-116[2]	D, see ^{115}Sb	7E+4	3E+5	1E-4	4E-7	-	-
		St. wall (9E+4)	-	-	-	1E-3	1E-2
	W, see ^{115}Sb	-	3E+5	1E-4	5E-7	-	-
51 Antimony-117	D, see ^{115}Sb	7E+4	2E+5	9E-5	3E-7	9E-4	9E-3
	W, see ^{115}Sb	-	3E+5	1E-4	4E-7	-	-
51 Antimony-118m	D, see ^{115}Sb	6E+3	2E+4	8E-6	3E-8	7E-5	7E-4
	W, see ^{115}Sb	5E+3	2E+4	9E-6	3E-8	-	-
51 Antimony-119	D, see ^{115}Sb	2E+4	5E+4	2E-5	6E-8	2E-4	2E-3
	W, see ^{115}Sb	2E+4	3E+4	1E-5	4E-8	-	-
51 Antimony-120[2] (16 min)	D, see ^{115}Sb	1E+5	4E+5	2E-4	6E-7	-	-
		St. wall (2E+5)	-	-	-	2E-3	2E-2
	W, see ^{115}Sb	-	5E+5	2E-4	7E-7	-	-
51 Antimony-120 (5.76 d)	D, see ^{115}Sb	1E+3	2E+3	9E-7	3E-9	1E-5	1E-4
	W, see ^{115}Sb	9E+2	1E+3	5E-7	2E-9	-	-
51 Antimony-122	D, see ^{115}Sb	8E+2	2E+3	1E-6	3E-9	-	-
		LLI wall (8E+2)	-	-	-	1E-5	1E-4
	W, see ^{115}Sb	7E+2	1E+3	4E-7	2E-9	-	-
51 Antimony-124m[2]	D, see ^{115}Sb	3E+5	8E+5	4E-4	1E-6	3E-3	3E-2
	W, see ^{115}Sb	2E+5	6E+5	2E-4	8E-7	-	-
51 Antimony-124	D, see ^{115}Sb	6E+2	9E+2	4E-7	1E-9	7E-6	7E-5
	W, see ^{115}Sb	5E+2	2E+2	1E-7	3E-10	-	-
51 Antimony-125	D, see ^{115}Sb	2E+3	2E+3	1E-6	3E-9	3E-5	3E-4
	W, see ^{115}Sb	-	5E+2	2E-7	7E-10	-	-
51 Antimony-126m[2]	D, see ^{115}Sb	5E+4	2E+5	8E-5	3E-7	-	-
		St. wall (7E+4)	-	-	-	9E-4	9E-3

	W, see ^{115}Sb	-	2E+5	8E-5	3E-7	-	-
51 Antimony-126	D, see ^{115}Sb	6E+2	1E+3	5E-7	2E-9	7E-6	7E-5
	W, see ^{115}Sb	5E+2	5E+2	2E-7	7E-10	-	-
51 Antimony-127	D, see ^{115}Sb	8E+2	2E+3	9E-7	3E-9	-	-
		LLI wall (8E+2)	-	-	-	1E-5	1E-4
	W, see ^{115}Sb	7E+2	9E+2	4E-7	1E-9	-	-
51 Antimony-128[2] (10.4 min)	D, see ^{115}Sb	8E+4	4E+5	2E-4	5E-7	-	-
		St. wall (1E+5)	-	-	-	1E-3	1E-2
	W, see ^{115}Sb	-	4E+5	2E-4	6E-7	-	-
51 Antimony-128 (9.01 h)	D, see ^{115}Sb	1E+3	4E+3	2E-6	6E-9	2E-5	2E-4
	W, see ^{115}Sb	-	3E+3	1E-6	5E-9	-	-
51 Antimony-129	D, see ^{115}Sb	3E+3	9E+3	4E-6	1E-8	4E-5	4E-4
	W, see ^{115}Sb	-	9E+3	4E-6	1E-8	-	-
51 Antimony-130[2]	D, see ^{115}Sb	2E+4	6E+4	3E-5	9E-8	3E-4	3E-3
	W, see ^{115}Sb	-	8E+4	3E-5	1E-7	-	-
51 Antimony-131[2]	D, see ^{115}Sb	1E+4	2E+4	1E-5	-	-	-
		Thyroid (2E+4)	Thyroid (4E+4)	-	6E-8	2E-4	2E-3
	W, see ^{115}Sb	-	2E+4	1E-5	-	-	-
		-	Thyroid (4E+4)	-	6E-8	-	-
52 Tellurium-116	D, all compounds except those given for W	8E+3	2E+4	9E-6	3E-8	1E-4	1E-3
	W, oxides, hydroxides, and nitrates	-	3E+4	1E-5	4E-8	-	-
52 Tellurium-121m	D, see ^{116}Te	5E+2	2E+2	8E-8	-	-	-
		Bone surf (7E+2)	Bone surf (4E+2)	-	5E-10	1E-5	1E-4
	W, see ^{116}Te	-	4E+2	2E-7	6E-10	-	-
52 Tellurium-121	D, see ^{116}Te	3E+3	4E+3	2E-6	6E-9	4E-5	4E-4
	W, see ^{116}Te	-	3E+3	1E-6	4E-9	-	-

52 Tellurium-123m	D, see ^{116}Te	6E+2	2E+2	9E-8	-	-	-
		Bone surf	Bone surf				
		(1E+3)	(5E+2)	-	8E-10	1E-5	1E-4
	W, see ^{116}Te	-	5E+2	2E-7	8E-10	-	-
52 Tellurium-123	D, see ^{116}Te	5E+2	2E+2	8E-8	-	-	-
		Bone surf	Bone surf				
		(1E+3)	(5E+2)	-	7E-10	2E-5	2E-4
	W, see ^{116}Te	-	4E+2	2E-7	-	-	-
			Bone surf				
		-	(1E+3)	-	2E-9	-	-
52 Tellurium-125m	D, see ^{116}Te	1E+3	4E+2	2E-7	-	-	-
		Bone surf	Bone surf				
		(1E+3)	(1E+3)	-	1E-9	2E-5	2E-4
	W, see ^{116}Te	-	7E+2	3E-7	1E-9	-	-
52 Tellurium-127m	D, see ^{116}Te	6E+2	3E+2	1E-7	-	9E-6	9E-5
			Bone surf				
		-	(4E+2)	-	6E-10	-	-
	W, see ^{116}Te	-	3E+2	1E-7	4E-10	-	-
52 Tellurium-127	D, see ^{116}Te	7E+3	2E+4	9E-6	3E-8	1E-4	1E-3
	W, see ^{116}Te	-	2E+4	7E-6	2E-8	-	-
52 Tellurium-129m	D, see ^{116}Te	5E+2	6E+2	3E-7	9E-10	7E-6	7E-5
	W, see ^{116}Te	-	2E+2	1E-7	3E-10	-	-
52 Tellurium-129[2]	D, see ^{116}Te	3E+4	6E+4	3E-5	9E-8	4E-4	4E-3
	W, see ^{116}Te	-	7E+4	3E-5	1E-7	-	-
52 Tellurium-131m	D, see ^{116}Te	3E+2	4E+2	2E-7	-	-	-
		Thyroid	Thyroid				
		(6E+2)	(1E+3)	-	2E-9	8E-6	8E-5
	W, see ^{116}Te	-	4E+2	2E-7	-	-	-
			Thyroid				
		-	(9E+2)	-	1E-9	-	-
52 Tellurium-131[2]	D, see ^{116}Te	3E+3	5E+3	2E-6	-	-	-

		Thyroid (6E+3)	Thyroid (1E+4)	-	2E-8	8E-5	8E-4
	W, see ^{116}Te	-	5E+3	2E-6	-	-	-
		-	Thyroid (1E+4)	-	2E-8	-	-
52 Tellurium-132	D, see ^{116}Te	2E+2	2E+2	9E-8	-	-	-
		Thyroid (7E+2)	Thyroid (8E+2)	-	1E-9	9E-6	9E-5
	W, see ^{116}Te	-	2E+2	9E-8	-	-	-
		-	Thyroid (6E+2)	-	9E-10	-	-
52 Tellurium-133m[2]	D, see ^{116}Te	3E+3	5E+3	2E-6	-	-	-
		Thyroid (6E+3)	Thyroid (1E+4)	-	2E-8	9E-5	9E-4
	W, see ^{116}Te	-	5E+3	2E-6	-	-	-
		-	Thyroid (1E+4)	-	2E-8	-	-
52 Tellurium-133[2]	D, see ^{116}Te	1E+4	2E+4	9E-6	-	-	-
		Thyroid (3E+4)	Thyroid (6E+4)	-	8E-8	4E-4	4E-3
	W, see ^{116}Te	-	2E+4	9E-6	-	-	-
		-	Thyroid (6E+4)	-	8E-8	-	-
52 Tellurium-134[2]	D, see ^{116}Te	2E+4	2E+4	1E-5	-	-	-
		Thyroid (2E+4)	Thyroid (5E+4)	-	7E-8	3E-4	3E-3
	W, see ^{116}Te	-	2E+4	1E-5	-	-	-
		-	Thyroid (5E+4)	-	7E-8	-	-
53 Iodine-120m[2]	D, all compounds	1E+4	2E+4	9E-6	3E-8	-	-
		Thyroid (1E+4)	-	-	-	2E-4	2E-3
53 Iodine-120[2]	D, all compounds	4E+3	9E+3	4E-6	-	-	-
		Thyroid (8E+3)	Thyroid (1E+4)	-	2E-8	1E-4	1E-3
53 Iodine-121	D, all compounds	1E+4	2E+4	8E-6	-	-	-
		Thyroid (3E+4)	Thyroid (5E+4)	-	7E-8	4E-4	4E-3

53 Iodine-123	D, all compounds	3E+3 Thyroid (1E+4)	6E+3 Thyroid (2E+4)	3E-6 -	- 2E-8	- 1E-4	- 1E-3
53 Iodine-124	D, all compounds	5E+1 Thyroid (2E+2)	8E+1 Thyroid (3E+2)	3E-8 -	- 4E-10	- 2E-6	- 2E-5
53 Iodine-125	D, all compounds	4E+1 Thyroid (1E+2)	6E+1 Thyroid (2E+2)	3E-8 -	- 3E-10	- 2E-6	- 2E-5
53 Iodine-126	D, all compounds	2E+1 Thyroid (7E+1)	4E+1 Thyroid (1E+2)	1E-8 -	- 2E-10	- 1E-6	- 1E-5
53 Iodine-128[2]	D, all compounds	4E+4 St. wall (6E+4)	1E+5 -	5E-5 -	2E-7 -	- 8E-4	- 8E-3
53 Iodine-129	D, all compounds	5E+0 Thyroid (2E+1)	9E+0 Thyroid (3E+1)	4E-9 -	- 4E-11	- 2E-7	- 2E-6
53 Iodine-130	D, all compounds	4E+2 Thyroid (1E+3)	7E+2 Thyroid (2E+3)	3E-7 -	- 3E-9	- 2E-5	- 2E-4
53 Iodine-131	D, all compounds	3E+1 Thyroid (9E+1)	5E+1 Thyroid (2E+2)	2E-8 -	- 2E-10	- 1E-6	- 1E-5
53 Iodine-132m[2]	D, all compounds	4E+3 Thyroid (1E+4)	8E+3 Thyroid (2E+4)	4E-6 -	- 3E-8	- 1E-4	- 1E-3
53 Iodine-132	D, all compounds	4E+3 Thyroid (9E+3)	8E+3 Thyroid (1E+4	3E-6 -	- 2E-8	- 1E-4	- 1E-3
53 Iodine-133	D, all compounds	1E+2 Thyroid (5E+2)	3E+2 Thyroid (9E+2)	1E-7 -	- 1E-9	- 7E-6	- 7E-5
53 Iodine-134[2]	D, all compounds	2E+4 Thyroid (3E+4)	5E+4 -	2E-5 -	6E-8 -	- 4E-4	- 4E-3
53 Iodine-135	D, all compounds	8E+2	2E+3	7E-7	-	-	-

		Thyroid (3E+3)	Thyroid (4E+3)	-	6E-9	3E-5	3E-4
54 Xenon-120[2]	Submersion[1]	-	-	1E-5	4E-8	-	-
54 Xenon-121[2]	Submersion[1]	-	-	2E-6	1E-8	-	-
54 Xenon-122	Submersion[1]	-	-	7E-5	3E-7	-	-
54 Xenon-123	Submersion[1]	-	-	6E-6	3E-8	-	-
54 Xenon-125	Submersion[1]	-	-	2E-5	7E-8	-	-
54 Xenon-127	Submersion[1]	-	-	1E-5	6E-8	-	-
54 Xenon-129m	Submersion[1]	-	-	2E-4	9E-7	-	-
54 Xenon-131m	Submersion[1]	-	-	4E-4	2E-6	-	-
54 Xenon-133m	Submersion[1]	-	-	1E-4	6E-7	-	-
54 Xenon-133	Submersion[1]	-	-	1E-4	5E-7	-	-
54 Xenon-135m[2]	Submersion[1]	-	-	9E-6	4E-8	-	-
54 Xenon-135	Submersion[1]	-	-	1E-5	7E-8	-	-
54 Xenon-138[2]	Submersion[1]	-	-	4E-6	2E-8	-	-
55 Cesium-125[2]	D, all compounds	5E+4	1E+5	6E-5	2E-7	-	-
		St. wall (9E+4)	-	-	-	1E-3	1E-2
55 Cesium-127	D, all compounds	6E+4	9E+4	4E-5	1E-7	9E-4	9E-3
55 Cesium-129	D, all compounds	2E+4	3E+4	1E-5	5E-8	3E-4	3E-3
55 Cesium-130[2]	D, all compounds	6E+4	2E+5	8E-5	3E-7	-	-
		St. wall (1E+5)	-	-	-	1E-3	1E-2
55 Cesium-131	D, all compounds	2E+4	3E+4	1E-5	4E-8	3E-4	3E-3
55 Cesium-132	D, all compounds	3E+3	4E+3	2E-6	6E-9	4E-5	4E-4
55 Cesium-134m	D, all compounds	1E+5	1E+5	6E-5	2E-7	-	-
		St. wall (1E+5)	-	-	-	2E-3	2E-2

55 Cesium-134	D, all compounds	7E+1	1E+2	4E-8	2E-10	9E-7	9E-6
55 Cesium-135m[2]	D, all compounds	1E+5	2E+5	8E-5	3E-7	1E-3	1E-2
55 Cesium-135	D, all compounds	7E+2	1E+3	5E-7	2E-9	1E-5	1E-4
55 Cesium-136	D, all compounds	4E+2	7E+2	3E-7	9E-10	6E-6	6E-5
55 Cesium-137	D, all compounds	1E+2	2E+2	6E-8	2E-10	1E-6	1E-5
55 Cesium-138[2]	D, all compounds	2E+4	6E+4	2E-5	8E-8	-	-
		St. wall (3E+4)	-	-	-	4E-4	4E-3
56 Barium-126[2]	D, all compounds	6E+3	2E+4	6E-6	2E-8	8E-5	8E-4
56 Barium-128	D, all compounds	5E+2	2E+3	7E-7	2E-9	7E-6	7E-5
56 Barium-131m[2]	D, all compounds	4E+5	1E+6	6E-4	2E-6	-	-
		St. wall (5E+5)	-	-	-	7E-3	7E-2
56 Barium-131	D, all compounds	3E+3	8E+3	3E-6	1E-8	4E-5	4E-4
56 Barium-133m	D, all compounds	2E+3	9E+3	4E-6	1E-8	-	-
		LLI wall (3E+3)	-	-	-	4E-5	4E-4
56 Barium-133	D, all compounds	2E+3	7E+2	3E-7	9E-10	2E-5	2E-4
56 Barium-135m	D, all compounds	3E+3	1E+4	5E-6	2E-8	4E-5	4E-4
56 Barium-139[2]	D, all compounds	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
56 Barium-140	D, all compounds	5E+2	1E+3	6E-7	2E-9	-	-
		LLI wall (6E+2)	-	-	-	8E-6	8E-5
56 Barium-141[2]	D, all compounds	2E+4	7E+4	3E-5	1E-7	3E-4	3E-3
56 Barium-142[2]	D, all compounds	5E+4	1E+5	6E-5	2E-7	7E-4	7E-3
57 Lanthanum-131[2]	D, all compounds except those given for W	5E+4	1E+5	5E-5	2E-7	6E-4	6E-3
	W, oxides and hydroxides	-	2E+5	7E-5	2E-7	-	-

57 Lanthanum-132	D, see ^{131}La	3E+3	1E+4	4E-6	1E-8	4E-5	4E-4
	W, see ^{131}La	-	1E+4	5E-6	2E-8	-	-
57 Lanthanum-135	D, see ^{131}La	4E+4	1E+5	4E-5	1E-7	5E-4	5E-3
	W, see ^{131}La	-	9E+4	4E-5	1E-7	-	-
57 Lanthanum-137	D, see ^{131}La	1E+4	6E+1	3E-8	-	2E-4	2E-3
		-	Liver (7E+1)	-	1E-10	-	-
	W, see ^{131}La	-	3E+2	1E-7	-	-	-
		-	Liver (3E+2)	-	4E-10	-	-
57 Lanthanum-138	D, see ^{131}La	9E+2	4E+0	1E-9	5E-12	1E-5	1E-4
	W, see ^{131}La	-	1E+1	6E-9	2E-11	-	-
57 Lanthanum-140	D, see ^{131}La	6E+2	1E+3	6E-7	2E-9	9E-6	9E-5
	W, see ^{131}La	-	1E+3	5E-7	2E-9	-	-
57 Lanthanum-141	D, see ^{131}La	4E+3	9E+3	4E-6	1E-8	5E-5	5E-4
	W, see ^{131}La	-	1E+4	5E-6	2E-8	-	-
57 Lanthanum-142[2]	D, see ^{131}La	8E+3	2E+4	9E-6	3E-8	1E-4	1E-3
	W, see ^{131}La	-	3E+4	1E-5	5E-8	-	-
57 Lanthanum-143[2]	D, see ^{131}La	4E+4	1E+5	4E-5	1E-7	-	-
		St. wall (4E+4)	-	-	-	5E-4	5E-3
	W, see ^{131}La	-	9E+4	4E-5	1E-7	-	-
58 Cerium-134	W, all compounds except those given for Y	5E+2	7E+2	3E-7	1E-9	-	-
		LLI wall (6E+2)	-	-	-	8E-6	8E-5
	Y, oxides, hydroxides, and fluorides	-	7E+2	3E-7	9E-10	-	-
58 Cerium-135	W, see ^{134}Ce	2E+3	4E+3	2E-6	5E-9	2E-5	2E-4
	Y, see ^{134}Ce	-	4E+3	1E-6	5E-9	-	-
58 Cerium-137m	W, see ^{134}Ce	2E+3	4E+3	2E-6	6E-9	-	-
		LLI wall (2E+3)	-	-	-	3E-5	3E-4
	Y, see ^{134}Ce	-	4E+3	2E-6	5E-9	-	-
58 Cerium-137	W, see ^{134}Ce	5E+4	1E+5	6E-5	2E-7	7E-4	7E-3
	Y, see ^{134}Ce	-	1E+5	5E-5	2E-7	-	-

58 Cerium-139	W, see ^{134}Ce	5E+3	8E+2	3E-7	1E-9	7E-5	7E-4
	Y, see ^{134}Ce	-	7E+2	3E-7	9E-10	-	-
58 Cerium-141	W, see ^{134}Ce	2E+3	7E+2	3E-7	1E-9	-	-
		LLI wall (2E+3)	-	-	-	3E-5	3E-4
	Y, see ^{134}Ce	-	6E+2	2E-7	8E-10	-	-
58 Cerium-143	W, see ^{134}Ce	1E+3	2E+3	8E-7	3E-9	-	-
		LLI wall (1E+3)	-	-	-	2E-5	2E-4
	Y, see ^{134}Ce	-	2E+3	7E-7	2E-9	-	-
58 Cerium-144	W, see ^{134}Ce	2E+2	3E+1	1E-8	4E-11	-	-
		LLI wall (3E+2)	-	-	-	3E-6	3E-5
	Y, see ^{134}Ce	-	1E+1	6E-9	2E-11	-	-
59 Praseodymium-136[2]	W, all compounds except those given for Y	5E+4	2E+5	1E-4	3E-7	-	-
		St. wall (7E+4)	-	-	-	1E-3	1E-2
	Y, oxides, hydroxides, carbides, and fluorides	-	2E+5	9E-5	3E-7	-	-
59 Praseodymium-137[2]	W, see ^{136}Pr	4E+4	2E+5	6E-5	2E-7	5E-4	5E-3
	Y, see ^{136}Pr	-	1E+5	6E-5	2E-7	-	-
59 Praseodymium-138m	W, see ^{136}Pr	1E+4	5E+4	2E-5	8E-8	1E-4	1E-3
	Y, see ^{136}Pr	-	4E+4	2E-5	6E-8	-	-
59 Praseodymium-139	W, see ^{136}Pr	4E+4	1E+5	5E-5	2E-7	6E-4	6E-3
	Y, see ^{136}Pr	-	1E+5	5E-5	2E-7	-	-
59 Praseodymium-142m[2]	W, see ^{136}Pr	8E+4	2E+5	7E-5	2E-7	1E-3	1E-2
	Y, see ^{136}Pr	-	1E+5	6E-5	2E-7	-	-
59 Praseodymium-142	W, see ^{136}Pr	1E+3	2E+3	9E-7	3E-9	1E-5	1E-4
	Y, see ^{136}Pr	-	2E+3	8E-7	3E-9	-	-
59 Praseodymium-143	W, see ^{136}Pr	9E+2	8E+2	3E-7	1E-9	-	-
		LLI wall (1E+3)	-	-	-	2E-5	2E-4

	Y, see ^{136}Pr	-	7E+2	3E-7	9E-10	-	-
59 Praseodymium-144[2]	W, see ^{136}Pr	3E+4	1E+5	5E-5	2E-7	-	-
		St. wall (4E+4)	-	-	-	6E-4	6E-3
	Y, see ^{136}Pr	-	1E+5	5E-5	2E-7	-	-
59 Praseodymium-145	W, see ^{136}Pr	3E+3	9E+3	4E-6	1E-8	4E-5	4E-4
	Y, see ^{136}Pr	-	8E+3	3E-6	1E-8	-	-
59 Praseodymium-147[2]	W, see ^{136}Pr	5E+4	2E+5	8E-5	3E-7	-	-
		St. wall (8E+4)	-	-	-	1E-3	1E-2
	Y, see ^{136}Pr	-	2E+5	8E-5	3E-7	-	-
60 Neodymium-136[2]	W, all compounds except those given for Y	1E+4	6E+4	2E-5	8E-8	2E-4	2E-3
	Y, oxides, hydroxides, carbides, and fluorides	-	5E+4	2E-5	8E-8	-	-
60 Neodymium-138	W, see ^{136}Nd	2E+3	6E+3	3E-6	9E-9	3E-5	3E-4
	Y, see ^{136}Nd	-	5E+3	2E-6	7E-9	-	-
60 Neodymium-139m	W, see ^{136}Nd	5E+3	2E+4	7E-6	2E-8	7E-5	7E-4
	Y, see ^{136}Nd	-	1E+4	6E-6	2E-8	-	-
60 Neodymium-139[2]	W, see ^{136}Nd	9E+4	3E+5	1E-4	5E-7	1E-3	1E-2
	Y, see ^{136}Nd	-	3E+5	1E-4	4E-7	-	-
60 Neodymium-141	W, see ^{136}Nd	2E+5	7E+5	3E-4	1E-6	2E-3	2E-2
	Y, see ^{136}Nd	-	6E+5	3E-4	9E-7	-	-
60 Neodymium-147	W, see ^{136}Nd	1E+3	9E+2	4E-7	1E-9	-	-
		LLI wall (1E+3)	-	-	-	2E-5	2E-4
	Y, see ^{136}Nd	-	8E+2	4E-7	1E-9	-	-
60 Neodymium-149[2]	W, see ^{136}Nd	1E+4	3E+4	1E-5	4E-8	1E-4	1E-3
	Y, see ^{136}Nd	-	2E+4	1E-5	3E-8	-	-
60 Neodymium-151[2]	W, see ^{136}Nd	7E+4	2E+5	8E-5	3E-7	9E-4	9E-3
	Y, see ^{136}Nd	-	2E+5	8E-5	3E-7	-	-
61 Promethium-141[2]	W, all compounds						

	except those given for Y	5E+4	2E+5	8E-5	3E-7	-	-
		St. wall (6E+4)	-	-	-	8E-4	8E-3
	Y, oxides, hydroxides, carbides, and fluorides	-	2E+5	7E-5	2E-7	-	-
61 Promethium-143	W, see ^{141}Pm	5E+3	6E+2	2E-7	8E-10	7E-5	7E-4
	Y, see ^{141}Pm	-	7E+2	3E-7	1E-9	-	-
61 Promethium-144	W, see ^{141}Pm	1E+3	1E+2	5E-8	2E-10	2E-5	2E-4
	Y, see ^{141}Pm	-	1E+2	5E-8	2E-10	-	-
61 Promethium-145	W, see ^{141}Pm	1E+4	2E+2	7E-8	-	1E-4	1E-3
		-	Bone surf (2E+2)	-	3E-10	-	-
	Y, see ^{141}Pm	-	2E+2	8E-8	3E-10	-	-
61 Promethium-146	W, see ^{141}Pm	2E+3	5E+1	2E-8	7E-11	2E-5	2E-4
	Y, see ^{141}Pm	-	4E+1	2E-8	6E-11	-	-
61 Promethium-147	W, see ^{141}Pm	4E+3	1E+2	5E-8	-	-	-
		LLI wall (5E+3)	Bone surf (2E+2)	-	3E-10	7E-5	7E-4
	Y, see ^{141}Pm	-	1E+2	6E-8	2E-10	-	-
61 Promethium-148m	W, see ^{141}Pm	7E+2	3E+2	1E-7	4E-10	1E-5	1E-4
	Y, see ^{141}Pm	-	3E+2	1E-7	5E-10	-	-
61 Promethium-148	W, see ^{141}Pm	4E+2	5E+2	2E-7	8E-10	-	-
		LLI wall (5E+2)	-	-	-	7E-6	7E-5
	Y, see ^{141}Pm	-	5E+2	2E-7	7E-10	-	-
61 Promethium-149	W, see ^{141}Pm	1E+3	2E+3	8E-7	3E-9	-	-
		LLI wall (1E+3)	-	-	-	2E-5	2E-4
	Y, see ^{141}Pm	-	2E+3	8E-7	2E-9	-	-
61 Promethium-150	W, see ^{141}Pm	5E+3	2E+4	8E-6	3E-8	7E-5	7E-4
	Y, see ^{141}Pm	-	2E+4	7E-6	2E-8	-	-
61 Promethium-151	W, see ^{141}Pm	2E+3	4E+3	1E-6	5E-9	2E-5	2E-4

	Y, see ^{141}Pm	-	3E+3	1E-6	4E-9	-	-
62 Samarium-141m[2]	W, all compounds	3E+4	1E+5	4E-5	1E-7	4E-4	4E-3
62 Samarium-141[2]	W, all compounds	5E+4	2E+5	8E-5	2E-7	-	-
		St. wall (6E+4)	-	-	-	8E-4	8E-3
62 Samarium-142[2]	W, all compounds	8E+3	3E+4	1E-5	4E-8	1E-4	1E-3
62 Samarium-145	W, all compounds	6E+3	5E+2	2E-7	7E-10	8E-5	8E-4
62 Samarium-146	W, all compounds	1E+1	4E-2	1E-11	-	-	-
		Bone surf (3E+1)	Bone surf (6E-2)	-	9E-14	3E-7	3E-6
62 Samarium-147	W, all compounds	2E+1	4E-2	2E-11	-	-	-
		Bone surf (3E+1)	Bone surf (7E-2)	-	1E-13	4E-7	4E-6
62 Samarium-151	W, all compounds	1E+4	1E+2	4E-8	-	-	-
		LLI wall (1E+4)	Bone surf (2E+2)	-	2E-10	2E-4	2E-3
62 Samarium-153	W, all compounds	2E+3	3E+3	1E-6	4E-9	-	-
		LLI wall (2E+3)	-	-	-	3E-5	3E-4
62 Samarium-155[2]	W, all compounds	6E+4	2E+5	9E-5	3E-7	-	-
		St. wall (8E+4)	-	-	-	1E-3	1E-2
62 Samarium-156	W, all compounds	5E+3	9E+3	4E-6	1E-8	7E-5	7E-4
63 Europium-145	W, all compounds	2E+3	2E+3	8E-7	3E-9	2E-5	2E-4
63 Europium-146	W, all compounds	1E+3	1E+3	5E-7	2E-9	1E-5	1E-4
63 Europium-147	W, all compounds	3E+3	2E+3	7E-7	2E-9	4E-5	4E-4
63 Europium-148	W, all compounds	1E+3	4E+2	1E-7	5E-10	1E-5	1E-4
63 Europium-149	W, all compounds	1E+4	3E+3	1E-6	4E-9	2E-4	2E-3
63 Europium-150 (12.62 h)	W, all compounds	3E+3	8E+3	4E-6	1E-8	4E-5	4E-4

63 Europium-150 (34.2 y)	W, all compounds	8E+2	2E+1	8E-9	3E-11	1E-5	1E-4
63 Europium-152m	W, all compounds	3E+3	6E+3	3E-6	9E-9	4E-5	4E-4
63 Europium-152	W, all compounds	8E+2	2E+1	1E-8	3E-11	1E-5	1E-4
63 Europium-154	W, all compounds	5E+2	2E+1	8E-9	3E-11	7E-6	7E-5
63 Europium-155	W, all compounds	E+3	9E+1	4E-8	-	5E-5	5E-4
		-	Bone surf (1E+2)	-	2E-10	-	-
63 Europium-156	W, all compounds	6E+2	5E+2	2E-7	6E-10	8E-6	8E-5
63 Europium-157	W, all compounds	2E+3	5E+3	2E-6	7E-9	3E-5	3E-4
63 Europium-158[2]	W, all compounds	2E+4	6E+4	2E-5	8E-8	3E-4	3E-3
64 Gadolinium-145[2]	D, all compounds except those given for W	5E+4	2E+5	6E-5	2E-7	-	-
		St. wall (5E+4)	-	-	-	6E-4	6E-3
	W, oxides, hydroxides, and fluorides	-	2E+5	7E-5	2E-7	-	-
64 Gadolinium-146	D, see ^{145}Gd	1E+3	1E+2	5E-8	2E-10	2E-5	2E-4
	W, see ^{145}Gd	-	3E+2	1E-7	4E-10	-	-
64 Gadolinium-147	D, see ^{145}Gd	2E+3	4E+3	2E-6	6E-9	3E-5	3E-4
	W, see ^{145}Gd	-	4E+3	1E-6	5E-9	-	-
64 Gadolinium-148	D, see ^{145}Gd	1E+1	8E-3	3E-12	-	-	-
		Bone surf (2E+1)	Bone surf (2E-2)	-	2E-14	3E-7	3E-6
	W, see ^{145}Gd	-	3E-2	1E-11	-	-	-
		-	Bone surf (6E-2)	-	8E-14	-	-
64 Gadolinium-149	D, see ^{145}Gd	3E+3	2E+3	9E-7	3E-9	4E-5	4E-4
	W, see ^{145}Gd	-	2E+3	1E-6	3E-9	-	-
64 Gadolinium-151	D, see ^{145}Gd	6E+3	4E+2	2E-7	-	9E-5	9E-4

		-	Bone surf (6E+2)	-	9E-10	-	-
	W, see ^{145}Gd	-	1E+3	5E-7	2E-9	-	-
64 Gadolinium-152	D, see ^{145}Gd	2E+1	1E-2	4E-12	-	-	-
		Bone surf (3E+1)	Bone surf (2E-2)	-	3E-14	4E-7	4E-6
	W, see ^{145}Gd	-	4E-2	2E-11	-	-	-
		-	Bone surf (8E-2)	-	1E-13	-	-
64 Gadolinium-153	D, see ^{145}Gd	5E+3	1E+2	6E-8	-	6E-5	6E-4
		-	Bone surf (2E+2)	-	3E-10	-	-
	W, see ^{145}Gd	-	6E+2	2E-7	8E-10	-	-
64 Gadolinium-159	D, see ^{145}Gd	3E+3	8E+3	3E-6	1E-8	4E-5	4E-4
	W, see ^{145}Gd	-	6E+3	2E-6	8E-9	-	-
65 Terbium-147[2]	W, all compounds	9E+3	3E+4	1E-5	5E-8	1E-4	1E-3
65 Terbium-149	W, all compounds	5E+3	7E+2	3E-7	1E-9	7E-5	7E-4
65 Terbium-150	W, all compounds	5E+3	2E+4	9E-6	3E-8	7E-5	7E-4
65 Terbium-151	W, all compounds	4E+3	9E+3	4E-6	1E-8	5E-5	5E-4
65 Terbium-153	W, all compounds	5E+3	7E+3	3E-6	1E-8	7E-5	7E-4
65 Terbium-154	W, all compounds	2E+3	4E+3	2E-6	6E-9	2E-5	2E-4
65 Terbium-155	W, all compounds	6E+3	8E+3	3E-6	1E-8	8E-5	8E-4
65 Terbium-156m (5.0h)	W, all compounds	2E+4	3E+4	1E-5	4E-8	2E-4	2E-3
65 Terbium-156m (24.4h)	W, all compounds	7E+3	8E+3	3E-6	1E-8	1E-4	1E-3
65 Terbium-156	W, all compounds	1E+3	1E+3	6E-7	2E-9	1E-5	1E-4
65 Terbium-157	W, all compounds	5E+4	3E+2	1E-7	-	-	-
		LLI	Bone				

		wall (5E+4)	surf (6E+2)	-	8E-10	7E-4	7E-3
65 Terbium-158	W, all compounds	1E+3	2E+1	8E-9	3E-11	2E-5	2E-4
65 Terbium-160	W, all compounds	8E+2	2E+2	9E-8	3E-10	1E-5	1E-4
65 Terbium-161	W, all compounds	2E+3	2E+3	7E-7	2E-9	-	-
		LLI wall (2E+3)	-	-	-	3E-5	3E-4
66 Dysprosium-155	W, all compounds	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3
66 Dysprosium-157	W, all compounds	2E+4	6E+4	3E-5	9E-8	3E-4	3E-3
66 Dysprosium-159	W, all compounds	1E+4	2E+3	1E-6	3E-9	2E-4	2E-3
66 Dysprosium-165	W, all compounds	1E+4	5E+4	2E-5	6E-8	2E-4	2E-3
66 Dysprosium-166	W, all compounds	6E+2	7E+2	3E-7	1E-9	-	-
		LLI wall (8E+2)	-	-	-	1E-5	1E-4
67 Holmium-155[2]	W, all compounds	4E+4	2E+5	6E-5	2E-7	6E-4	6E-3
67 Holmium-157[2]	W, all compounds	3E+5	1E+6	6E-4	2E-6	4E-3	4E-2
67 Holmium-159[2]	W, all compounds	2E+5	1E+6	4E-4	1E-6	3E-3	3E-2
67 Holmium-161	W, all compounds	1E+5	4E+5	2E-4	6E-7	1E-3	1E-2
67 Holmium-162m[2]	W, all compounds	5E+4	3E+5	1E-4	4E-7	7E-4	7E-3
67 Holmium-162[2]	W, all compounds	5E+5	2E+6	1E-3	3E-6	-	-
		St. wall (8E+5)	-	-	-	1E-2	1E-1
67 Holmium-164m[2]	W, all compounds	1E+5	3E+5	1E-4	4E-7	1E-3	1E-2
67 Holmium-164[2]	W, all compounds	2E+5	6E+5	3E-4	9E-7	-	-
		St. wall (2E+5)	-	-	-	3E-3	3E-2
67 Holmium-166m	W, all compounds	6E+2	7E+0	3E-9	9E-12	9E-6	9E-5
67 Holmium-166	W, all compounds	9E+2	2E+3	7E-7	2E-9	-	-
		LLI wall (9E+2)	-	-	-	1E-5	1E-4
67 Holmium-167	W, all compounds	2E+4	6E+4	2E-5	8E-8	2E-4	2E-3

68 Erbium-161	W, all compounds	2E+4	6E+4	3E-5	9E-8	2E-4	2E-3
68 Erbium-165	W, all compounds	6E+4	2E+5	8E-5	3E-7	9E-4	9E-3
68 Erbium-169	W, all compounds	3E+3	3E+3	1E-6	4E-9	-	-
		LLI wall (4E+3)	-	-	-	5E-5	5E-4
68 Erbium-171	W, all compounds	4E+3	1E+4	4E-6	1E-8	5E-5	5E-4
68 Erbium-172	W, all compounds	1E+3	1E+3	6E-7	2E-9	-	-
		LLI wall (1E+3)	-	-	-	2E-5	2E-4
69 Thulium-162[2]	W, all compounds	7E+4	3E+5	1E-4	4E-7	-	-
		St. wall (7E+4)	-	-	-	1E-3	1E-2
69 Thulium-166	W, all compounds	4E+3	1E+4	6E-6	2E-8	6E-5	6E-4
69 Thulium-167	W, all compounds	2E+3	2E+3	8E-7	3E-9	-	-
		LLI wall (2E+3)	-	-	-	3E-5	3E-4
69 Thulium-170	W, all compounds	8E+2	2E+2	9E-8	3E-10	-	-
		LLI wall (1E+3)	-	-	-	1E-5	1E-4
69 Thulium-171	W, all compounds	1E+4	3E+2	1E-7	-	-	-
		LLI wall (1E+4)	Bone surf (6E+2)	-	8E-10	2E-4	2E-3
69 Thulium-172	W, all compounds	7E+2	1E+3	5E-7	2E-9	-	-
		LLI wall (8E+2)	-	-	-	1E-5	1E-4
69 Thulium-173	W, all compounds	4E+3	1E+4	5E-6	2E-8	6E-5	6E-4
69 Thulium-175[2]	W, all compounds	7E+4	3E+5	1E-4	4E-7	-	-
		St. wall (9E+4)	-	-	-	1E-3	1E-2
70 Ytterbium-162[2]	W, all compounds except those given for Y	7E+4	3E+5	1E-4	4E-7	1E-3	1E-2
	Y, oxides, hydroxides, and fluorides	-	3E+5	1E-4	4E-7	-	-

70 Ytterbium-166	W, see ^{162}Yb	1E+3	2E+3	8E-7	3E-9	2E-5	2E-4
	Y, see ^{162}Yb	-	2E+3	8E-7	3E-9	-	-
70 Ytterbium-167[2]	W, see ^{162}Yb	3E+5	8E+5	3E-4	1E-6	4E-3	4E-2
	Y, see ^{162}Yb	-	7E+5	3E-4	1E-6	-	-
70 Ytterbium-169	W, see ^{162}Yb	2E+3	8E+2	4E-7	1E-9	2E-5	2E-4
	Y, see ^{162}Yb	-	7E+2	3E-7	1E-9	-	-
70 Ytterbium-175	W, see ^{162}Yb	3E+3	4E+3	1E-6	5E-9	-	-
		LLI wall (3E+3)	-	-	-	4E-5	4E-4
	Y, see ^{162}Yb	-	3E+3	1E-6	5E-9	-	-
70 Ytterbium-177[2]	W, see ^{162}Yb	2E+4	5E+4	2E-5	7E-8	2E-4	2E-3
	Y, see ^{162}Yb	-	5E+4	2E-5	6E-8	-	-
70 Ytterbium-178[2]	W, see ^{162}Yb	1E+4	4E+4	2E-5	6E-8	2E-4	2E-3
	Y, see ^{162}Yb	-	4E+4	2E-5	5E-8	-	-
71 Lutetium-169	W, all compounds except those given for Y	3E+3	4E+3	2E-6	6E-9	3E-5	3E-4
	Y, oxides, hydroxides, and fluorides	-	4E+3	2E-6	6E-9	-	-
71 Lutetium-170	W, see ^{169}Lu	1E+3	2E+3	9E-7	3E-9	2E-5	2E-4
	Y, see ^{169}Lu	-	2E+3	8E-7	3E-9	-	-
71 Lutetium-171	W, see ^{169}Lu	2E+3	2E+3	8E-7	3E-9	3E-5	3E-4
	Y, see ^{169}Lu	-	2E+3	8E-7	3E-9	-	-
71 Lutetium-172	W, see ^{169}Lu	1E+3	1E+3	5E-7	2E-9	1E-5	1E-4
	Y, see ^{169}Lu	-	1E+3	5E-7	2E-9	-	-
71 Lutetium-173	W, see ^{169}Lu	5E+3	3E+2	1E-7	-	7E-5	7E-4
		-	Bone surf (5E+2)	-	6E-10	-	-
	Y, see ^{169}Lu	-	3E+2	1E-7	4E-10	-	-
71 Lutetium-174m	W, see ^{169}Lu	2E+3	2E+2	1E-7	-	-	-
		LLI wall (3E+3)	Bone surf (3E+2)	-	5E-10	4E-5	4E-4
	Y, see ^{169}Lu	-	2E+2	9E-8	3E-10	-	-

71 Lutetium-174	W, see ^{169}Lu	5E+3	1E+2	5E-8	-	7E-5	7E-4
		-	Bone surf (2E+2)	-	3E-10	-	-
	Y, see ^{169}Lu	-	2E+2	6E-8	2E-10	-	-
71 Lutetium-176m	W, see ^{169}Lu	8E+3	3E+4	1E-5	3E-8	1E-4	1E-3
	Y, see ^{169}Lu	-	2E+4	9E-6	3E-8	-	-
71 Lutetium-176	W, see ^{169}Lu	7E+2	5E+0	2E-9	-	1E-5	1E-4
		-	Bone surf (1E+1)	-	2E-11	-	-
	Y, see ^{169}Lu	-	8E+0	3E-9	1E-11	-	-
71 Lutetium-177m	W, see ^{169}Lu	7E+2	1E+2	5E-8	-	1E-5	1E-4
		-	Bone surf (1E+2)	-	2E-10	-	-
	Y, see ^{169}Lu	-	8E+1	3E-8	1E-10	-	-
71 Lutetium-177	W, see ^{169}Lu	2E+3	2E+3	9E-7	3E-9	-	-
		LLI wall (3E+3)	-	-	-	4E-5	4E-4
	Y, see ^{169}Lu	-	2E+3	9E-7	3E-9	-	-
71 Lutetium-178m[2]	W, see ^{169}Lu	5E+4	2E+5	8E-5	3E-7	-	-
		St. wall (6E+4)	-	-	-	8E-4	8E-3
	Y, see ^{169}Lu	-	2E+5	7E-5	2E-7	-	-
71 Lutetium-178[2]	W, see ^{169}Lu	4E+4	1E+5	5E-5	2E-7	-	-
		St. wall (4E+4)	-	-	-	6E-4	6E-3
	Y, see ^{169}Lu	-	1E+5	5E-5	2E-7	-	-
71 Lutetium-179	W, see ^{169}Lu	6E+3	2E+4	8E-6	3E-8	9E-5	9E-4
	Y, see ^{169}Lu	-	2E+4	6E-6	3E-8	-	-
72 Hafnium-170	D, all compounds except those given for W	3E+3	6E+3	2E-6	8E-9	4E-5	4E-4

	W, oxides, hydroxides, carbides, and nitrates	-	5E+3	2E-6	6E-9	-	-
72 Hafnium-172	D, see ^{170}Hf	1E+3	9E+0	4E-9	-	2E-5	2E-4
			Bone surf				
		-	(2E+1)	-	3E-11	-	-
	W, see ^{170}Hf	-	4E+1	2E-8	-	-	-
			Bone surf				
		-	(6E+1)	-	8E-11	-	-
72 Hafnium-173	D, see ^{170}Hf	5E+3	1E+4	5E-6	2E-8	7E-5	7E-4
	W, see ^{170}Hf	-	1E+4	5E-6	2E-8	-	-
72 Hafnium-175	D, see ^{170}Hf	3E+3	9E+2	4E-7	-	4E-5	4E-4
			Bone surf				
		-	(1E+3)	-	1E-9	-	-
	W, see ^{170}Hf	-	1E+3	5E-7	2E-9	-	-
72 Hafnium-177m[2]	D, see ^{170}Hf	2E+4	6E+4	2E-5	8E-8	3E-4	3E-3
	W, see ^{170}Hf	-	9E+4	4E-5	1E-7	-	-
72 Hafnium-178m	D, see ^{170}Hf	3E+2	1E+0	5E-10	-	3E-6	3E-5
			Bone surf				
		-	(2E+0)	-	3E-12	-	-
	W, see ^{170}Hf	-	5E+0	2E-9	-	-	-
			Bone surf				
		-	(9E+0)	-	1E-11	-	-
72 Hafnium-179m	D, see ^{170}Hf	1E+3	3E+2	1E-7	-	1E-5	1E-4
			Bone surf				
		-	(6E+2)	-	8E-10	-	-
	W, see ^{170}Hf	-	6E+2	3E-7	8E-10	-	-
72 Hafnium-180m	D, see ^{170}Hf	7E+3	2E+4	9E-6	3E-8	1E-4	1E-3
	W, see ^{170}Hf	-	3E+4	1E-5	4E-8	-	-
72 Hafnium-181	D, see ^{170}Hf	1E+3	2E+2	7E-8	-	2E-5	2E-4

		-	Bone surf (4E+2)	-	6E-10	-	-
	W, see ^{170}Hf	-	4E+2	2E-7	6E-10	-	-
72 Hafnium-182m[2]	D, see ^{170}Hf	4E+4	9E+4	4E-5	1E-7	5E-4	5E-3
	W, see ^{170}Hf	-	1E+5	6E-5	2E-7	-	-
72 Hafnium-182	D, see ^{170}Hf	2E+2	8E-1	3E-10	-	-	-
		Bone surf (4E+2)	Bone surf (2E+0)	-	2E-12	5E-6	5E-5
	W, see ^{170}Hf	-	3E+0	1E-9	-	-	-
		-	Bone surf (7E+0)	-	1E-11	-	-
72 Hafnium-183[2]	D, see ^{170}Hf	2E+4	5E+4	2E-5	6E-8	3E-4	3E-3
	W, see ^{170}Hf	-	6E+4	2E-5	8E-8	-	-
72 Hafnium-184	D, see ^{170}Hf	2E+3	8E+3	3E-6	1E-8	3E-5	3E-4
	W, see ^{170}Hf	-	6E+3	3E-6	9E-9	-	-
73 Tantalum-172[2]	W, all compounds except those given for Y	4E+4	1E+5	5E-5	2E-7	5E-4	5E-3
	Y, elemental Ta, oxides, hydroxides, halides, carbides, nitrates, and nitrides	-	1E+5	4E-5	1E-7	-	-
73 Tantalum-173	W, see ^{172}Ta	7E+3	2E+4	8E-6	3E-8	9E-5	9E-4
	Y, see ^{172}Ta	-	2E+4	7E-6	2E-8	-	-
73 Tantalum-174[2]	W, see ^{172}Ta	3E+4	1E+5	4E-5	1E-7	4E-4	4E-3
	Y, see ^{172}Ta	-	9E+4	4E-5	1E-7	-	-
73 Tantalum-175	W, see ^{172}Ta	6E+3	2E+4	7E-6	2E-8	8E-5	8E-4
	Y, see ^{172}Ta	-	1E+4	6E-6	2E-8	-	-
73 Tantalum-176	W, see ^{172}Ta	4E+3	1E+4	5E-6	2E-8	5E-5	5E-4
	Y, see ^{172}Ta	-	1E+4	5E-6	2E-8	-	-
73 Tantalum-177	W, see ^{172}Ta	1E+4	2E+4	8E-6	3E-8	2E-4	2E-3
	Y, see ^{172}Ta	-	2E+4	7E-6	2E-8	-	-

73 Tantalum-178	W, see ^{172}Ta	2E+4	9E+4	4E-5	1E-7	2E-4	2E-3
	Y, see ^{172}Ta	-	7E+4	3E-5	1E-7	-	-
73 Tantalum-179	W, see ^{172}Ta	2E+4	5E+3	2E-6	8E-9	3E-4	3E-3
	Y, see ^{172}Ta	-	9E+2	4E-7	1E-9	-	-
73 Tantalum-180m	W, see ^{172}Ta	2E+4	7E+4	3E-5	9E-8	3E-4	3E-3
	Y, see ^{172}Ta	-	6E+4	2E-5	8E-8	-	-
73 Tantalum-180	W, see ^{172}Ta	1E+3	4E+2	2E-7	6E-10	2E-5	2E-4
	Y, see ^{172}Ta	-	2E+1	1E-8	3E-11	-	-
73 Tantalum-182m[2]	W, see ^{172}Ta	2E+5	5E+5	2E-4	8E-7	-	-
		St. wall (2E+5)	-	-	-	3E-3	3E-2
	Y, see ^{172}Ta	-	4E+5	2E-4	6E-7	-	-
73 Tantalum-182	W, see ^{172}Ta	8E+2	3E+2	1E-7	5E-10	1E-5	1E-4
	Y, see ^{172}Ta	-	1E+2	6E-8	2E-10	-	-
73 Tantalum-183	W, see ^{172}Ta	9E+2	1E+3	5E-7	2E-9	-	-
		LLI wall (1E+3)	-	-	-	2E-5	2E-4
	Y, see ^{172}Ta	-	1E+3	4E-7	1E-9	-	-
73 Tantalum-184	W, see ^{172}Ta	2E+3	5E+3	2E-6	8E-9	3E-5	3E-4
	Y, see ^{172}Ta	-	5E+3	2E-6	7E-9	-	-
73 Tantalum-185[2]	W, see ^{172}Ta	3E+4	7E+4	3E-5	1E-7	4E-4	4E-3
	Y, see ^{172}Ta	-	6E+4	3E-5	9E-8	-	-
73 Tantalum-186[2]	W, see ^{172}Ta	5E+4	2E+5	1E-4	3E-7	-	-
		St. wall (7E+4)	-	-	-	1E-3	1E-2
	Y, see ^{172}Ta	-	2E+5	9E-5	3E-7	-	-
74 Tungsten-176	D, all compounds	1E+4	5E+4	2E-5	7E-8	1E-4	1E-3
74 Tungsten-177	D, all compounds	2E+4	9E+4	4E-5	1E-7	3E-4	3E-3
74 Tungsten-178	D, all compounds	5E+3	2E+4	8E-6	3E-8	7E-5	7E-4
74 Tungsten-179[2]	D, all compounds	5E+5	2E+6	7E-4	2E-6	7E-3	7E-2
74 Tungsten-181	D, all compounds	2E+4	3E+4	1E-5	5E-8	2E-4	2E-3
74 Tungsten-185	D, all compounds	2E+3	7E+3	3E-6	9E-9	-	-

		LLI wall (3E+3)	-	-	-	4E-5	4E-4
74 Tungsten-187	D, all compounds	2E+3	9E+3	4E-6	1E-8	3E-5	3E-4
74 Tungsten-188	D, all compounds	4E+2	1E+3	5E-7	2E-9	-	-
		LLI wall (5E+2)	-	-	-	7E-6	7E-5
75 Rhenium-177[2]	D, all compounds except those given for W	9E+4	3E+5	1E-4	4E-7	-	-
		St. wall (1E+5)	-	-	-	2E-3	2E-2
	W, oxides, hydroxides, and nitrates	-	4E+5	1E-4	5E-7	-	-
75 Rhenium-178[2]	D, see ^{177}Re	7E+4	3E+5	1E-4	4E-7	-	-
		St. wall (1E+5)	-	-	-	1E-3	1E-2
	W, see ^{177}Re	-	3E+5	1E-4	4E-7	-	-
75 Rhenium-181	D, see ^{177}Re	5E+3	9E+3	4E-6	1E-8	7E-5	7E-4
	W, see ^{177}Re	-	9E+3	4E-6	1E-8	-	-
75 Rhenium-182 (12.7h)	D, see ^{177}Re	7E+3	1E+4	5E-6	2E-8	9E-5	9E-4
	W, see ^{177}Re	-	2E+4	6E-6	2E-8	-	-
75 Rhenium-182 (64.0h)	D, see ^{177}Re	1E+3	2E+3	1E-6	3E-9	2E-5	2E-4
	W, see ^{177}Re	-	2E+3	9E-7	3E-9	-	-
75 Rhenium-184m	D, see ^{177}Re	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
	W, see ^{177}Re	-	4E+2	2E-7	6E-10	-	-
75 Rhenium-184	D, see ^{177}Re	2E+3	4E+3	1E-6	5E-9	3E-5	3E-4
	W, see ^{177}Re	-	1E+3	6E-7	2E-9	-	-
75 Rhenium-186m	D, see ^{177}Re	1E+3	2E+3	7E-7	-	-	-
		St. wall (2E+3)	St. wall (2E+3)	-	3E-9	2E-5	2E-4
	W, see ^{177}Re	-	2E+2	6E-8	2E-10	-	-
75 Rhenium-186	D, see ^{177}Re	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
	W, see ^{177}Re	-	2E+3	7E-7	2E-9	-	-
75 Rhenium-187	D, see ^{177}Re	6E+5	8E+5	4E-4	-	8E-3	8E-2
			St. wall				

		-	(9E+5)	-	1E-6	-	-
	W, see ^{177}Re	-	1E+5	4E-5	1E-7	-	-
75 Rhenium-188m[2]	D, see ^{177}Re	8E+4	1E+5	6E-5	2E-7	1E-3	1E-2
	W, see ^{177}Re	-	1E+5	6E-5	2E-7	-	-
75 Rhenium-188	D, see ^{177}Re	2E+3	3E+3	1E-6	4E-9	2E-5	2E-4
	W, see ^{177}Re	-	3E+3	1E-6	4E-9	-	-
75 Rhenium-189	D, see ^{177}Re	3E+3	5E+3	2E-6	7E-9	4E-5	4E-4
	W, see ^{177}Re	-	4E+3	2E-6	6E-9	-	-
76 Osmium-180[2]	D, all compounds except those given for W and Y	1E+5	4E+5	2E-4	5E-7	1E-3	1E-2
	W, halides and nitrates	-	5E+5	2E-4	7E-7	-	-
	Y, oxides and hydroxides	-	5E+5	2E-4	6E-7	-	-
76 Osmium-181[2]	D, see ^{180}Os	1E+4	4E+4	2E-5	6E-8	2E-4	2E-3
	W, see ^{180}Os	-	5E+4	2E-5	6E-8	-	-
	Y, see ^{180}Os	-	4E+4	2E-5	6E-8	-	-
76 Osmium-182	D, see ^{180}Os	2E+3	6E+3	2E-6	8E-9	3E-5	3E-4
	W, see ^{180}Os	-	4E+3	2E-6	6E-9	-	-
	Y, see ^{180}Os	-	4E+3	2E-6	6E-9	-	-
76 Osmium-185	D, see ^{180}Os	2E+3	5E+2	2E-7	7E-10	3E-5	3E-4
	W, see ^{180}Os	-	8E+2	3E-7	1E-9	-	-
	Y, see ^{180}Os	-	8E+2	3E-7	1E-9	-	-
76 Osmium-189m	D, see ^{180}Os	8E+4	2E+5	1E-4	3E-7	1E-3	1E-2
	W, see ^{180}Os	-	2E+5	9E-5	3E-7	-	-
	Y, see ^{180}Os	-	2E+5	7E-5	2E-7	-	-
76 Osmium-191m	D, see ^{180}Os	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
	W, see ^{180}Os	-	2E+4	8E-6	3E-8	-	-
	Y, see ^{180}Os	-	2E+4	7E-6	2E-8	-	-
76 Osmium-191	D, see ^{180}Os	2E+3	2E+3	9E-7	3E-9	-	-
		LLI wall (3E+3)	-	-	-	3E-5	3E-4
	W, see ^{180}Os	-	2E+3	7E-7	2E-9	-	-
	Y, see ^{180}Os	-	1E+3	6E-7	2E-9	-	-

76 Osmium-193	D, see ^{180}Os	2E+3	5E+3	2E-6	6E-9	-	-
		LLI wall (2E+3)	-	-	-	2E-5	2E-4
	W, see ^{180}Os	-	3E+3	1E-6	4E-9	-	-
	Y, see ^{180}Os	-	3E+3	1E-6	4E-9	-	-
76 Osmium-194	D, see ^{180}Os	4E+2	4E+1	2E-8	6E-11	-	-
		LLI wall (6E+2)	-	-	-	8E-6	8E-5
	W, see ^{180}Os	-	6E+1	2E-8	8E-11	-	-
	Y, see ^{180}Os	-	8E+0	3E-9	1E-11	-	-
77 Iridium-182[2]	D, all compounds except those given for W and Y	4E+4	1E+5	6E-5	2E-7	-	-
		St. wall (4E+4)	-	-	-	6E-4	6E-3
	W, halides, nitrates, and metallic iridium	-	2E+5	6E-5	2E-7	-	-
	Y, oxides and hydroxides	-	1E+5	5E-5	2E-7	-	-
77 Iridium-184	D, see ^{182}Ir	8E+3	2E+4	1E-5	3E-8	1E-4	1E-3
	W, see ^{182}Ir	-	3E+4	1E-5	5E-8	-	-
	Y, see ^{182}Ir	-	3E+4	1E-5	4E-8	-	-
77 Iridium-185	D, see ^{182}Ir	5E+3	1E+4	5E-6	2E-8	7E-5	7E-4
	W, see ^{182}Ir	-	1E+4	5E-6	2E-8	-	-
	Y, see ^{182}Ir	-	1E+4	4E-6	1E-8	-	-
77 Iridium-186	D, see ^{182}Ir	2E+3	8E+3	3E-6	1E-8	3E-5	3E-4
	W, see ^{182}Ir	-	6E+3	3E-6	9E-9	-	-
	Y, see ^{182}Ir	-	6E+3	2E-6	8E-9	-	-
77 Iridium-187	D, see ^{182}Ir	1E+4	3E+4	1E-5	5E-8	1E-4	1E-3
	W, see ^{182}Ir	-	3E+4	1E-5	4E-8	-	-
	Y, see ^{182}Ir	-	3E+4	1E-5	4E-8	-	-
77 Iridium-188	D, see ^{182}Ir	2E+3	5E+3	2E-6	6E-9	3E-5	3E-4
	W, see ^{182}Ir	-	4E+3	1E-6	5E-9	-	-
	Y, see ^{182}Ir	-	3E+3	1E-6	5E-9	-	-
77 Iridium-189	D, see ^{182}Ir	5E+3	5E+3	2E-6	7E-9	-	-
		LLI wall (5E+3)	-	-	-	7E-5	7E-4
	W, see ^{182}Ir	-	4E+3	2E-6	5E-9	-	-
	Y, see ^{182}Ir	-	4E+3	1E-6	5E-9	-	-

77 Iridium-190m[2]	D, see ^{182}Ir	2E+5	2E+5	8E-5	3E-7	2E-3	2E-2
	W, see ^{182}Ir	-	2E+5	9E-5	3E-7	-	-
	Y, see ^{182}Ir	-	2E+5	8E-5	3E-7	-	-
77 Iridium-190	D, see ^{182}Ir	1E+3	9E+2	4E-7	1E-9	1E-5	1E-4
	W, see ^{182}Ir	-	1E+3	4E-7	1E-9	-	-
	Y, see ^{182}Ir	-	9E+2	4E-7	1E-9	-	-
77 Iridium-192m	D, see ^{182}Ir	3E+3	9E+1	4E-8	1E-10	4E-5	4E-4
	W, see ^{182}Ir	-	2E+2	9E-8	3E-10	-	-
	Y, see ^{182}Ir	-	2E+1	6E-9	2E-11	-	-
77 Iridium-192	D, see ^{182}Ir	9E+2	3E+2	1E-7	4E-10	1E-5	1E-4
	W, see ^{182}Ir	-	4E+2	2E-7	6E-10	-	-
	Y, see ^{182}Ir	-	2E+2	9E-8	3E-10	-	-
77 Iridium-194m	D, see ^{182}Ir	6E+2	9E+1	4E-8	1E-10	9E-6	9E-5
	W, see ^{182}Ir	-	2E+2	7E-8	2E-10	-	-
	Y, see ^{182}Ir	-	1E+2	4E-8	1E-10	-	-
77 Iridium-194	D, see ^{182}Ir	1E+3	3E+3	1E-6	4E-9	1E-5	1E-4
	W, see ^{182}Ir	-	2E+3	9E-7	3E-9	-	-
	Y, see ^{182}Ir	-	2E+3	8E-7	3E-9	-	-
77 Iridium-195m	D, see ^{182}Ir	8E+3	2E+4	1E-5	3E-8	1E-4	1E-3
	W, see ^{182}Ir	-	3E+4	1E-5	4E-8	-	-
	Y, see ^{182}Ir	-	2E+4	9E-6	3E-8	-	-
77 Iridium-195	D, see ^{182}Ir	1E+4	4E+4	2E-5	6E-8	2E-4	2E-3
	W, see ^{182}Ir	-	5E+4	2E-5	7E-8	-	-
	Y, see ^{182}Ir	-	4E+4	2E-5	6E-8	-	-
78 Platinum-186	D, all compounds	1E+4	4E+4	2E-5	5E-8	2E-4	2E-3
78 Platinum-188	D, all compounds	2E+3	2E+3	7E-7	2E-9	2E-5	2E-4
78 Platinum-189	D, all compounds	1E+4	3E+4	1E-5	4E-8	1E-4	1E-3
78 Platinum-191	D, all compounds	4E+3	8E+3	4E-6	1E-8	5E-5	5E-4
78 Platinum-193m	D, all compounds	3E+3	6E+3	3E-6	8E-9	-	-
		LLI wall (3E+4)	-	-	-	4E-5	4E-4
78 Platinum-193	D, all compounds	4E+4	2E+4	1E-5	3E-8	-	-
		LLI wall (5E+4)	-	-	-	6E-4	6E-3
78 Platinum-195m	D, all compounds	2E+3	4E+3	2E-6	6E-9	-	-

		LLI wall (2E+3)	-	-	-	3E-5	3E-4
78 Platinum-197m[2]	D, all compounds	2E+4	4E+4	2E-5	6E-8	2E-4	2E-3
78 Platinum-197	D, all compounds	3E+3	1E+4	4E-6	1E-8	4E-5	4E-4
78 Platinum-199[2]	D, all compounds	5E+4	1E+5	6E-5	2E-7	7E-4	7E-3
78 Platinum-200	D, all compounds	1E+3	3E+3	1E-6	5E-9	2E-5	2E-4
79 Gold-193	D, all compounds except those given for W and Y	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3
	W, halides and nitrates	-	2E+4	9E-6	3E-8	-	-
	Y, oxides and hydroxides	-	2E+4	8E-6	3E-8	-	-
79 Gold-194	D, see ^{193}Au	3E+3	8E+3	3E-6	1E-8	4E-5	4E-4
	W, see ^{193}Au	-	5E+3	2E-6	8E-9	-	-
	Y, see ^{193}Au	-	5E+3	2E-6	7E-9	-	-
79 Gold-195	D, see ^{193}Au	5E+3	1E+4	5E-6	2E-8	7E-5	7E-4
	W, see ^{193}Au	-	1E+3	6E-7	2E-9	-	-
	Y, see ^{193}Au	-	4E+2	2E-7	6E-10	-	-
79 Gold-198m	D, see ^{193}Au	1E+3	3E+3	1E-6	4E-9	1E-5	1E-4
	W, see ^{193}Au	-	1E+3	5E-7	2E-9	-	-
	Y, see ^{193}Au	-	1E+3	5E-7	2E-9	-	-
79 Gold-198	D, see ^{193}Au	1E+3	4E+3	2E-6	5E-9	2E-5	2E-4
	W, see ^{193}Au	-	2E+3	8E-7	3E-9	-	-
	Y, see ^{193}Au	-	2E+3	7E-7	2E-9	-	-
79 Gold-199	D, see ^{193}Au	3E+3	9E+3	4E-6	1E-8	-	-
		LLI wall (3E+3)	-	-	-	4E-5	4E-4
	W, see ^{193}Au	-	4E+3	2E-6	6E-9	-	-
	Y, see ^{193}Au	-	4E+3	2E-6	5E-9	-	-
79 Gold-200m	D, see ^{193}Au	1E+3	4E+3	1E-6	5E-9	2E-5	2E-4
	W, see ^{193}Au	-	3E+3	1E-6	4E-9	-	-
	Y, see ^{193}Au	-	2E+4	1E-6	3E-9	-	-

79 Gold-200[2]	D, see ^{193}Au	3E+4	6E+4	3E-5	9E-8	4E-4	4E-3
	W, see ^{193}Au	-	8E+4	3E-5	1E-7	-	-
	Y, see ^{193}Au	-	7E+4	3E-5	1E-7	-	-
79 Gold-201[2]	D, see ^{193}Au	7E+4	2E+5	9E-5	3E-7	-	-
		St. wall (9E+4)	-	-	-	1E-3	1E-2
	W, see ^{193}Au	-	2E+5	1E-4	3E-7	-	-
	Y, see ^{193}Au	-	2E+5	9E-5	3E-7	-	-
80 Mercury-193m	Vapor	-	8E+3	4E-6	1E-8	-	-
	Organic D	4E+3	1E+4	5E-6	2E-8	6E-5	6E-4
	D, sulfates	3E+3	9E+3	4E-6	1E-8	4E-5	4E-4
	W, oxides, hydroxides, halides, nitrates, and sulfides	-	8E+3	3E-6	1E-8	-	-
80 Mercury-193	Vapor	-	3E+4	1E-5	4E-8	-	-
	Organic D	2E+4	6E+4	3E-5	9E-8	3E-4	3E-3
	D, see ^{193m}Hg	2E+4	4E+4	2E-5	6E-8	2E-4	2E-3
	W, see ^{193m}Hg	-	4E+4	2E-5	6E-8	-	-
80 Mercury-194	Vapor	-	3E+1	1E-8	4E-11	-	-
	Organic D	2E+1	3E+1	1E-8	4E-11	2E-7	2E-6
	D, see ^{193m}Hg	8E+2	4E+1	2E-8	6E-11	1E-5	1E-4
	W, see ^{193m}Hg	-	1E+2	5E-8	2E-10	-	-
80 Mercury-195m	Vapor	-	4E+3	2E-6	6E-9	-	-
	Organic D	3E+3	6E+3	3E-6	8E-9	4E-5	4E-4
	D, see ^{193m}Hg	2E+3	5E+3	2E-6	7E-9	3E-5	3E-4
	W, see ^{193m}Hg	-	4E+3	2E-6	5E-9	-	-
80 Mercury-195	Vapor	-	3E+4	1E-5	4E-8	-	-
	Organic D	2E+4	5E+4	2E-5	6E-8	2E-4	2E-3
	D, see ^{193m}Hg	1E+4	4E+4	1E-5	5E-8	2E-4	2E-3
	W, see ^{193m}Hg	-	3E+4	1E-5	5E-8	-	-
80 Mercury-197m	Vapor	-	5E+3	2E-6	7E-9	-	-
	Organic D	4E+3	9E+3	4E-6	1E-8	5E-5	5E-4

	D, see ^{193m}Hg	3E+3	7E+3	3E-6	1E-8	4E-5	4E-4
	W, see ^{193m}Hg	-	5E+3	2E-6	7E-9	-	-
80 Mercury-197	Vapor	-	8E+3	4E-6	1E-8	-	-
	Organic D	7E+3	1E+4	6E-6	2E-8	9E-5	9E-4
	D, see ^{193m}Hg	6E+3	1E+4	5E-6	2E-8	8E-5	8E-4
	W, see ^{193m}Hg	-	9E+3	4E-6	1E-8	-	-
80 Mercury-199m[2]	Vapor	-	8E+4	3E-5	1E-7	-	-
	Organic D	6E+4	2E+5	7E-5	2E-7	-	-
		St. wall (1E+5)	-	-	-	1E-3	1E-2
	D, see ^{193m}Hg	6E+4	1E+5	6E-5	2E-7	8E-4	8E-3
	W, see ^{193m}Hg	-	2E+5	7E-5	2E-7	-	-
80 Mercury-203	Vapor	-	8E+2	4E-7	1E-9	-	-
	Organic D	5E+2	8E+2	3E-7	1E-9	7E-6	7E-5
	D, see ^{193m}Hg	2E+3	1E+3	5E-7	2E-9	3E-5	3E-4
	W, see ^{193m}Hg	-	1E+3	5E-7	2E-9	-	-
81 Thallium-194m[2]	D, all compounds	5E+4	2E+5	6E-5	2E-7	-	-
		St. wall (7E+4)	-	-	-	1E-3	1E-2
81 Thallium-194[2]	D, all compounds	3E+5	6E+5	2E-4	8E-7	-	-
		St. wall (3E+5)	-	-	-	4E-3	4E-2
81 Thallium-195[2]	D, all compounds	6E+4	1E+5	5E-5	2E-7	9E-4	9E-3
81 Thallium-197	D, all compounds	7E+4	1E+5	5E-5	2E-7	1E-3	1E-2
81 Thallium-198m[2]	D, all compounds	3E+4	5E+4	2E-5	8E-8	4E-4	4E-3
81 Thallium-198	D, all compounds	2E+4	3E+4	1E-5	5E-8	3E-4	3E-3
81 Thallium-199	D, all compounds	6E+4	8E+4	4E-5	1E-7	9E-4	9E-3
81 Thallium-200	D, all compounds	8E+3	1E+4	5E-6	2E-8	1E-4	1E-3
81 Thallium-201	D, all compounds	2E+4	2E+4	9E-6	3E-8	2E-4	2E-3
81 Thallium-202	D, all compounds	4E+3	5E+3	2E-6	7E-9	5E-5	5E-4

81 Thallium-204	D, all compounds	2E+3	2E+3	9E-7	3E-9	2E-5	2E-4
82 Lead-195m[2]	D, all compounds	6E+4	2E+5	8E-5	3E-7	8E-4	8E-3
82 Lead-198	D, all compounds	3E+4	6E+4	3E-5	9E-8	4E-4	4E-3
82 Lead-199[2]	D, all compounds	2E+4	7E+4	3E-5	1E-7	3E-4	3E-3
82 Lead-200	D, all compounds	3E+3	6E+3	3E-6	9E-9	4E-5	4E-4
82 Lead-201	D, all compounds	7E+3	2E+4	8E-6	3E-8	1E-4	1E-3
82 Lead-202m	D, all compounds	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3
82 Lead-202	D, all compounds	1E+2	5E+1	2E-8	7E-11	2E-6	2E-5
82 Lead-203	D, all compounds	5E+3	9E+3	4E-6	1E-8	7E-5	7E-4
82 Lead-205	D, all compounds	4E+3	1E+3	6E-7	2E-9	5E-5	5E-4
82 Lead-209	D, all compounds	2E+4	6E+4	2E-5	8E-8	3E-4	3E-3
82 Lead-210	D, all compounds	6E-1	2E-1	1E-10	-	-	-
		Bone surf (1E+0)	Bone surf (4E-1)	-	6E-13	1E-8	1E-7
82 Lead-211[2]	D, all compounds	1E+4	6E+2	3E-7	9E-10	2E-4	2E-3
82 Lead-212	D, all compounds	8E+1	3E+1	1E-8	5E-11	-	-
		Bone surf (1E+2)	-	-	-	2E-6	2E-5
82 Lead-214[2]	D, all compounds	9E+3	8E+2	3E-7	1E-9	1E-4	1E-3
83 Bismuth-200[2]	D, nitrates	3E+4	8E+4	4E-5	1E-7	4E-4	4E-3
	W, all other compounds	-	1E+5	4E-5	1E-7	-	-
83 Bismuth-201[2]	D, see ^{200}Bi	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
	W, see ^{200}Bi	-	4E+4	2E-5	5E-8	-	-
83 Bismuth-202[2]	D, see ^{200}Bi	1E+4	4E+4	2E-5	6E-8	2E-4	2E-3
	W, see ^{200}Bi	-	8E+4	3E-5	1E-7	-	-
83 Bismuth-203	D, see ^{200}Bi	2E+3	7E+3	3E-6	9E-9	3E-5	3E-4
	W, see ^{200}Bi	-	6E+3	3E-6	9E-9	-	-

83 Bismuth-205	D, see ^{200}Bi	1E+3	3E+3	1E-6	3E-9	2E-5	2E-4
	W, see ^{200}Bi	-	1E+3	5E-7	2E-9	-	-
83 Bismuth-206	D, see ^{200}Bi	6E+2	1E+3	6E-7	2E-9	9E-6	9E-5
	W, see ^{200}Bi	-	9E+2	4E-7	1E-9	-	-
83 Bismuth-207	D, see ^{200}Bi	1E+3	2E+3	7E-7	2E-9	1E-5	1E-4
	W, see ^{200}Bi	-	4E+2	1E-7	5E-10	-	-
83 Bismuth-210m	D, see ^{200}Bi	4E+1	5E+0	2E-9	-	-	-
		Kidneys (6E+1)	Kidneys (6E+0)	-	9E-12	8E-7	8E-6
	W, see ^{200}Bi	-	7E-1	3E-10	9E-13	-	-
83 Bismuth-210	D, see ^{200}Bi	8E+2	2E+2	1E-7	-	1E-5	1E-4
		-	Kidneys (4E+2)	-	5E-10	-	-
	W, see ^{200}Bi	-	3E+1	1E-8	4E-11	-	-
83 Bismuth-212[2]	D, see ^{200}Bi	5E+3	2E+2	1E-7	3E-10	7E-5	7E-4
	W, see ^{200}Bi	-	3E+2	1E-7	4E-10	-	-
83 Bismuth-213[2]	D, see ^{200}Bi	7E+3	3E+2	1E-7	4E-10	1E-4	1E-3
	W, see ^{200}Bi	-	4E+2	1E-7	5E-10	-	-
83 Bismuth-214[2]	D, see ^{200}Bi	2E+4	8E+2	3E-7	1E-9	-	-
		St. wall (2E+4)	-	-	-	3E-4	3E-3
	W, see ^{200}Bi	-	9E-2	4E-7	1E-9	-	-
84 Polonium-203[2]	D, all compounds except those given for W	3E+4	6E+4	3E-5	9E-8	3E-4	3E-3
	W, oxides, hydroxides, and nitrates	-	9E+4	4E-5	1E-7	-	-
84 Polonium-205[2]	D, see ^{203}Po	2E+4	4E+4	2E-5	5E-8	3E-4	3E-3
	W, see ^{203}Po	-	7E+4	3E-5	1E-7	-	-
84 Polonium-207	D, see ^{203}Po	8E+3	3E+4	1E-5	3E-8	1E-4	1E-3
	W, see ^{203}Po	-	3E+4	1E-5	4E-8	-	-
84 Polonium-210	D, see ^{203}Po	3E+0	6E-1	3E-10	9E-13	4E-8	4E-7
	W, see ^{203}Po	-	6E-1	3E-10	9E-13	-	-
85 Astatine-207[2]	D, halides	6E+3	3E+3	1E-6	4E-9	8E-5	8E-4

	W	-	2E+3	9E-7	3E-9	-	-
85 Astatine-211	D, halides	1E+2	8E+1	3E-8	1E-10	2E-6	2E-5
	W	-	5E+1	2E-8	8E-11	-	-
86 Radon-220	With daughters removed	-	2E+4	7E-6	2E-8	-	-
	With daughters present	-	2E+1 (or 12 working level months)	9E-9 (or 1.0 working level)	3E-11	-	-
86 Radon-222	With daughters removed	-	1E+4	4E-6	1E-8	-	-
	With daughters present	-	1E+2 (or 4 working level months)	3E-8 (or 0.33 working level)	1E-10	-	-
87 Francium-222[2]	D, all compounds	2E+3	5E+2	2E-7	6E-10	3E-5	3E-4
87 Francium-223[2]	D, all compounds	6E+2	8E+2	3E-7	1E-9	8E-6	8E-5
88 Radium-223	W, all compounds	5E+0	7E-1	3E-10	9E-13	-	-
		Bone surf (9E+0)	-	-	-	1E-7	1E-6
88 Radium-224	W, all compounds	8E+0	2E+0	7E-10	2E-12	-	-
		Bone surf (2E+1)	-	-	-	2E-7	2E-6
88 Radium-225	W, all compounds	8E+0	7E-1	3E-10	9E-13	-	-
		Bone surf (2E+1)	-	-	-	2E-7	2E-6
88 Radium-226	W, all compounds	2E+0	6E-1	3E-10	9E-13	-	-
		Bone surf (5E+0)	-	-	-	6E-8	6E-7
88 Radium-227[2]	W, all compounds	2E+4	1E+4	6E-6	-	-	-
		Bone	Bone				

		surf (2E+4)	surf (2E+4)	-	3E-8	3E-4	3E-3
88 Radium-228	W, all compounds	2E+0 Bone surf (4E+0)	1E+0 -	5E-10 -	2E-12 -	- 6E-8	- 6E-7
89 Actinium-224	D, all compounds except those given for W and Y	2E+3 LLI wall (2E+3)	3E+1 Bone surf (4E+1)	1E-8 -	- 5E-11	- 3E-5	- 3E-4
	W, halides and nitrates	-	5E+1	2E-8	7E-11	-	-
	Y, oxides and hydroxides	-	5E+1	2E-8	6E-11	-	-
89 Actinium-225	D, see ^{224}Ac	5E+1 LLI wall (5E+1)	3E-1 Bone surf (5E-1)	1E-10 -	- 7E-13	- 7E-7	- 7E-6
	W, see ^{224}Ac	-	6E-1	3E-10	9E-13	-	-
	Y, see ^{224}Ac	-	6E-1	3E-10	9E-13	-	-
89 Actinium-226	D, see ^{224}Ac	1E+2 LLI wall (1E+2)	3E+0 Bone surf (4E+0)	1E-9 -	- 5E-12	- 2E-6	- 2E-5
	W, see ^{224}Ac	-	5E+0	2E-9	7E-12	-	-
	Y, see ^{224}Ac	-	5E+0	2E-9	6E-12	-	-
89 Actinium-227	D, see ^{224}Ac	2E-1 Bone surf (4E-1)	4E-4 Bone surf (8E-4)	2E-13 -	- 1E-15	- 5E-9	- 5E-8
	W, see ^{224}Ac	-	2E-3 Bone surf (3E-3)	7E-13 -	- 4E-15	- -	- -
	Y, see ^{224}Ac	-	4E-3	2E-12	6E-15	-	-
89 Actinium-228	D, see ^{224}Ac	2E+3	9E+0	4E-9	-	3E-5	3E-4

		-	Bone surf (2E+1)	-	2E-11	-	-
	W, see ^{224}Ac	-	4E+1	2E-8	-	-	-
		-	Bone surf (6E+1)	-	8E-11	-	-
	Y, see ^{224}Ac	-	4E+1	2E-8	6E-11	-	-
90 Thorium-226[2]	W, all compounds except those given for Y	5E+3	2E+2	6E-8	2E-10	-	-
		St. wall (5E+3)	-	-	-	7E-5	7E-4
	Y, oxides and hydroxides	-	1E+2	6E-8	2E-10	-	-
90 Thorium-227	W, see ^{226}Th	1E+2	3E-1	1E-10	5E-13	2E-6	2E-5
	Y, see ^{226}Th	-	3E-1	1E-10	5E-13	-	-
90 Thorium-228	W, see ^{226}Th	6E+0	1E-2	4E-12	-	-	-
		Bone surf (1E+1)	Bone surf (2E-2)	-	3E-14	2E-7	2E-6
	Y, see ^{226}Th	-	2E-2	7E-12	2E-14	-	-
90 Thorium-229	W, see ^{226}Th	6E-1	9E-4	4E-13	-	-	-
		Bone surf (1E+0)	Bone surf (2E-3)	-	3E-15	2E-8	2E-7
	Y, see ^{226}Th	-	2E-3	1E-12	-	-	-
		-	Bone surf (3E-3)	-	4E-15	-	-
90 Thorium-230	W, see ^{226}Th	4E+0	6E-3	3E-12	-	-	-
		Bone surf (9E+0)	Bone surf (2E-2)	-	2E-14	1E-7	1E-6
	Y, see ^{226}Th	-	2E-2	6E-12	-	-	-
		-	Bone surf (2E-2)	-	3E-14	-	-

90 Thorium-231	W, see ^{226}Th	4E+3	6E+3	3E-6	9E-9	5E-5	5E-4
	Y, see ^{226}Th	-	6E+3	3E-6	9E-9	-	-
90 Thorium-232	W, see ^{226}Th	7E-1	1E-3	5E-13	-	-	-
		Bone surf	Bone surf				
		(2E+0)	(3E-3)	-	4E-15	3E-8	3E-7
	Y, see ^{226}Th	-	3E-3	1E-12	-	-	-
			Bone surf				
		-	(4E-3)	-	6E-15	-	-
90 Thorium-234	W, see ^{226}Th	3E+2	2E+2	8E-8	3E-10	-	-
		LLI wall					
		(4E+2)	-	-	-	5E-6	5E-5
	Y, see ^{226}Th	-	2E+2	6E-8	2E-10	-	-
91 Protactinium-227[2]	W, all compounds except those given for Y	4E+3	1E+2	5E-8	2E-10	5E-5	5E-4
	Y, oxides and hydroxides	-	1E+2	4E-8	1E-10	-	-
91 Protactinium-228	W, see ^{227}Pa	1E+3	1E+1	5E-9	-	2E-5	2E-4
			Bone surf				
		-	(2E+1)	-	3E-11	-	-
	Y, see ^{226}Pa	-	1E+1	5E-9	2E-11	-	-
91 Protactinium-230	W, see ^{227}Pa	6E+2	5E+0	2E-9	7E-12	-	-
		Bone surf					
		(9E+2)	-	-	-	1E-5	1E-4
	Y, see ^{227}Pa	-	4E+0	1E-9	5E-12	-	-
91 Protactinium-231	W, see ^{227}Pa	2E-1	2E-3	6E-13	-	-	-
		Bone surf	Bone surf				
		(5E-1)	(4E-3)	-	6E-15	6E-9	6E-8
	Y, see ^{226}Pa	-	4E-3	2E-12	-	-	-
			Bone surf				
		-	(6E-3)	-	8E-15	-	-

91 Protactinium-232	W, see ^{227}Pa	1E+3	2E+1	9E-9	-	2E-5	2E-4
		-	Bone surf (6E+1)	-	8E-11	-	-
	Y, see ^{227}Pa	-	6E+1	2E-8	-	-	-
		-	Bone surf (7E+1)	-	1E-10	-	-
91 Protactinium-233	W, see ^{227}Pa	1E+3	7E+2	3E-7	1E-9	-	-
		LLI wall (2E+3)	-	-	-	2E-5	2E-4
	Y, see ^{227}Pa	-	6E+2	2E-7	8E-10	-	-
91 Protactinium-234	W, see ^{227}Pa	2E+3	8E+3	3E-6	1E-8	3E-5	3E-4
	Y, see ^{227}Pa	-	7E+3	3E-6	9E-9	-	-
92 Uranium-230	D, UF_6, UO_2F_2, $UO_2(NO_3)_2$	4E+0	4E-1	2E-10	-	-	-
		Bone surf (6E+0)	Bone surf (6E-1)	-	8E-13	8E-8	8E-7
	W, UO_3, UF_4, UCl_4	-	4E-1	1E-10	5E-13	-	-
	Y, UO_2, U_3O_8	-	3E-1	1E-10	4E-13	-	-
92 Uranium-231	D, see ^{230}U	5E+3	8E+3	3E-6	1E-8	-	-
		LLI wall (4E+3)	-	-	-	6E-5	6E-4
	W, see ^{230}U	-	6E+3	2E-6	8E-9	-	-
	Y, see ^{230}U	-	5E+3	2E-6	6E-9	-	-
92 Uranium-232	D, see ^{230}U	2E+0	2E-1	9E-11	-	-	-
		Bone surf (4E+0)	Bone surf (4E-1)	-	6E-13	6E-8	6E-7
	W, see ^{230}U	-	4E-1	2E-10	5E-13	-	-
	Y, see $_{230}U$	-	8E-3	3E-12	1E-14	-	-
92 Uranium-233	D, see ^{230}U	1E+1	1E+0	5E-10	-	-	-
		Bone surf (2E+1)	Bone surf (2E+0)	-	3E-12	3E-7	3E-6

	W, see ^{230}U	-	7E-1	3E-10	1E-12	-	-
	Y, see ^{230}U	-	4E-2	2E-11	5E-14	-	-
92 Uranium-234[3]	D, see ^{230}U	1E+1 Bone surf (2E+1)	1E+0 Bone surf (2E+0)	5E-10 -	- 3E-12	- 3E-7	- 3E-6
	W, see ^{230}U	-	7E-1	3E-10	1E-12	-	-
	Y, see ^{230}U	-	4E-2	2E-11	5E-1	-	-
92 Uranium-235[3]	D, see ^{230}U	1E+1 Bone surf (2E+1)	1E+0 Bone surf (2E+0)	6E-10 -	- 3E-12	- 3E-7	- 3E-6
	W, see ^{230}U	-	8E-1	3E-10	1E-12	-	-
	Y, see ^{230}U	-	4E-2	2E-11	6E-14	-	-
92 Uranium-236	D, see ^{230}U	1E+1 Bone surf (2E+1)	1E+0 Bone surf (2E+0)	5E-10 -	- 3E-12	- 3E-7	- 3E-6
	W, see ^{230}U	-	8E-1	3E-10	1E-12	-	-
	Y, see ^{230}U	-	4E-2	2E-11	6E-14	-	-
92 Uranium-237	D, see ^{230}U	2E+3 LLI wall (2E+3)	3E+3 -	1E-6 -	4E-9 -	- 3E-5	- 3E-4
	W, see ^{230}U	-	2E+3	7E-7	2E-9	-	-
	Y, see ^{230}U	-	2E+3	6E-7	2E-9	-	-
92 Uranium-238[3]	D, see ^{230}U	1E+1 Bone surf (2E+1)	1E+0 Bone surf (2E+0)	6E-10 -	- 3E-12	- 3E-7	- 3E-6
	W, see ^{230}U	-	8E-1	3E-10	1E-12	-	-
	Y, see ^{230}U	-	4E-2	2E-11	6E-14	-	-
92 Uranium-239[2]	D, see ^{230}U	7E+4	2E+5	8E-5	3E-7	9E-4	9E-3

	W, see ^{230}U	-	2E+5	7E-5	2E-7	-	-
	Y, see ^{230}U	-	2E+5	6E-5	2E-7	-	-
92 Uranium-240	D, see ^{230}U	1E+3	4E+3	2E-6	5E-9	2E-5	2E-4
	W, see ^{230}U	-	3E+3	1E-6	4E-9	-	-
	Y, see ^{230}U	-	2E+3	1E-6	3E-9	-	-
92 Uranium-natural[3]	D, see ^{230}U	1E+1	1E+0	5E-10	-	-	-
		Bone surf	Bone surf				
		(2E+1)	(2E+0)	-	3E-12	3E-7	3E-6
	W, see ^{230}U	-	8E-1	3E-10	9E-13	-	-
	Y, see ^{230}U	-	5E-2	2E-11	9E-14	-	-
93 Neptunium-232[2]	W, all compounds	1E+5	2E+3	7E-7	-	2E-3	2E-2
			Bone surf				
		-	(5E+2)	-	6E-9	-	-
93 Neptunium-233[2]	W, all compounds	8E+5	3E+6	1E-3	4E-6	1E-2	1E-1
93 Neptunium-234	W, all compounds	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
93 Neptunium-235	W, all compounds	2E+4	8E+2	3E-7	-	-	-
		LLI wall	Bone surf				
		(2E+4)	(1E+3)	-	2E-9	3E-4	3E-3
93 Neptunium-236 (1.15E+5y)	W, all compounds	3E+0	2E-2	9E-12	-	-	-
		Bone surf	Bone surf				
		(6E+0)	(5E-2)	-	8E-14	9E-8	9E-7
93 Neptunium-236 (22.5h)	W, all compounds	3E+3	3E+1	1E-8	-	-	-
		Bone surf	Bone surf				
		(4E+3)	(7E+1)	-	1E-10	5E-5	5E-4
93 Neptunium-237	W, all compounds	5E-1	4E-3	2E-12	-	-	-
		Bone surf	Bone surf				
		(1E+0)	(1E-2)	-	1E-14	2E-8	2E-7
93 Neptunium-238	W, all compounds	1E+3	6E+1	3E-8	-	2E-5	2E-4
			Bone surf				

		-	(2E+2)	-	2E-10	-	-
93 Neptunium-239	W, all compounds	2E+3	2E+3	9E-7	3E-9	-	-
		LLI wall (2E+3)	-	-	-	2E-5	2E-4
93 Neptunium-240[2]	W, all compounds	2E+4	8E+4	3E-5	1E-7	3E-4	3E-3
94 Plutonium-234	W, all compounds except PuO_2	8E+3	2E+2	9E-8	3E-10	1E-4	1E-3
	Y, PuO_2	-	2E+2	8E-8	3E-10	-	-
94 Plutonium-235[2]	W, see ^{234}Pu	9E+5	3E+6	1E-3	4E-6	1E-2	1E-1
	Y, see ^{234}Pu	-	3E+6	1E-3	3E-6	-	-
94 Plutonium-236	W, see ^{234}Pu	2E+0	2E-2	8E-12	-	-	-
		Bone surf (4E+0)	Bone surf (4E-2)	-	5E-14	6E-8	6E-7
	Y, see ^{234}Pu	-	4E-2	2E-11	6E-14	-	-
94 Plutonium-237	W, see ^{234}Pu	1E+4	3E+3	1E-6	5E-9	2E-4	2E-3
	Y, see ^{234}Pu	-	3E+3	1E-6	4E-9	-	-
94 Plutonium-238	W, see ^{234}Pu	9E-1	7E-3	3E-12	-	-	-
		Bone surf (2E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7
	Y, see ^{234}Pu	-	2E-2	8E-12	2E-14	-	-
94 Plutonium-239	W, see ^{234}Pu	8E-1	6E-3	3E-12	-	-	-
		Bone surf (1E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7
	Y, see ^{234}Pu	-	2E-2	7E-12	-	-	-
		-	Bone surf (2E-2)	-	2E-14	-	-
94 Plutonium-240	W, see ^{234}Pu	8E-1	6E-3	3E-12	-	-	-
		Bone surf (1E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7
	Y, see ^{234}Pu	-	2E-2	7E-12	-	-	-
			Bone surf				

		-	(2E-2)	-	2E-14	-	-
94 Plutonium-241	W, see ^{234}Pu	4E+1	3E-1	1E-10	-	-	-
		Bone surf (7E+1)	Bone surf (6E-1)	-	8E-13	1E-6	1E-5
	Y, see ^{234}Pu	-	8E-1	3E-10	-	-	-
		-	Bone surf (1E+0)	-	1E-12	-	-
94 Plutonium-242	W, see ^{234}Pu	8E-1	7E-3	3E-12	-	-	-
		Bone surf (1E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7
	Y, see ^{234}Pu	-	2E-2	7E-12	-	-	-
		-	Bone surf (2E-2)	-	2E-14	-	-
94 Plutonium-243	W, see ^{234}Pu	2E+4	4E+4	2E-5	5E-8	2E-4	2E-3
	Y, see ^{234}Pu	-	4E+4	2E-5	5E-8	-	-
94 Plutonium-244	W, see ^{234}Pu	8E-1	7E-3	3E-12	-	-	-
		Bone surf (2E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7
	Y, see ^{234}Pu	-	2E-2	7E-12	-	-	-
		-	Bone surf (2E-2)	-	2E-14	-	-
94 Plutonium-245	W, see ^{234}Pu	2E+3	5E+3	2E-6	6E-9	3E-5	3E-4
	Y, see ^{234}Pu	-	4E+3	2E-6	6E-9	-	-
94 Plutonium-246	W, see ^{234}Pu	4E+2	3E+2	1E-7	4E-10	-	-
		LLI wall (4E+2)	-	-	-	6E-6	6E-5
	Y, see ^{234}Pu	-	3E+2	1E-7	4E-10	-	-
95 Americium-237[2]	W, all compounds	8E+4	3E+5	1E-4	4E-7	1E-3	1E-2
95 Americium-238[2]	W, all compounds	4E+4	3E+3	1E-6	-	5E-4	5E-3
			Bone				

		-	surf (6E+3)	-	9E-9	-	-
95	Americium-239	W, all compounds	5E+3	1E+4	5E-6	2E-8	7E-5	7E-4
95	Americium-240	W, all compounds	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
95	Americium-241	W, all compounds	8E-1	6E-3	3E-12	-	-	-
			Bone surf (1E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7
95	Americium-242m	W, all compounds	8E-1	6E-3	3E-12	-	-	-
			Bone surf (1E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7
95	Americium-242	W, all compounds	4E+3	8E+1	4E-8	-	5E-5	5E-4
			-	Bone surf (9E+1)	-	1E-10	-	-
95	Americium-243	W, all compounds	8E-1	6E-3	3E-12	-	-	-
			Bone surf (1E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7
95	Americium-244m[2]	W, all compounds	6E+4	4E+3	2E-6	-	-	-
			St. wall (8E+4)	Bone surf (7E+3)	-	1E-8	1E-3	1E-2
95	Americium-244	W, all compounds	3E+3	2E+2	8E-8	-	4E-5	4E-4
			-	Bone surf (3E+2)	-	4E-10	-	-
95	Americium-245	W, all compounds	3E+4	8E+4	3E-5	1E-7	4E-4	4E-3
95	Americium-246m[2]	W, all compounds	5E+4	2E+5	8E-5	3E-7	-	-
			St. wall (6E+4)	-	-	-	8E-4	8E-3
95	Americium-246[2]	W, all compounds	3E+4	1E+5	4E-5	1E-7	4E-4	4E-3
96	Curium-238	W, all compounds	2E+4	1E+3	5E-7	2E-9	2E-4	2E-3
96	Curium-240	W, all compounds	6E+1	6E-1	2E-10	-	-	-

	Bone surf (8E+1)	Bone surf (6E-1)	-	9E-13	1E-6	1E-5
96 Curium-241 W, all compounds	1E+3	3E+1	1E-8	-	2E-5	2E-4
	-	Bone surf (4E+1)	-	5E-11	-	-
96 Curium-242 W, all compounds	3E+1	3E-1	1E-10	-	-	-
	Bone surf (5E+1)	Bone surf (3E-1)	-	4E-13	7E-7	7E-6
96 Curium-243 W, all compounds	1E+0	9E-3	4E-12	-	-	-
	Bone surf (2E+0)	Bone surf (2E-2)	-	2E-14	3E-8	3E-7
96 Curium-244 W, all compounds	1E+0	1E-2	5E-12	-	-	-
	Bone surf (3E+0)	Bone surf (2E-2)	-	3E-14	3E-8	3E-7
96 Curium-245 W, all compounds	7E-1	6E-3	3E-12	-	-	-
	Bone surf (1E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7
96 Curium-246 W, all compounds	7E-1	6E-3	3E-12	-	-	-
	Bone surf (1E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7
96 Curium-247 W, all compounds	8E-1	6E-3	3E-12	-	-	-
	Bone surf (1E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7
96 Curium-248 W, all compounds	2E-1	2E-3	7E-13	-	-	-
	Bone surf (4E-1)	Bone surf (3E-3)	-	4E-15	5E-9	5E-8
96 Curium-249[2] W, all compounds	5E+4	2E+4	7E-6	-	7E-4	7E-3
	-	Bone surf (3E+4)	-	4E-8	-	-
96 Curium-250 W, all compounds	4E-2	3E-4	1E-13	-	-	-

		Bone surf (6E-2)	Bone surf (5E-4)	-	8E-16	9E-10	9E-9
97 Berkelium-245	W, all compounds	2E+3	1E+3	5E-7	2E-9	3E-5	3E-4
97 Berkelium-246	W, all compounds	3E+3	3E+3	1E-6	4E-9	4E-5	4E-4
97 Berkelium-247	W, all compounds	5E-1	4E-3	2E-12	-	-	-
		Bone surf (1E+0)	Bone surf (9E-3)	-	1E-14	2E-8	2E-7
97 Berkelium-249	W, all compounds	2E+2	2E+0	7E-10	-	-	-
		Bone surf (5E+2)	Bone surf (4E+0)	-	5E-12	6E-6	6E-5
97 Berkelium-250	W, all compounds	9E+3	3E+2	1E-7	-	1E-4	1E-3
		-	Bone surf (7E+2)	-	1E-9	-	-
98 Californium-244[2]	W, all compounds except those given for Y	3E+4	6E+2	2E-7	8E-10	-	-
		St. wall (3E+4)	-	-	-	4E-4	4E-3
	Y, oxides and hydroxides	-	6E+2	2E-7	8E-10	-	-
98 Californium-246	W, see ^{244}Cf	4E+2	9E+0	4E-9	1E-11	5E-6	5E-5
	Y, see ^{244}Cf	-	9E+0	4E-9	1E-11	-	-
98 Californium-248	W, see ^{244}Cf	8E+0	6E-2	3E-11	-	-	-
		Bone surf (2E+1)	Bone surf (1E-1)	-	2E-13	2E-7	2E-6
	Y, see ^{244}Cf	-	1E-1	4E-11	1E-13	-	-
98 Californium-249	W, see ^{244}Cf	5E-1	4E-3	2E-12	-	-	-
		Bone surf (1E+0)	Bone surf (9E-3)	-	1E-14	2E-8	2E-7
	Y, see ^{244}Cf	-	1E-2	4E-12	-	-	-
			Bone surf				

		-	(1E-2)	-	2E-14	-	-
98 Californium-250	W, see ^{244}Cf	1E+0 Bone surf (2E+0)	9E-3 Bone surf (2E-2)	4E-12 -	- 3E-14	- 3E-8	- 3E-7
	Y, see ^{244}Cf	-	3E-2	1E-11	4E-14	-	-
98 Californium-251	W, see ^{244}Cf	5E-1 Bone surf (1E+0)	4E-3 Bone surf (9E-3)	2E-12 -	- 1E-14	- 2E-8	- 2E-7
	Y, see ^{244}Cf	- -	1E-2 Bone surf (1E-2)	4E-12 -	- 2E-14	- -	- -
98 Californium-252	W, see ^{244}Cf	2E+0 Bone surf (5E+0)	2E-2 Bone surf (4E-2)	8E-12 -	- 5E-14	- 7E-8	- 7E-7
	Y, see ^{244}Cf	-	3E-2	1E-11	5E-14	-	-
98 Californium-253	W, see ^{244}Cf	2E+2 Bone surf (4E+2)	2E+0 -	8E-10 -	3E-12 -	- 5E-6	- 5E-5
	Y, see ^{244}Cf	-	2E+0	7E-10	2E-12	-	-
98 Californium-254	W, see ^{244}Cf	2E+0	2E-2	9E-12	3E-14	3E-8	3E-7
	Y, see ^{244}Cf	-	2E-2	7E-12	2E-14	-	-
99 Einsteinium-250	W, all compounds	4E+4 -	5E+2 Bone surf (1E+3)	2E-7 -	- 2E-9	6E-4 -	6E-3 -
99 Einsteinium-251	W, all compounds	7E+3 -	9E+2 Bone surf (1E+3)	4E-7 -	- 2E-9	1E-4 -	1E-3 -
99 Einsteinium-253	W, all compounds	2E+2	1E+0	6E-10	2E-12	2E-6	2E-5
99 Einsteinium-254m	W, all compounds	3E+2 LLI wall	1E+1	4E-9	1E-11	-	-

		(3E+2)	-	-	-	4E-6	4E-5
99 Einsteinium-254	W, all compounds	8E+0	7E-2	3E-11	-	-	-
		Bone surf (2E+1)	Bone surf (1E-1)	-	2E-13	2E-7	2E-6
100 Fermium-252	W, all compounds	5E+2	1E+1	5E-9	2E-11	6E-6	6E-5
100 Fermium-253	W, all compounds	1E+3	1E+1	4E-9	1E-11	1E-5	1E-4
100 Fermium-254	W, all compounds	3E+3	9E+1	4E-8	1E-10	4E-5	4E-4
100 Fermium-255	W, all compounds	5E+2	2E+1	9E-9	3E-11	7E-6	7E-5
100 Fermium-257	W, all compounds	2E+1	2E-1	7E-11	-	-	-
		Bone surf (4E+1)	Bone surf (2E-1)	-	3E-13	5E-7	5E-6
101 Mendelevium-257	W, all compounds	7E+3	8E+1	4E-8	-	1E-4	1E-3
		-	Bone surf (9E+1)	-	1E-10	-	-
101 Mendelevium-258	W, all compounds	3E+1	2E-1	1E-10	-	-	-
		Bone surf (5E+1)	Bone surf (3E-1)	-	5E-13	6E-7	6E-6
Any single radionuclide not listed above with decay mode other than alpha emission or spontaneous fission and with radioactive half-life less than 2 hours	Submersion [1]	-	2E+2	1E-7	1E-9	-	-
Any single radionuclide not listed above with decay mode other than alpha emission or spontaneous fission and with radioactive half-life greater than 2 hours. . . .		-	2E-1	1E-10	1E-12	1E-8	1E-7
Any single radionuclide not listed above that decays by alpha emission or spontaneous fission, or any mixture for which either the identity or the concentration of any radionuclide in the mixture is not known. . . .		-	4E-4	2E-13	1E-15	2E-9	2E-8

FOOTNOTES:

[1]"Submersion" means that values given are for submersion in a hemispherical semi-infinite cloud of airborne material.

[2]These radionuclides have radiological half-lives of less than 2 hours. The total effective dose equivalent received during operations with these radionuclides might include a significant contribution from external exposure. The DAC values for all radionuclides, other than those designated Class "Submersion," are based upon the committed effective dose equivalent due to the intake of the radionuclide into the body and do NOT include potentially significant contributions to dose equivalent from external exposures. The licensee may substitute 1E-7uCi/ml for the listed DAC to account for the submersion dose prospectively, but should use individual monitoring devices or other radiation measuring instruments that measure external exposure to demonstrate compliance with the limits. (See RHA 3.7)

[3]For soluble mixtures of U-238, U-234, and U-235 in air, chemical toxicity may be the limiting factor (see RHA 3.5.5). If the percent by weight (enrichment) of U-235 is not greater than 5, the concentration value for a 40-hour workweek is 0.2 milligrams uranium per cubic meter of air average. For any enrichment, the product of the average concentration and time of exposure during a 40-hour workweek shall not exceed 8E-3 (SA) uCi-hr/ml, where SA is the specific activity of the uranium inhaled. The specific activity for natural uranium is 6.77E-7 curies per gram U. The specific activity for other mixtures of U-238, U-235, and U-234, if not known, shall be:

SA = 3.6E-7 curies/gram U U-depleted
SA = $[0.4 + 0.38\,(\text{enrichment}) + 0.0034\,(\text{enrichment})^2]$ E-6 , enrichment $\geq$ 0.72
where enrichment is the percentage by weight of U-235, expressed as percent.

NOTE: 1. If the identity of each radionuclide in a mixture is known but the concentration of one or more of the radionuclides in the mixture is not known, the DAC for the mixture shall be the most restrictive DAC of any radionuclide in the mixture.

NOTE: 2. If the identity of each radionuclide in the mixture is not known, but it is known that certain radionuclides specified in this appendix are not present in the mixture, the inhalation ALI, DAC, and effluent and sewage concentrations for the mixture are the lowest values specified in this appendix for any radionuclide that is not known to be absent from the mixture; or

	Table 1 Occupational Values			Table 2 Effluent Concentrations		Table 3 Releases to Sewers
	Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
	Oral Ingestion	Inhalation				Monthly Average
Radionuclide	ALI (uCi)	ALI (uCi)	DAC (uCi/ml)	Air (uCi/ml)	Water (uCi/ml)	Conc. (uCi/ml)
If it is known that Ac-227-D and Cm-250-W are not present	-	7E-4	3E-13	-	-	-
If, in addition, it is known that Ac-227-W,Y, Th-229-W,Y, Th-230-W,						

Th-232-W,Y, Pa-231-W,Y, Np-237-W, Pu-239-W, Pu-240-W, Pu-242-W, Am-241-W, Am-242m-W, Am-243-W, Cm-245-W, Cm-246-W, Cm-247-W, Cm-248-W, Bk-247-W, Cf-249-W, and Cf-251-W are not present	-	7E-3	3E-12	-	-	-
If, in addition, it is known that Sm-146-W, Sm-147-W, Gd-148-D,W, Gd-152-D,W, Th-228-W,Y, Th-230-Y, U-232-Y, U-233-Y, U-234-Y, U-235-Y, U-236-Y, U-238-Y, Np-236-W, Pu-236-W,Y, Pu-238-W,Y, Pu-239-Y, Pu-240-Y, Pu-242-Y, Pu-244-W,Y, Cm-243-W, Cm-244-W, Cf-248-W, Cf-249-Y, Cf-250-W,Y, Cf-251-Y, Cf-252-W,Y, and Cf-254-W,Y are not present	-	7E-2	3E-11	-	-	-
If, in addition, it is known that Pb-210-D, Bi-210m-W, Po-210-D,W, Ra-223-W, Ra-225-W, Ra-226-W, Ac-225-D,W,Y, Th-227-W,Y, U-230-D,W,Y, U-232-D,W, Pu-241-W, Cm-240-W, Cm-242-W, Cf-248-Y, Es-254-W, Fm-257-W, and Md-258-W are not present	-	7E-1	3E-10	-	-	-
Radionuclide						
If, in addition, it is known that Si-32-Y, Ti-44-Y, Fe-60-D, Sr-90-Y, Zr-93-D, Cd-113m-D, Cd-113-D, In-115-D,W, La-138-D, Lu-176-W, Hf-178m-D,W, Hf-182-D,W, Bi-210m-D, Ra-224-W, Ra-228-W, Ac-226-D,W,Y, Pa-230-W,Y, U-233-D,W, U-234-D,W, U-235-D,W, U-236-D,W, U-238-D,W, Pu-241-Y, Bk-249-W, Cf-253-W,Y, and Es-253-W are not present	-	7E+0	3E-9	-	-	-
If it is known that Ac-227-D,W,Y, Th-229-W,Y, Th-232-W,Y, Pa-231-W,Y, Cm-248-W, and Cm-250-W are not present	-	-	-	1E-14	-	-
If, in addition, it is known that Sm-146-W, Gd-148-D,W, Gd-152-D, Th-228-W,Y, Th-230-W,Y, U-232-Y, U-233-Y, U-234-Y, U-235-Y, U-236-Y,						

U-238-Y, U-Nat-Y, Np-236-W, Np-237-W, Pu-236-W,Y, Pu-238-W,Y, Pu-239-W,Y, Pu-240-W,Y, Pu-242-W,Y, Pu-244-W,Y, Am-241-W, Am-242m-W, Am-243-W, Cm-243-W, Cm-244-W, Cm-245-W, Cm-246-W, Cm-247-W, Bk-247-W, Cf-249-W,Y, Cf-250-W,Y, Cf-251-W,Y, Cf-252-W,Y, and Cf-254-W,Y are not present	-	-	-	1E-13	-	-
If, in addition, it is known that Sm-147-W, Gd-152-W, Pb-210-D, Bi-210m-W, Po-210-D,W, Ra-223-W, Ra-225-W, Ra-226-W, Ac-225-D,W,Y, Th-227-W,Y, U-230-D,W,Y, U-232-D,W, U-Nat-W, Pu-241-W, Cm-240-W, Cm-242-W, Cf-248-W,Y, Es-254-W, Fm-257-W, and Md-258-W are not present	-	-	-	1E-12	-	-
Radionuclide						
If, in addition it is known that Fe-60, Sr-90, Cd-113m, Cd-113, In-115, I-129, Cs-134, Sm-145, Sm-147, Gd-148, Gd-152, Hg-194 (organic), Bi-210m, Ra-223, Ra-224, Ra-225, Ac-225, Th-228, Th-230, U-233, U-234, U-235, U-236, U-238, U-Nat, Cm-242, Cf-248, Es-254, Fm-257, and Md-258 are not present	-	-	-	-	1E-6	1E-5

NOTE 3. If a mixture of radionuclides consists of uranium and its daughters in ore dust (10um AMAD particle distribution assumed) prior to chemical separation of the uranium from the ore, the following values may be used for the DAC of the mixture: 6E-11 uCi of gross alpha activity from uranium-238, uranium-234, thorium-230, and radium-226 per milliliter of air; 3E-11 uCi of natural uranium per milliliter of air; or 45 micrograms of natural uranium per cubic meter of air.

NOTE 4. If the identity and concentration of each radionuclide in a mixture are known, the limiting values should be derived as follows: determine, for each radionuclide in the mixture, the ratio between the concentration present in the mixture and the concentration otherwise established in Appendix B for the specific radionuclide when not in a mixture. The sum of such ratios for all of the radionuclides in the mixture may not exceed "1" (i.e., "unity").

Example: If radionuclides "A," "B," and "C" are present in concentrations C_A, C_B, and C_C, and if the applicable DACs are DAC_A, DAC_B, and DAC_C, respectively, then the concentrations shall be limited so that the following relationship exists:

$$\frac{C_A}{DAC_A} + \frac{C_B}{DAC_B} + \frac{C_C}{DAC_C} \leq 1$$

RHA 3.54. [Appendix C] Quantities [1] of Licensed Material Requiring Labeling.

Radionuclide	Quantity (uCi)
Hydrogen-3	1,000
Beryllium-7	1,000
Beryllium-10	1
Carbon-11	1,000
Carbon-14	1,000
Fluorine-18	1,000
Sodium-22	10
Sodium-24	100
Magnesium-28	100
Aluminum-26	10
Silicon-31	1,000
Silicon-32	1
Phosphorus-32	10
Phosphorus-33	100
Sulfur-35	100
Chlorine-36	10

Radionuclide	Quantity (uCi)
Chlorine-38	1,000
Chlorine-39	1,000
Argon-39	1,000
Argon-41	1,000
Potassium-40	100
Potassium-42	1,000
Potassium-43	1,000
Potassium-44	1,000
Potassium-45	1,000
Calcium-41	100
Calcium-45	100
Calcium-47	100
Scandium-43	1,000
Scandium-44m	100
Scandium-44	100
Scandium-46	10
Scandium-47	100
Scandium-48	100
Scandium-49	1,000
Titanium-44	1
Titanium-45	1,000
Vanadium-47	1,000
Vanadium-48	100
Vanadium-49	1,000
Chromium-48	1,000
Chromium-49	1,000
Chromium-51	100
Manganese-51	1,000
Manganese-52m	1,000
Manganese-52	100
Manganese-53	1,000
Manganese-54	100
Manganese-56	1,000
Iron-52	100
Iron-55	100
Iron-59	10
Iron-60	1
Cobalt-55	100
Cobalt-56	10
Cobalt-57	100
Cobalt-58m	1,000
Cobalt-58	100
Cobalt-60m	1,000
Cobalt-60	1
Cobalt-61	1,000
Cobalt-62m	1,000
Nickel-56	100
Nickel-57	100
Nickel-59	100
Nickel-63	100
Nickel-65	1,000
Nickel-66	10
Copper-60	1,000
Copper-61	1,000
Copper-64	1,000
Copper-67	1,000
Zinc-62	100
Zinc-63	1,000
Zinc-65	10
Zinc-69m	100
Zinc-69	1,000
Zinc-71m	1,000
Zinc-72	100

Radionuclide	Quantity (uCi)
Gallium-65	1,000
Gallium-66	100
Gallium-67	1,000
Gallium-68	1,000
Gallium-70	1,000
Gallium-72	100
Gallium-73	1,000
Germanium-66	1,000
Germanium-67	1,000
Germanium-68	10
Germanium-69	1,000
Germanium-71	1,000
Germanium-75	1,000
Germanium-77	1,000
Germanium-78	1,000
Arsenic-69	1,000
Arsenic-70	1,000
Arsenic-71	100
Arsenic-72	100
Arsenic-73	100
Arsenic-74	100
Arsenic-76	100
Arsenic-77	100
Arsenic-78	1,000
Selenium-70	1,000
Selenium-73m	1,000
Selenium-73	100
Selenium-75	100
Selenium-79	100
Selenium-81m	1,000
Selenium-81	1,000
Selenium-83	1,000
Bromine-74m	1,000
Bromine-74	1,000
Bromine-75	1,000
Bromine-76	100
Bromine-77	1,000
Bromine-80m	1,000
Bromine-80	1,000
Bromine-82	100
Bromine-83	1,000
Bromine-84	1,000
Krypton-74	1,000
Krypton-76	1,000
Krypton-77	1,000
Krypton-79	1,000
Krypton-81	1,000
Krypton-83m	1,000
Krypton-85m	1,000
Krypton-85	1,000
Krypton-87	1,000
Krypton-88	1,000
Rubidium-79	1,000
Rubidium-81m	1,000
Rubidium-81	1,000
Rubidium-82m	1,000
Rubidium-83	100
Rubidium-84	100
Rubidium-86	100
Rubidium-87	100
Rubidium-88	1,000
Rubidium-89	1,000
Strontium-80	100

Radionuclide	Quantity (uCi)
Strontium-81	1,000
Strontium-83	100
Strontium-85m	1,000
Strontium-85	100
Strontium-87m	1,000
Strontium-89	10
Strontium-90	0.1
Strontium-91	100
Strontium-92	100
Yttrium-86m	1,000
Yttrium-86	100
Yttrium-87	100
Yttrium-88	10
Yttrium-90m	1,000
Yttrium-90	10
Yttrium-91m	1,000
Yttrium-91	10
Yttrium-92	100
Yttrium-93	100
Yttrium-94	1,000
Yttrium-95	1,000
Zirconium-86	100
Zirconium-88	10
Zirconium-89	100
Zirconium-93	1
Zirconium-95	10
Zirconium-97	100
Niobium-88	1,000
Niobium-89m(66 min)	1,000
Niobium-89 (122 min)	1,000
Niobium-90	100
Niobium-93m	10
Niobium-94	1
Niobium-95m	100
Niobium-95	100
Niobium-96	100
Niobium-97	1,000
Niobium-98	1,000
Molybdenum-90	100
Molybdenum-93m	100
Molybdenum-93	10
Molybdenum-99	100
Molybdenum-101	1,000
Technetium-93m	1,000
Technetium-93	1,000
Technetium-94m	1,000
Technetium-94	1,000
Technetium-96m	1,000
Technetium-96	100
Technetium-97m	100
Technetium-97	1,000
Technetium-98	10
Technetium-99m	1,000
Technetium-99	100
Technetium-101	1,000
Technetium-104	1,000
Ruthenium-94	1,000
Ruthenium-97	1,000
Ruthenium-103	100
Ruthenium-105	1,000
Ruthenium-106	1
Rhodium-99m	1,000
Rhodium-99	100

Radionuclide	Quantity (uCi)
Rhodium-100	100
Rhodium-101m	1,000
Rhodium-101	10
Rhodium-102m	10
Rhodium-102	10
Rhodium-103m	1,000
Rhodium-105	100
Rhodium-106m	1,000
Rhodium-107	1,000
Palladium-100	100
Palladium-101	1,000
Palladium-103	100
Palladium-107	10
Palladium-109	100
Silver-102	1,000
Silver-103	1,000
Silver-104m	1,000
Silver-104	1,000
Silver-105	100
Silver-106m	100
Silver-106	1,000
Silver-108m	1
Silver-11Om	10
Silver-111	100
Silver-112	100
Silver-115	1,000
Cadmium-104	1,000
Cadmium-107	1,000
Cadmium-109	1
Cadmium-113m	0.1
Cadmium-113	100
Cadmium-115m	10
Cadmium-115	100
Cadmium-117m	1,000
Cadmium-117	1,000
Indium-109	1,000
Indium-110m(69.1m)	1,000
Indium-11O(4.9h)	1,000
Indium-111	100
Indium-112	1,000
Indium-113m	1,000
Indium-114m	10
Indium-115m	1,000
Indium-115	100
Indium-116m	1,000
Indium-117m	1,000
Indium-117	1,000
Indium-119m	1,000
Tin-110	100
Tin-111	1,000
Tin-113	100
Tin-117m	100
Tin-119m	100
Tin-121m	100
Tin-121	1,000
Tin-123m	1,000
Tin-123	10
Tin-125	10
Tin-126	10
Tin-127	1,000
Tin-128	1,000
Antimony-115	1,000
Antimony-116m	1,000

Radionuclide	Quantity (uCi)
Antimony-116	1,000
Antimony-117	1,000
Antimony-118m	1,000
Antimony-119	1,000
Antimony-120(16min.)	1,000
Antimony-120(5.76d)	100
Antimony-122	100
Antimony-124m	1,000
Antimony-124	10
Antimony-125	100
Antimony-126m	1,000
Antimony-126	100
Antimony-127	100
Antimony-128(10.4min.)	1,000
Antimony-128(9.01h)	100
Antimony-129	100
Antimony-130	1,000
Antimony-131	1,000
Tellurium-116	1,000
Tellurium-121m	10
Tellurium-121	100
Tellurium-123m	10
Tellurium-123	100
Tellurium-125m	10
Tellurium-127m	10
Tellurium-127	1,000
Tellurium-129m	10
Tellurium-129	1,000
Tellurium-131m	10
Tellurium-131	100
Tellurium-132	10
Tellurium-133m	100
Tellurium-133	1,000
Tellurium-134	1,000
Iodine-120m	1,000
Iodine-120	100
Iodine-121	1,000
Iodine-123	100
Iodine-124	10
Iodine-125	1
Iodine-126	1
Iodine-128	1,000
Iodine-129	1
Iodine-130	10
Iodine-131	1
Iodine-132m	100
Iodine-132	100
Iodine-133	10
Iodine-134	1,000
Iodine-135	100
Xenon-120	1,000
Xenon-121	1,000
Xenon-122	1,000
Xenon-123	1,000
Xenon-125	1,000
Xenon-127	1,000
Xenon-129m	1,000
Xenon-131m	1,000
Xenon-133m	1,000
Xenon-133	1,000
Xenon-135m	1,000
Xenon-135	1,000
Xenon-138	1,000

Radionuclide	Quantity (uCi)
Cesium-125	1,000
Cesium-127	1,000
Cesium-129	1,000
Cesium-130	1,000
Cesium-131	1,000
Cesium-132	100
Cesium-134m	1,000
Cesium-134	10
Cesium-135m	1,000
Cesium-135	100
Cesium-136	10
Cesium-137	10
Cesium-138	1,000
Barium-126	1,000
Barium-128	100
Barium-131m	1,000
Barium-131	100
Barium-133m	100
Barium-133	100
Barium-135m	100
Barium-139	1,000
Barium-140	100
Barium-141	1,000
Barium-142	1,000
Lanthanum-131	1,000
Lanthanum-132	100
Lanthanum-135	1,000
Lanthanum-137	10
Lanthanum-138	100
Lanthanum-140	100
Lanthanum-141	100
Lanthanum-142	1,000
Lanthanum-143	1,000
Cerium-134	100
Cerium-135	100
Cerium-137m	100
Cerium-137	1,000
Cerium-139	100
Cerium-141	100
Cerium-143	100
Cerium-144	1
Praseodymium-136	1,000
Praseodymium-137	1,000
Praseodymium-138m	1,000
Praseodymium-139	1,000
Praseodymium-142m	1,000
Praseodymium-142	100
Praseodymium-143	100
Praseodymium-144	1,000
Praseodymium-145	100
Praseodymium-147	1,000
Neodymium-136	1,000
Neodymium-138	100
Neodymium-139m	1,000
Neodymium-139	1,000
Neodymium-141	1,000
Neodymium-147	100
Neodymium-149	1,000
Neodymium-151	1,000
Promethium-141	1,000
Promethium-143	100
Promethium-144	10
Promethium-145	10

Radionuclide	Quantity (uCi)
Promethium-146	1
Promethium-147	10
Promethium-148m	10
Promethium-148	10
Promethium-149	100
Promethium-150	1,000
Promethium-151	100
Samarium-141m	1,000
Samarium-141	1,000
Samarium-142	1,000
Samarium-145	100
Samarium-146	1
Samarium-147	100
Samarium-151	10
Samarium-153	100
Samarium-155	1,000
Samarium-156	1,000
Europium-145	100
Europium-146	100
Europium-147	100
Europium-148	10
Europium-149	100
Europium-150(12.62h)	100
Europium-150(34.2y)	1
Europium-152m	100
Europium-152	1
Europium-154	1
Europium-155	10
Europium-156	100
Europium-157	100
Europium-158	1,000
Gadolinium-145	1,000
Gadolinium-146	10
Gadolinium-147	100
Gadolinium-148	0.001
Gadolinium-149	100
Gadolinium-151	10
Gadolinium-152	100
Gadolinium-153	10
Gadolinium-159	100
Terbium-147	1,000
Terbium-149	100
Terbium-150	1,000
Terbium-151	100
Terbium-153	1,000
Terbium-154	100
Terbium-155	1,000
Terbium-156m(5.0h)	1,000
Terbium-156m(24.4h)	1,000
Terbium-156	100
Terbium-157	10
Terbium-158	1
Terbium-160	10
Terbium-161	100
Dysprosium-155	1,000
Dysprosium-157	1,000
Dysprosium-159	100
Dysprosium-165	1,000
Dysprosium-166	100
Holmium-155	1,000
Holmium-157	1,000
Holmium-159	1,000
Holmium-161	1,000

Radionuclide	Quantity (uCi)
Holmium-162m	1,000
Holmium-162	1,000
Holmium-164m	1,000
Holmium-164	1,000
Holmium-166m	1
Holmium-166	100
Holmium-167	1,000
Erbium-161	1,000
Erbium-165	1,000
Erbium-169	100
Erbium-171	100
Erbium-172	100
Thulium-162	1,000
Thulium-166	100
Thulium-167	100
Thulium-170	10
Thulium-171	10
Thulium-172	100
Thulium-173	100
Thulium-175	1,000
Ytterbium-162	1,000
Ytterbium-166	100
Ytterbium-167	1,000
Ytterbium-169	100
Ytterbium-175	100
Ytterbium-177	1,000
Ytterbium-178	1,000
Lutetium-169	100
Lutetium-170	100
Lutetium-171	100
Lutetium-172	100
Lutetium-173	10
Lutetium-174m	10
Lutetium-174	10
Lutetium-176m	1,000
Lutetium-176	100
Lutetium-177m	10
Lutetium-177	100
Lutetium-178m	1,000
Lutetium-178	1,000
Lutetium-179	1,000
Hafnium-170	100
Hafnium-172	1
Hafnium-173	1,000
Hafnium-175	100
Hafnium-177m	1,000
Hafnium-178m	0.1
Hafnium-179m	10
Hafnium-180m	1,000
Hafnium-181	10
Hafnium-182m	1,000
Hafnium-182	0.1
Hafnium-183	1,000
Hafnium-184	100
Tantalum-172	1,000
Tantalum-173	1,000
Tantalum-174	1,000
Tantalum-175	1,000
Tantalum-176	100
Tantalum-177	1,000
Tantalum-178	1,000
Tantalum-179	100
Tantalum-180m	1,000

Radionuclide	Quantity (uCi)
Tantalum-180	100
Tantalum-182m	1,000
Tantalum-182	10
Tantalum-183	100
Tantalum-184	100
Tantalum-185	1,000
Tantalum-186	1,000
Tungsten-176	1,000
Tungsten-177	1,000
Tungsten-178	1,000
Tungsten-179	1,000
Tungsten-181	1,000
Tungsten-185	100
Tungsten-187	100
Tungsten-188	10
Rhenium-177	1,000
Rhenium-178	1,000
Rhenium-181	1,000
Rhenium-182(12.7h)	1,000
Rhenium-182(64.0h)	100
Rhenium-184m	10
Rhenium-184	100
Rhenium-186m	10
Rhenium-186	100
Rhenium-187	1,000
Rhenium-188m	1,000
Rhenium-188	100
Rhenium-189	100
Osmium-180	1,000
Osmium-181	1,000
Osmium-182	100
Osmium-185	100
Osmium-189m	1,000
Osmium-191m	1,000
Osmium-191	100
Osmium-193	100
Osmium-194	1
Iridium-182	1,000
Iridium-184	1,000
Iridium-185	1,000
Iridium-186	100
Iridium-187	1,000
Iridium-188	100
Iridium-189	100
Iridium-190m	1,000
Iridium-190	100
Iridium-192(73.8d)	1
Iridium-192m(1.4min)	10
Iridium-194m	10
Iridium-194	100
Iridium-195m	1,000
Iridium-195	1,000
Platinum-186	1,000
Platinum-188	100
Platinum-189	1,000
Platinum-191	100
Platinum-193m	100
Platinum-193	1,000
Platinum-195m	100
Platinum-197m	1,000
Platinum-197	100
Platinum-199	1,000
Platinum-200	100

Radionuclide	Quantity (uCi)
Gold-193	1,000
Gold-194	100
Gold-195	10
Gold-198m	100
Gold-198	100
Gold-199	100
Gold-200m	100
Gold-200	1,000
Gold-201	1,000
Mercury-193m	100
Mercury-193	1,000
Mercury-194	1
Mercury-195m	100
Mercury-195	1,000
Mercury-197m	100
Mercury-197	1,000
Mercury-199m	1,000
Mercury-203	100
Thallium-194m	1,000
Thallium-194	1,000
Thallium-195	1,000
Thallium-197	1,000
Thallium-198m	1,000
Thallium-198	1,000
Thallium-199	1,000
Thallium-200	1,000
Thallium-201	1,000
Thallium-202	100
Thallium-204	100
Lead-195m	1,000
Lead-198	1,000
Lead-199	1,000
Lead-200	100
Lead-201	1,000
Lead-202m	1,000
Lead-202	10
Lead-203	1,000
Lead-205	100
Lead-209	1,000
Lead-210	0.01
Lead-211	100
Lead-212	1
Lead-214	100
Bismuth-200	1,000
Bismuth-201	1,000
Bismuth-202	1,000
Bismuth-203	100
Bismuth-205	100
Bismuth-206	100
Bismuth-207	10
Bismuth-210m	0.1
Bismuth-210	1
Bismuth-212	10
Bismuth-213	10
Bismuth-214	100
Polonium-203	1,000
Polonium-205	1,000
Polonium-207	1,000
Polonium-210	0.1
Astatine-207	100
Astatine-211	10
Radon-220	1
Radon-222	1

Radionuclide	Quantity (uCi)
Francium-222	100
Francium-223	100
Radium-223	0.1
Radium-224	0.1
Radium-225	0.1
Radium-226	0.1
Radium-227	1,000
Radium-228	0.1
Actinium-224	1
Actinium-225	0.01
Actinium-226	0.1
Actinium-227	0.001
Actinium-228	1
Thorium-226	10
Thorium-227	0.001
Thorium-228	0.001
Thorium-229	0.001
Thorium-230	0.001
Thorium-231	100
Thorium-232	100
Thorium-234	10
Thorium-natural	100
Protactinium-227	10
Protactinium-228	1
Protactinium-230	0.1
Protactinium-231	0.001
Protactinium-232	1
rotactinium-233	100
Protactinium-234	100
Uranium-230	0.01
Uranium-231	100
Uranium-232	0.001
Uranium-233	0.001
Uranium-234	0.001
Uranium-235	0.001
Uranium-236	0.001
Uranium-237	100
Uranium-238	100
Uranium-239	1,000
Uranium-240	100
Uranium-natural	100
Neptunium-232	100
Neptunium-233	1,000
Neptunium-234	100
Neptunium-235	100
Neptunium-236(1.15x105y)	0.001
Neptunium-236(22.5h)	1
Neptunium-237	1.001
Neptunium-238	10
Neptunium-239	100
Neptunium-240	1,000
Plutonium-234	10
Plutonium-235	1,000
Plutonium-236	0.001
Plutonium-237	100
Plutonium-238	0.001
Plutonium-239	0.001
Plutonium-240	0.001
Plutonium-241	0.01
Plutonium-242	0.001
Plutonium-243	1,000
Plutonium-244	0.001
Plutonium-245	100

Radionuclide	Quantity (uCi)
Americium-237	1,000
Americium-238	100
Americium-239	1,000
Americium-240	100
Americium-241	0.001
Americium-242m	0.001
Americium-242	10
Americium-243	0.001
Americium-244m	100
Americium-244	10
Americium-245	1,000
Americium-246m	1,000
Americium-246	1,000
Curium-238	100
Curium-240	0.1
Curium-241	1
Curium-242	0.01
Curium-243	0.001
Curium-244	0.001
Curium-245	0.001
Curium-246	0.001
Curium-247	0.001
Curium-248	0.001
Curium-249	1,000
Berkelium-245	100
Berkelium-246	100
Berkelium-247	0.001
Berkelium-249	0.1
Berkelium-250	10
Californium-244	100
Californium-246	1
Californium-248	0.01
Californium-249	0.001
Californium-250	0.001
Californium-251	0.001
Californium-252	0.001
Californium-253	0.1
Californium-254	0.001
Any alpha emitting radionuclide not listed above or mixtures of alpha emitters of unknown composition	0.001
Einsteinium-250	100
Einsteinium-251	100
Einsteinium-253	0.1
Einsteinium-254m	1
Einsteinium-254	0.01
Fermium-252	1
Fermium-253	1
Fermium-254	10
Fermium-255	1
Fermium-257	0.01
Mendelevium-257	10
Mendelevium-258	0.01
Any radionuclide other than alpha emitting radionuclides not listed above, or mixtures of beta emitters of unknown composition	0.01

[1] The quantities listed above were derived by taking 1/10th of the most restrictive ALI listed in table 1, columns 1 and 2, of appendix B, RHA 3.53 of this part, rounding to the nearest factor of 10, and arbitrarily constraining the values listed between 0.001 and 1,000 uCi.

Values of 100 uCi have been assigned for radionuclides having a radioactive half-life in excess of 109 years (except rhenium, 1000 uCi) to take into account their low specific activity.

Note: For purposes of RHA 3.22.5, RHA 3.25.1, and RHA 3.44.1 where there is involved a combination of radionuclides in known amounts, the limit for the combination should be derived as follows: determine, for each radionuclide in the combination, the ratio between the quantity present in the combination and the limit otherwise established for the specific radionuclide when not in combination. The sum of such ratios for all radionuclides in the combination may not exceed "1" (i.e., "unity").

RHA 3.55. [Appendix D] Requirements for Low-Level-Waste Transfer for Disposal at Land Disposal Facilities and Manifests.

3.55.1 **Manifest**

3.55.1.1 A waste generator, collector, or processor who transports, or offers for transportation, low-level radioactive waste intended for ultimate disposal at a licensed low-level radioactive waste land disposal facility must prepare a manifest reflecting information requested on applicable NRC Forms 540 (Uniform Low-Level Radioactive Waste Manifest [Shipping Paper]) and 541 (Uniform Low-Level Radioactive Waste Manifest [Container and Waste Description]) and, if necessary, on applicable NRC Form 542 (Uniform Low-Level Radioactive Waste Manifest [Manifest Index and Regional Compact Tabulation]). NRC Forms 540 and 540A must be completed and must physically accompany the pertinent low-level waste shipment. Upon agreement between shipper and consignee, NRC Forms 541 and 541A and 542 and 542A may be completed, transmitted, and stored in electronic media with the capability for producing legible, accurate, and complete records on the respective forms. For guidance in completing these forms, refer to the instructions that accompany the forms. Copies of manifests required by this appendix may be legible carbon copies, photocopies, or computer printouts that reproduce the data in the format of the uniform manifest. NRC Forms 540, 540A, 541, 541A, 542, and 542A, and the accompanying instructions, in hard copy, may be obtained from the Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 415–5877. This appendix includes information requirements of the Department of Transportation. Information on hazardous, medical, or other waste, required to meet Environmental Protection Agency (EPA) regulations, is not addressed in this section, and must be provided on the required EPA forms. However, the required EPA forms must accompany the Uniform Low-Level Radioactive Waste Manifest required by this part. Licensees are not required by the Department to comply with the manifesting requirements of this part when they ship:

3.55.1.1.1 LLW for processing and expect its return (i.e. for storage under their license) prior to disposal at a licensed land disposal facility;

3.55.1.1.2 LLW that is being returned to the licensee who is the "waste generator" or "generator," as defined in this part; or

3.55.1.1.3 Radioactively contaminated material to a "waste processor" that becomes the processor's "residual waste."

3.55.1.2 General Information. The shipper of the radioactive waste, shall provide the following information on the uniform manifest:

3.55.1.2.1 The name, facility address, and telephone number of the licensee shipping the waste;

3.55.1.2.2 An explicit declaration indicating whether the shipper is acting as a waste generator, collector, processor, or a combination of these identifiers for purposes of the manifest shipment; and

3.55.1.2.3 The name, address, and telephone number, or the name and EPA identification number for the carrier transporting the waste.

3.55.1.3 Shipment Information. The shipper of the radioactive waste shall provide the following information regarding the waste shipment on the uniform manifest:

3.55.1.3.1 The date of the waste shipment;

3.55.1.3.2 The total number of packages/disposal containers;

3.55.1.3.3 The disposal volume and disposal weight in the shipment;

3.55.1.3.4 The total radionuclide activity in the shipment;

3.55.1.3.5 The activity of each of the radionuclides H-3, C-14, Tc-99, and I-129 contained in the shipment; and

3.55.1.3.6 The total masses of U-233, U-235, and plutonium in special nuclear material, and the total mass of uranium and thorium in source material.

3.55.1.4 Disposal Container and Waste Information. The shipper of the radioactive waste shall provide the following information on the uniform manifest regarding the waste and each disposal container of waste in the shipment:

3.55.1.4.1 An alphabetic or numeric identification that uniquely identifies each disposal container in the shipment;

3.55.1.4.2 A physical description of the disposal container, including the manufacturer and model of any high integrity container;

3.55.1.4.3 The volume displaced by the disposal container;

3.55.1.4.4 The gross weight of the disposal container, including the waste;

3.55.1.4.5 For waste consigned to a disposal facility, the maximum radiation level at the surface of each disposal container;

3.55.1.4.6 A physical and chemical description of the waste;

3.55.1.4.7 The total weight percentage of chelating agent for any waste containing more than 0.1% chelating agent by weight, plus the identity of the principal chelating agent;

3.55.1.4.8 The approximate volume of waste within a container;

3.55.1.4.9 The use of solidification media, if any, and the identity of the solidification media vendor and brand name;

3.55.1.4.10 The identities and activities of individual radionuclides contained in each container, the masses of U-233, U-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material. For discrete waste types (i.e. activated materials, contaminated equipment, mechanical filters, sealed source/devices, and waste in solidification/stabilization media), the identities and activities of individual radionuclides associated with or contained on these waste types within a disposal container shall be reported;

3.55.1.4.11 The total radioactivity within each container; and

3.55.1.4.12 For wastes consigned to a disposal facility, the classification of the waste pursuant to Appendix E, RHA 3.56.1. Waste not meeting the structural stability requirements of Appendix E, RHA 3.56.2 must be identified.

3.55.1.5 Uncontainerized Waste Information. The shipper of the radioactive waste shall provide the following information on the uniform manifest regarding a waste shipment delivered without a disposal container:

3.55.1.5.1 The approximate volume and weight of the waste;

3.55.1.5.2 A physical and chemical description of the waste;

3.55.1.5.3 The total weight percentage of chelating agent if the chelating agent exceeds 0.1% by weight, plus the identity of the principal chelating agent;

3.55.1.5.4 For waste consigned to a disposal facility, the classification of the waste pursuant to Appendix E, RHA 3.56.1. Waste not meeting the structural stability requirements of Appendix E, RHA 3.56.2 must be identified;

3.55.1.5.5 The identities and activities of individual radionuclides contained in the waste, the masses of U-233, U-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material; and

3.55.1.5.6 For wastes consigned to a disposal facility, the maximum radiation levels at the surface of the waste.

3.55.1.6 Multi-Generator Disposal Container. This section applies to disposal containers enclosing mixtures of waste originating from different generators (The origin of the LLW resulting from a

processor's activities may be attributable to one or more "generators" [including "waste generators"] as defined in this part). It also applies to mixtures of wastes shipped in an uncontainerized form, for which portions of the mixture within the shipment originate from different generators.

3.55.1.6.1 For homogenous mixtures of waste, such as incinerator ash, provide the waste description applicable to the mixture and the volume of the waste attributed to each generator.

3.55.1.6.2 For heterogenous mixtures of waste, such as the combined products from a large compactor, identify each generator contributing waste to the disposal container, and for discrete waste types (i.e. activated materials, contaminated equipment, mechanical filters, sealed sources/devices, and wastes in solidification/stabilization media), the identities and activities of individual radionuclides contained on these waste types within the disposal container. For each generator, provide the following:

3.55.1.6.2.1 The volume of waste within the disposal container;

3.55.1.6.2.2 A physical and chemical description of the waste, including the solidification agent, if any;

3.55.1.6.2.3 The total weight percentage of chelating agents for any disposal container containing more than 0.1% chelating agent by weight, plus the identity of the principal chelating agent;

3.55.1.6.2.4 The solidification media, if any, and the identity of the solidification media vendor and brand name if the media is claimed to meet stability requirements in Appendix E, RHA 3.56.2; and

3.55.1.6.2.5 Radionuclide identities and activities contained in the waste, the masses of U-233, U-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material if contained in the waste.

3.55.2 **Certification**

An authorized representative of the waste generator, processor, or collector shall certify by signing and dating the shipment manifest that the transported materials are properly classified, described, packaged, marked, and labeled and are in proper condition for transportation according to the applicable regulations of the Department of Transportation and the Department. A collector in signing the certification is certifying that nothing has been done to the collected waste which would invalidate the waste generator's certification.

3.55.3 **Control and Tracking**

3.55.3.1 Any radioactive waste generator who transfers radioactive waste to a land disposal facility or a licensed waste collector shall comply with the requirements in RHA 3.55.3.1.1 through 3.55.3.1.9. Any radioactive waste generator who transfers waste to a licensed waste processor who treats or repackages waste shall comply with the requirements of RHA 3.55.3.1.4 thru 3.55.3.1.9. A licensee shall:

3.55.3.1.1 Prepare all wastes so that the waste is classified according to Appendix E, RHA 3.56.1 and meets the waste characteristics requirements in Appendix E, RHA 3.56.1;

3.55.3.1.2 Label each disposal container (or transport package if potential radiation hazards preclude labeling of the individual disposal container) of waste to identify whether it is Class A waste, Class B waste, Class C waste, or greater than Class C waste, in accordance with Appendix E, RHA 3.56.1.

3.55.3.1.3 Conduct a quality control program to ensure compliance with Appendix E, RHA 3.56.1 and 3.56.2., the program must include management evaluation of audits;

3.55.3.1.4 Prepare the NRC Uniform Low-Level Radioactive Waste Manifest as required by Appendix D, RHA 3.55.1 and 3.55.2;

3.55.3.1.5 Forward a copy or electronically transfer the Uniform Low-level Radioactive Waste Manifest to the intended consignee so that (1) either receipt of the manifest precedes the LLW shipment or (2)the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both (1) and (2) is also acceptable;

3.55.3.1.6 Include NRC Form 540 (and NRC Form 540A, if required) with the shipment regardless of the option chosen in RHA 3.55.3.1.5;

3.55.3.1.7 Receive acknowledgement of the receipt of the shipment in the form of a signed copy of NRC Form 540;

3.55.3.1.8 Retain a copy of or electronically store the Uniform Low-Level Radioactive Waste Manifest and documentation of acknowledgment of receipt as the record of transfer of licensed material as required by RHA 2.18 of these regulations; and

3.55.3.1.9 For any shipments or any part of a shipment for which acknowledgment of receipt has not been received within the times set forth in this section, conduct an investigation in accordance with RHA 3.55.3.5.

3.55.3.2 Any waste collector licensee who handles only prepackaged waste shall:

3.55.3.2.1 Acknowledge receipt of the waste from the shipper within 1 week of receipt by returning a signed copy of NRC Form 540;

3.55.3.2.2 Prepare a new manifest to reflect consolidated shipments that meet the requirements of this appendix. The waste collector shall ensure that, for each container of waste in the shipment, the manifest identifies the generator of that container of waste;

3.55.3.2.3 Forward a copy or electronically transfer the Uniform Low-Level Radioactive Waste Manifest to the intended consignee so that either: (1)Receipt of the manifest precedes the LLW shipment or (2) the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both (1) and (2) is also acceptable;

3.55.3.2.4 Include NRC Form 540 (and NRC Form 540A, if required) with the shipment regardless of the option chosen in RHA 3.55.3.2.3;

3.55.3.2.5 Receive acknowledgement of the receipt of the shipment in the form of a signed copy of NRC Form 540;

3.55.3.2.6 Retain a copy of or electronically store the Uniform Low-Level Radioactive Waste Manifest and documentation of acknowledgement of receipt as the record of transfer of licensed material as required by RHA 2.18;

3.55.3.2.7 For any shipments or any part of a shipment for which acknowledgment of receipt is not received within the times set forth in this appendix, conduct an investigation in accordance with RHA 3.55.3.5; and

3.55.3.2.8 Notify the shipper and the Department when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been canceled.

3.55.3.3 Any licensed waste processor who treats or repackages wastes shall:

3.55.3.3.1 Acknowledge receipt of the waste from the shipper within 1 week of receipt by returning a signed copy of NRC Form 540;

3.55.3.3.2 Prepare a new manifest that meets the requirements of this appendix. Preparation of the new manifest reflects that the processor is responsible for meeting these requirements. For each container of waste in the shipment, the manifest shall identify the waste generators, the preprocessed waste volume, and the other information as required RHA 3.55.1.5;

3.55.3.3.3 Prepare all wastes so that the waste is classified according to Appendix E, RHA 3.56.1 and meets the waste characteristics requirements in Appendix E, RHA 3.56.2;

3.55.3.3.4 Label each package of waste to identify whether it is Class A waste, Class B waste, or Class C waste, in accordance with Appendix E, RHA 3.56.1 and RHA 3.56.3;

3.55.3.3.5 Conduct a quality assurance program to assure compliance with Appendix E, RHA 3.56.1 and RHA 3.56.2. The program shall include management evaluation of audits;

3.55.3.3.6 Forward a copy or electronically transfer the Uniform Low-Level Radioactive Waste Manifest to the intended consignee so that either: (1) Receipt of the manifest precedes the LLW shipment or (2) the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both (1) and (2) is also acceptable; or equivalent documentation by the collector;

3.55.3.3.7 Include NRC Form 540 (and NRC Form 540A, if required) with the shipment regardless of the option chosen in RHA 3.55.3.3.6;

3.55.3.3.8 Receive acknowledgement of the receipt of the shipment in the form of a signed copy of NRC Form 540;

3.55.3.3.9 Retain a copy of or electronically store the Uniform Low-Level Radioactive Waste Manifest and documentation of acknowledgement of receipt as the record of transfer of licensed material as required by RHA 2.18; and

3.55.3.3.10 For any shipment or part of a shipment for which acknowledgment of receipt has not been received within the times set forth in this appendix, conduct an investigation in accordance with RHA 3.55.3.5.

3.55.3.3.11 Notify the shipper and the Department when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advanced manifest, unless notified by the shipper that the shipment has been canceled.

3.55.3.4 The land disposal facility operator shall:

3.55.3.4.1 Acknowledge receipt of the waste within 1 week of receipt by returning as a minimum, a signed copy of NRC Form 540 to the shipper. The shipper to be notified is the licensee who last possessed the waste and transferred the waste to the operator. If any discrepancy exists between materials listed on the Uniform Low-Level Radioactive Waste Manifest and materials received, copies or electronic transfer of the affected forms must be returned indicating the discrepancy;

3.55.3.4.2 Maintain copies of all completed manifests and electronically store the information required by RHA 7.32 on a storage medium approved by the Department until the Department authorizes their disposition; and

3.55.3.4.3 Notify the shipper (i.e., the generator, the collector, or processor) and the Department when any shipment or part of a shipment has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been canceled.

3.55.3.5 Any shipment or part of a shipment for which acknowledgment is not received within the times set forth in this section must:

3.55.3.5.1 Be investigated by the shipper if the shipper has not received notification or receipt within 20 days after transfer; and

3.55.3.5.2 Be traced and reported. The investigation shall include tracing the shipment and filing a report with the Department. Each licensee who conducts a trace investigation shall file a written report with the Department within 2 weeks of completion of the investigation.

HISTORY: Amended by SCSR 42–2 Doc. No. 4791, eff February 23, 2018.

RHA 3.56. [Appendix E] Classification and Characteristics of Low-Level Radioactive Waste.

3.56.1 **Classification of Radioactive Waste for Land Disposal**

3.56.1.1 **Considerations.** Determination of the classification of radioactive waste involves two considerations. First, consideration must be given to the concentration of long-lived radionuclides (and their shorter-lived precursors) whose potential hazard will persist long after such precautions as institutional controls, improved waste form, and deeper disposal have ceased to be effective. These precautions delay the time when long-lived radionuclides could cause exposures. In addition, the magnitude of the potential dose is limited by the concentration and availability of the radionuclide at the time of exposure. Second, consideration must be given to the concentration of shorter-lived radionuclides for which requirements on institutional controls, waste form, and disposal methods are effective.

3.56.1.2 **Classes of waste.**

3.56.1.2.1 Class A waste is waste that is usually segregated from other waste classes at the disposal site. The physical form and characteristics of Class A waste must meet the minimum requirements set forth in RHA 3.56.2.1. If Class A waste also meets the stability requirements set forth in RHA 3.56.2.2 it is not necessary to segregate the waste for disposal.

3.56.1.2.2 Class B waste is waste that must meet more rigorous requirements on waste form to ensure stability after disposal. The physical form and characteristics of Class B waste must meet both the minimum and stability requirements set forth in RHA 3.56.2.

3.56.1.2.3 Class C waste is waste that not only must meet more rigorous requirements on waste form to ensure stability but also requires additional measures at the disposal facility to protect against inadvertent intrusion. The physical form and characteristics of Class C waste must meet both the minimum and stability requirements set forth in RHA 3.56.2.

3.56.1.3 **Classification determined by long-lived radionuclides.** If the radioactive waste contains only radionuclides listed in Table III, classification shall be determined as follows:

3.56.1.3.1 If the concentration does not exceed 0.1 times the value in Table I, the waste is Class A.

3.56.1.3.2 If the concentration exceeds 0.1 times the value in Table I, but does not exceed the value in Table I, the waste is Class C.

3.56.1.3.3 If the concentration exceeds the value in Table I, the waste is not generally acceptable for land disposal.

3.56.1.3.4 For wastes containing mixtures of radionuclides listed in Table I, the total concentration shall be determined by the sum of fractions rule described in RHA 3.56.1.7.

TABLE I

Radionuclide	Concentration curie cubic meter [a]	nanocurie/gram [b]
C-14	8	
C-14 in activated metal	80	
Ni-59 in activated metal	220	
Nb-94 in activated metal	0.2	
Tc-99	3	
I-129	0.08	
Alpha emitting transuranic radionuclides with half-life greater than five years		100
Pu-241		3,500
Cm-242		20,000
Ra-226		100

[a] To convert the C/m ^{3} values to gigabecquerel (GBq)/cubic meter, multiply the C/m ^{3} value by 37
[b] To convert the nC/g values to becquerel (Bq)gram, multiply the nC/g value by 37.

3.56.1.4 **Classification determined by short-lived radionuclides.** If the waste does not contain any of the radionuclides listed in Table I, classification shall be determined based on the concentrations shown in Table II. However, as specified in RHA 3.56.1.6 if radioactive waste does not contain any nuclides listed in either Table I or II, it is Class A.

3.56.1.4.1 If the concentration does not exceed the value in Column 1, the waste is Class A.

3.56.1.4.2 If the concentration exceeds the value in Column 1 but does not exceed the value in Column 2, the waste is Class B.

3.56.1.4.3 If the concentration exceeds the value in Column 2 but does not exceed the value in Column 3, the waste is Class C.

3.56.1.4.4 If the concentration exceeds the value in Column 3, the waste is not generally acceptable for near-surface disposal.

3.56.1.4.5 For wastes containing mixtures of the radionuclides listed in Table II, the total concentration shall be determined by the sum of fractions rule described in RHA 3.56.1.7.

TABLE II

Radionuclide	Concentration, Column 1	curie/cubic Column 2	meter * Column 3
Total of all radionuclides with less than 5-year half-life	700	*	*
H-3	40	*	*
Co-60	700	*	*
Ni-63	3.5	70	700

Radionuclide	Concentration, Column 1	curie/cubic Column 2	meter * Column 3
Ni-63 in activated metal	35	700	7000
Sr-90	0.04	150	7000
Cs-137	1	44	4600

DEPARTMENT NOTE: To convert the Ci/m^3 value to gigabecquerel (GBq)/cubic meter, multiply the Ci/m^3 value by 37. There are no limits established for these radionuclides in Class B or C wastes. Practical considerations such as the effects of external radiation and internal heat generation on transportation, handling, and disposal will limit the concentrations for these wastes. These wastes shall be Class B unless the concentrations of other radionuclides in Table II determine the waste to be Class C independent of these radionuclides.

3.56.1.5 **Classification determined by both long-and short-lived radionuclides.** If the radioactive waste contains a mixture of radionuclides, some of which are listed in Table I and some of which are listed in Table II, classification shall be determined as follows:

3.56.1.5.1 If the concentration of a radionuclide listed in Table I is less than 0.1 times the value listed in Table I, the class shall be that determined by the concentration of radionuclides listed in Table II.

3.56.1.5.2 If the concentration of a radionuclide listed in Table I exceed 0.1 times the value listed in Table I, but does not exceed the value in Table I, the waste shall be Class C, provided the concentration of radionuclides listed in Table II does not exceed the value shown in Column 3 of Table II.

3.56.1.6 **Classification of wastes with radionuclides other than those listed in Tables I and II.** If the waste does not contain any radionuclides listed in either Table I or II, it is Class A.

3.56.1.7 **The sum of the fractions rule for mixtures of radionuclides.** For determining classification for waste that contains a mixture of radionuclides, it is necessary to determine the sum of fractions by dividing each radionuclide's concentration by the appropriate limit and adding the resulting values. The appropriate limits must all be taken from the same column of the same table. The sum of the fractions for the column must be less than 1.0 if the waste class is to be determined by that column. Example: A waste contains Sr-90 in a concentration of 1.85 TBq/m^3 (50 Ci/m^3) and Cs-137 in a concentration of 814 GBq/m^3 (22 Ci/m^3). Since the concentrations both exceed the values in Column 1, Table II, they must be compared to Column 2 values. For Sr-90 fraction, $^{50}/_{150}$ = 0.33., for Cs-137 fraction, $^{22}/_{44}$ = 0.5; the sum of the fractions = 0.83. Since the sum is less than 1.0, the waste is Class B.

3.56.1.8 **Determination of concentrations in wastes.** The concentration of a radionuclide may be determined by indirect methods such as use of scaling factors which relate the inferred concentration of one radionuclide to another that is measured, or radionuclide material accountability, if there is reasonable assurance that the indirect methods can be correlated with actual measurements. The concentration of a radionuclide may be averaged over the volume of the waste, or weight of the waste if the units are expressed a becquerel (nanocurie) per gram.

3.56.2 **Radioactive Waste Characteristics**

3.56.2.1 The following are minimum requirements for all classes of waste and are intended to facilitate handling and provide protection of health and safety of personnel at the disposal site.

3.56.2.1.1 Wastes shall be packaged in conformance with the conditions of the license issued to the site operator to which the waste will be shipped. Where the conditions of the site license are more restrictive than the provisions of Part VII, the site license conditions shall govern.

3.56.2.1.2 Wastes shall not be packaged for disposal in cardboard or fiberboard boxes.

3.56.2.1.3 Liquid waste shall be packaged in sufficient absorbent material to absorb twice the volume of the liquid.

3.56.2.1.4 Solid waste containing liquid shall contain as little free-standing and non-corrosive liquid as is reasonably achievable, but in no case shall the liquid exceed 1% of the volume.

3.56.2.1.5 Waste shall not be readily capable of detonation or of explosive decomposition or reaction at normal pressures and temperatures, or of explosive reaction with water.

3.56.2.1.6 Waste shall not contain, or be capable of generating, quantities of toxic gases, vapors, or fumes harmful to persons transporting, handling, or disposing of the waste. This does not apply to radioactive gaseous waste packaged in accordance with RHA 3.56.2.1.8.

3.56.2.1.7 Waste must not be pyrophoric.[1] Pyrophoric materials contained in wastes shall be treated, prepared, and packaged to be nonflammable.

3.56.2.1.8 Wastes in a gaseous form shall be packaged at an absolute pressure that does not exceed 1.5 atmospheres at 20°C. Total activity shall not exceed 3.7 TBq (100 Ci) per container.

3.56.2.1.9 Wastes containing hazardous, biological, pathogenic, or infectious material shall be treated to reduce to the maximum extent practicable the potential hazard from the non-radiological materials.

3.56.2.2 The following requirements are intended to provide stability of the waste. Stability is intended to ensure that the waste does not degrade and affect overall stability of the site through slumping, collapse, or other failure of the disposal unit and thereby lead to water infiltration. Stability is also a factor in limiting exposure to an inadvertent intruder, since it provides a recognizable and nondispersible waste.

3.56.2.2.1 Waste shall have structural stability. A structurally stable waste form will generally maintain its physical dimensions and its form, under the expected disposal conditions such as weight of overburden and compaction equipment, the presence of moisture, and microbial activity, and internal factors such as radiation effects and chemical changes. Structural stability can be provided by the waste form itself, processing the waste to stable form, or placing the waste in a disposal container or structure that provides stability after disposal.

3.56.2.2.2 Notwithstanding the provisions in RHA 3.56.2.1.3 and 3.56.2.1.4, wastes, or wastes containing liquid, shall be converted into a form that contains as little free-standing and non-corrosive liquid as is reasonably achievable, but in no case shall the liquid exceed 1% of the volume of the waste when the waste is in a disposal container designed to ensure stability, or 0.5% of the volume of the waste for waste processed to a stable form.

3.56.2.2.3 Void spaces within the waste and between the waste and its package shall be reduced to the extent practicable.

3.56.3 **Labeling**

Each package of waste shall be clearly labeled to identify whether it is Class A, Class B, or Class C waste, in accordance with RHA 3.56.1.

Editor's Note
Scrivener errors corrected in 2012.

RHA 3.57. [Appendix F] Radiological Criteria for License Termination.

3.57.1 **General Provisions and Scope**

3.57.1.1 The criteria in this appendix apply to the decommissioning of facilities licensed under Regulation 61–63, Title A, as well as other facilities subject to the Department's jurisdiction under the Atomic Energy and Radiation Control Act, Section 13–7–10 of the 1976 S.C. Code, as amended. For low-level waste disposal facilities, the criteria apply only to ancillary surface facilities that support radioactive waste disposal activities. The criteria do not apply to uranium and thorium recovery facilities already subject to Appendix A to 10 CFR part 40 or to uranium solution extraction facilities.

3.57.1.2 The criteria in this appendix do not apply to sites which:

3.57.1.2.1 Have been decommissioned prior to the effective date of the rule in accordance with criteria identified in the Site Decommissioning Management Plan (SDMP) Action Plan;

3.57.1.2.2 Have previously submitted and received Department approval on a license termination plan (LTP) or decommissioning plan that is compatible with the SDMP Action Plan criteria; or

[1] "Pyrophoric liquid" means any liquid that ignites spontaneously in dry or moist air at or below 130°F (54.4°C). A pyrophoric solid is any solid material, other than one classed as an explosive, which under normal conditions is liable to cause fires through friction, retained heat from manufacturing or processing, or which can be ignited readily and, when ignited, burns so vigorously and persistently as to create a serious transportation, handling, or disposal hazard. Included are spontaneously combustible and water-reactive materials.

3.57.1.2.3 Submit a sufficient LTP or decommissioning plan before August 20, 1998 and such LTP or decommissioning plan is approved by the Department before August 20, 1999 and in accordance with the criteria identified in the SDMP Action Plan, except that if an EIS is required in the submittal, there will be a provision for day-to-day extension.

3.57.1.3 After a site has been decommissioned and the license terminated in accordance with the criteria in this appendix, the Department will require additional cleanup only if, based on new information, it determines that the criteria of this appendix were not met and residual radioactivity remaining at the site could result in significant threat to public health and safety.

3.57.1.4 When calculating TEDE to the average member of the critical group the licensee shall determine the peak annual TEDE dose expected within the first 1000 years after decommissioning.

3.57.2 **Radiological Criteria for Unrestricted Use**

A site will be considered acceptable for unrestricted use if the residual radioactivity that is distinguishable from background radiation results in a TEDE to an average member of the critical group that does not exceed 25 millirem (0.25 mSv) per year, including that from groundwater, and the residual radioactivity has been reduced to levels that are as low as reasonably achievable (ALARA). Determination of the levels which are ALARA must take into account consideration of any detriments, such as deaths from transportation accidents, expected to potentially result from decontamination and waste disposal.

3.57.3 **Criteria for License Termination Under Restricted Conditions**

A site will be considered acceptable for license termination under restricted conditions if:

3.57.3.1 The licensee can demonstrate that further reductions in residual radioactivity necessary to comply with the provisions of RHA 3.57.2 would result in net public or environmental harm or were not being made because the residual levels associated with restricted conditions are ALARA. Determination of the levels which are ALARA must take into account consideration of any detriments, such as traffic accidents, expected to potentially result from decontamination and waste disposal;

3.57.3.2 The licensee has made provisions for legally enforceable institutional controls that provide reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 25 millirem (0.25 mSv) per year;

3.57.3.3 The licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site. Acceptable financial assurance mechanisms are:

3.57.3.3.1 Funds placed into a trust segregated from the licensee's assets and outside the licensee's administrative control, and in which the adequacy of the trust funds is to be assessed based on an assumed annual 1 percent real rate of return on investment;

3.57.3.3.2 A statement of intent in the case of Federal, State, or local Government licensees, as described in RHA 1.15.10.4; or

3.57.3.3.3 When a governmental entity is assuming custody and ownership of a site, an arrangement that is deemed acceptable by such governmental entity.

3.57.3.4 The licensee has submitted a decommissioning plan or License Termination Plan (LTP) to the Department indicating the licensee's intent to decommission in accordance with RHA 2.11.4, and specifying that the licensee intends to decommission by restricting use of the site. The licensee shall document in the LTP or decommissioning plan how the advice of individuals and institutions in the community who may be affected by the decommissioning has been sought and incorporated, as appropriate, following analysis of that advice.

3.57.3.4.1 Licensees proposing to decommission by restricting use of the site shall seek advice from such affected parties regarding the following matters concerning the proposed decommissioning:

3.57.3.4.1.1 Whether provisions for institutional controls proposed by the licensee;

3.57.3.4.1.1.1 Will provide reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 25 millirem (0.25 mSv) TEDE per year;

3.57.3.4.1.1.2 Will be enforceable; and

3.57.3.4.1.1.3 Will not impose undue burdens on the local community or other affected parties.

3.57.3.4.1.2 Whether the licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site:

3.57.3.4.2 In seeking advice on the issues identified in RHA 3.57.3.4.1, the licensee shall provide for:

3.57.3.4.2.1 Participation by representatives of a broad cross section of community interests who may be affected by the decommissioning;

3.57.3.4.2.2 An opportunity for a comprehensive, collective discussion on the issues by the participants represented; and

3.57.3.4.2.3 A publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues; and

3.57.3.5 Residual radioactivity at the site has been reduced so that if the institutional controls were no longer in effect, there is reasonable assurance that the TEDE from residual radioactivity distinguishable background to the average member of the critical group is as low as reasonably achievable and would not exceed either:

3.57.3.5.1 100 millirem (1 mSv) per year; or

3.57.3.5.2 500 millirem (5 mSv) per year provided the licensee:

3.57.3.5.2.1 Demonstrates that further reductions in residual radioactivity necessary to comply with the 100 millirem/year (1 mSv/yr) value of RHA 3.57.3.5.1 are not technically achievable, would be prohibitively expensive, or would result in net public or environment harm;

3.57.3.5.2.2 Makes provisions for durable institutional controls;

3.57.3.5.2.3 Provides sufficient financial assurance to enable a responsible government entity or independent third party, including a governmental custodian of a site, both to carry out periodic rechecks of the site no less frequently than every 5 years to assure that the institutional controls remain in place as necessary to meet the criteria of RHA 3.57.3.2 and to assume and carry out responsibilities for any necessary control and maintenance of those controls. Acceptable financial assurance mechanisms are those in RHA 3.57.3.3.

3.57.4 **Alternate Criteria for License Termination**

3.57.4.1 The Department may terminate a licensee using alternate criteria greater than those criteria of RHA 3.57.2, 3.57.3.2, and 3.57.3.4.1.1.1, if the licensee:

3.57.4.1.1 Provides assurance that the public health and safety would continue to be protected, and it is unlikely that the dose from all man-made sources combined, other than medical, would be more than the 1 mSv/yr (100 mrem/yr) limit of RHA 3.13 and 3.14, by submitting an analysis of possible sources of exposure;

3.57.4.1.2 Has employed to the extent practical restrictions on site use according to the provisions of RHA 3.57.3 in minimizing exposures at the site; and

3.57.4.1.3 Reduces doses to ALARA levels, taking into consideration any detriments such as traffic accidents expected to potentially result from decontamination and waste disposal.

3.57.4.1.4 Has submitted a decommissioning plan or License Termination Plan (LTP) to the Department indicating the licensee's intent to decommission in accordance with RHA 2.11.4, and specifying that the licensee proposes to decommission by use of alternate criteria. The licensee shall document in the decommissioning plan or LTP how the advice of individuals and institutions in the community who may be affected by the decommissioning has been sought and addressed, as

appropriate, following analysis of that advice. In seeking such advice, the licensee shall provide for:

3.57.4.1.4.1 Participation by representatives of a broad cross section of community interests who may be affected by the decommissioning;

3.57.4.1.4.2 An opportunity for a comprehensive, collective discussion on the issues by the participants represented; and

3.57.4.1.4.3 A publicly available summary of the result of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues.

3.57.4.2 The use of alternate criteria to terminate a license requires the approval of the Department after consideration of the Department staff's recommendations that will address any comments provided by the Environmental Protection Agency and any public comments submitted pursuant to RHA 3.57.5.

3.57.4.3 Has provided sufficient financial assurance in the form of a trust fund to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site.

3.57.5 **Public Notification and Public Participation**

Upon the receipt of an LTP or decommissioning plan from the licensee, or a proposal by the licensee for release of a site pursuant to RHA 3.57.3 or 3.57.4, or whenever the Department deems such notice to be in the public interest, the Department shall:

3.57.5.1 Notify and solicit comments from:

3.57.5.1.1 Local and State governments in the vicinity of the site and any Indian nation or other indigenous people that have treaty or statutory rights that could be affected by the decommissioning; and

3.57.5.1.2 The Environmental Protection Agency for cases where the licensee proposes to release a site pursuant to RHA 3.57.4.

3.57.5.2 Publish a notice in the Federal Register and in a forum, such as local newspapers, letters to State or local organizations, or other appropriate forum, that is readily accessible to individuals in the vicinity of the site, and solicit comments from affected parties.

3.57.6 Minimization of contamination

3.57.6.1 Applicants for licenses, other than renewals, whose applications are submitted after August 20, 1997, shall describe in the application how facility design and procedures for operation will minimize,to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste.

3.57.6.2 Licensees shall, to the extent practical, conduct operations to minimize the introduction of residual radioactivity into the site, including the subsurface, in accordance with the existing radiation protection requirements in RHA 3.4 and radiological criteria for license termination in RHA 3.57, Appendix F.

HISTORY: Amended by State Register Volume 38, Issue No. 10, Doc. No. 4462, eff October 24, 2014.

RHA 3.58. [Appendix G] Nationally Tracked Sources - Serialization and Reports of Transactions.

Each licensee who manufactures a nationally tracked source after February 6, 2007 shall assign a unique serial number to each nationally tracked source. Serial numbers must be composed only of alpha-numeric characters. Each licensee who manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report to the National Source Tracking System as specified in paragraphs 3.58.1 through 3.58.5 of this section for each type of transaction.

3.58.1 Each licensee who manufactures a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

3.58.1.1 The name, address, and license number of the reporting licensee;

3.58.1.2 The name of the individual preparing the report;

3.58.1.3 The manufacturer, model, and serial number of the source;

3.58.1.4 The radioactive material in the source;

3.58.1.5 The initial source strength in becquerels (curies) at the time of manufacture; and

3.58.1.6 The manufacture date of the source.

3.58.2 Each licensee that transfers a nationally tracked source to another person shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

3.58.2.1 The name, address, and license number of the reporting licensee;

3.58.2.2 The name of the individual preparing the report;

3.58.2.3 The name and license number of the recipient facility and the shipping address;

3.58.2.4 The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

3.58.2.5 The radioactive material in the source;

3.58.2.6 The initial or current source strength in becquerels (curies);

3.58.2.7 The date for which the source strength is reported;

3.58.2.8 The shipping date;

3.58.2.9 The estimated arrival date; and

3.58.2.10 For nationally tracked sources transferred as waste under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification of the container with the nationally tracked source.

3.58.3 Each licensee that receives a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

3.58.3.1 The name, address, and license number of the reporting licensee;

3.58.3.2 The name of the individual preparing the report;

3.58.3.3 The name, address, and license number of the person that provided the source;

3.58.3.4 The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

3.58.3.5 The radioactive material in the source;

3.58.3.6 The initial or current source strength in becquerels (curies);

3.58.3.7 The date for which the source strength is reported;

3.58.3.8 The date of receipt; and

3.58.3.9 For material received under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification with the nationally tracked source.

3.58.4 Each licensee that disassembles a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

3.58.4.1 The name, address, and license number of the reporting licensee;

3.58.4.2 The name of the individual preparing the report;

3.58.4.3 The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

3.58.4.4 The radioactive material in the source;

3.58.4.5 The initial or current source strength in becquerels (curies);

3.58.4.6 The date for which the source strength is reported;

3.58.4.7 The disassemble date of the source.

3.58.5 Each Licensee who disposes of nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

3.58.5.1 The name, address, and license number of the reporting licensee;

3.58.5.2 The name of the individual preparing the report;

3.58.5.3 The waste manifest number;

3.58.5.4 The container identification with the nationally tracked source;

3.58.5.5 The date of disposal; and

3.58.5.6 The method of disposal.

3.58.6 The reports discussed in paragraphs 3.58.1 through 3.58.5 of this section must be submitted by the close of the next business day after the transaction. A single report may be submitted for multiple sources and transactions. The reports must be submitted to the National Source Tracking System by using:

3.58.6.1 The on-line National Source Tracking System;

3.58.6.2 Electronically using a computer-readable format;

3.58.6.3 By facsimile;

3.58.6.4 By mail to the address on the National Source Tracking Transaction Report Form (NRC Form 748); or

3.58.6.5 By telephone with follow-up by facsimile or mail.

3.58.7 Each licensee shall correct any error in previously filed reports or file a new report for any missed transaction within 5 business days of the discovery of the error or missed transaction. Such errors may be detected by a variety of methods such as administrative reviews or by physical inventories required by regulation. In addition, each licensee shall reconcile the inventory of nationally tracked sources possessed by the licensee against that licensees data in the National Source Tracking System. The reconciliation must be conducted during the month of January in each year. The reconciliation process must include resolving any discrepancies between the National Source Tracking System and the actual inventory by filing the reports identified by paragraphs 3.58.1 through 3.58.5 of this section. By January 31 of each year, each licensee must submit to the National Source Tracking System confirmation that the data in the National Source Tracking System is correct.

3.58.8 Each licensee that possesses Category 1 nationally tracked sources shall have reported its initial inventory of Category 1 nationally tacked sources to the National Source Tracking System by January 31, 2009. Each licensee that possesses Category 2 nationally tracked sources shall have reported its initial inventory of Category 2 nationally tracked sources to the National Source Tracking System by January 31, 2009. The information may be submitted by using any of the methods identified by paragraph 3.58.6.1 through 3.58.6.4 of this section. The initial inventory report must include the following information:

3.58.8.1 The name, address, and license number of the reporting licensee;

3.58.8.2 The name of the individual preparing the report;

3.58.8.3 The manufacturer, model, and serial number of each nationally tracked source or, if not available, other information to uniquely identify the source;

3.58.8.4 The radioactive material in the sealed source;

3.58.8.5 The initial or current source strength in becquerels (curies); and

3.58.8.6 The date for which the source strength is reported.

Nationally Tracked Source Thresholds

The Terabecquerel (TBq) values are the regulatory standard. The curie (Ci) values specified are obtained by converting from the TBq value. The curie values are provided for practical usefulness only and are rounded after conversion.

Radioactive Material	Category 1 (TBq)	Category 1 (Ci)	Category 2 (TBq)	Category 2 (Ci)
Actinium-227	20	540	0.2	5.4
Americium-241	60	1600	0.6	16
Americium-241/Be	60	1600	0.6	16
Californium-252	20	540	0.2	5.4
Cobalt-60	30	810	0.3	8.1

Radioactive Material	Category 1 (TBq)	Category 1 (Ci)	Category 2 (TBq)	Category 2 (Ci)
Curium-244	50	1400	0.5	14
Cesium-137	100	2700	1	27
Gadolinium-153	1000	27000	10	270
Iridium-192	80	2200	0.8	22
Plutonium-238	60	1600	0.6	16
Plutonium-239/Be	60	1600	0.6	16
Polonium-210	60	1600	0.6	16
Promethium-147	40000	1100000	400	11000
Radium-226	40	1100	0.4	11
Selenium-75	200	5400	2	54
Strontium-90	1000	27000	10	270
Thorium-228	20	540	0.2	5.4
Thorium-229	20	540	0.2	5.4
Thulium-170	20000	540000	200	5400
Ytterbium-169	300	8100	3	81

HISTORY: Amended by State Register Volume 38, Issue No. 10, Doc. No. 4462, eff October 24, 2014.

PART IV
USE OF RADIONUCLIDES IN THE HEALTH PROFESSIONS

SUBPART A
General Information

RHA 4.1. Purpose and Scope.

This part contains the requirements and provisions for the medical use of radioactive material and for issuance of specific licenses authorizing the medical use of this material. These requirements and provisions provide for the radiation safety of workers, the general public, patients, and human research subjects. The requirements and provisions of this part are in addition to, and not in substitution for, others in this chapter. The requirements and provisions of parts I, II, III and VI of this chapter apply to applicants and licensees subject to this part unless specifically exempted.

The Department provides that licensees will have up to 2 years after the effective date of the final rule to comply with the training requirements for authorized users, authorized medical physicists, authorized nuclear pharmacists, and Radiation Safety Officers. During this 2-year period, licensees will have the option of complying with either requirements of Subpart J or the requirements in Subparts B and D-H of this Part.

RHA 4.2. Definitions.

4.2.1 "Address of use" means the building or buildings that are identified on the license and where radioactive material may be received, prepared, used, or stored.

4.2.2 "Agreement State" means any State with which the Nuclear Regulatory Commission (hereafter referred to as NRC) or the Atomic Energy Commission has entered into an effective agreement under subsection 274b of the Atomic Energy Act of 1954, as amended.

4.2.3 "Area of use" means a portion of an address of use that has been set aside for the purpose of receiving, preparing, using, or storing radioactive material.

4.2.4 "*Associate Radiation Safety Officer*" means an individual who-

4.2.4.1 Meets the requirements in RHA 4.20 and RHA 4.24; and

4.2.4.2 Is currently identified as an Associate Radiation Safety Officer for the types of use of radioactive material for which the individual has been assigned duties and tasks by the Radiation Safety Officer on-

4.2.4.2.1 A specific medical use license issued by the Nuclear Regulatory Commission or an Agreement State; or

4.2.4.2.2 A medical use permit issued by a Nuclear Regulatory Commission master material licensee.

4.2.5 "Authorized medical physicist" means an individual who-

4.2.5.1 Meets the requirements in RHA 4.21.1 and RHA 4.24; or

4.2.5.2 Is identified as an authorized medical physicist or teletherapy physicist on-

4.2.5.2.1 A specific medical use license issued by the NRC or an Agreement state;

4.2.5.2.2 A medical use permit issued by an NRC master material licensee;

4.2.5.2.3 A permit issued by an NRC or Agreement State broad scope medical use licensee; or

4.2.5.2.4 A permit issued by an NRC master material license broad scope medical use permittee.

4.2.6 "Authorized nuclear pharmacist" means a pharmacist who-

4.2.6.1 Meets the requirements in RHA 4.22.1 and RHA 4.24; or

4.2.6.2 Is identified as an authorized nuclear pharmacist on-

4.2.6.2.1 A specific license issued by the NRC or Agreement State that authorizes medical use or the practice of nuclear pharmacy; or

4.2.6.2.2 A permit issued by an NRC master material licensee that authorizes medical use or the practice of nuclear pharmacy; or

4.2.6.2.3 A permit issued by an NRC or Agreement State broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or

4.2.6.2.4 A permit issued by an NRC master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy; or

4.2.6.3 Is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or

4.2.6.4 Is designated as an authorized nuclear pharmacist in accordance with RHA 2.7.5.2.4.

4.2.7 "Authorized user" means a physician, dentist, or podiatrist who-

4.2.7.1 Meets the requirements in RHA 4.24 and RHA 4.36.1, RHA 4.39.1, RHA 4.43.1, RHA 4.44.1.1, RHA 4.45.1.1, RHA 4.54.1.1, RHA 4.57.1.1, or RHA 4.74.1.1; or

4.2.7.2 Is identified as an authorized user on-

4.2.7.2.1 An NRC or Agreement State license that authorizes the medical use of radioactive material;

4.2.7.2.2 A permit issued by an NRC master material licensee that is authorized to permit the medical use of radioactive material;

4.2.7.2.3 A permit issued by an NRC or Agreement State specific licensee of broad scope that is authorized to permit the medical use of radioactive material; or

4.2.7.2.4 A permit issued by an NRC master material license broad scope permittee that is authorized to permit the medical use of radioactive material.

4.2.8 "Brachytherapy" means a method of radiation therapy in which sources are used to deliver a radiation dose at a distance of up to a few centimeters by surface, intracavitary, intraluminal, or interstitial application.

4.2.9 "Brachytherapy source" means a radioactive source or a manufacturer-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.

4.2.10 "Client's address" means the area of use or a temporary job site for the purpose of providing mobile medical service in accordance with RHA 4.33.

4.2.11 "Consortium" means an association of medical use licensees and a PET radionuclide production facility in the same geographical area that jointly own or share in the operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use in producing radioactive drugs within the consortium for noncommercial distributions among its associated members for medical use. The PET radionuclide production facility within the consortium must be located at an educational institution or a Federal facility or a medical facility.

4.2.12 "Dedicated check source" means a radioactive source that is used to assure the constant operation of a radiation detection or measurement device over several months or years.

4.2.13 "Dentist" means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice dentistry.

4.2.14 "High dose-rate remote afterloader," as used in this part, means a brachytherapy device that remotely delivers a dose rate in excess of 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

4.2.15 "Low dose-rate remote afterloader," as used in this part, means a brachytherapy device that remotely delivers a dose rate of less than or equal to 2 gray (200 rads) per hour at the point or surface where the dose is prescribed.

4.2.16 "Management" means the chief executive officer or other individual having the authority to manage, direct, or administer the licensee's activities, or those persons' delegate or delegates.

4.2.17 "Manual brachytherapy," as used in this part, means a type of brachytherapy in which the brachytherapy sources (e.g., seeds, ribbons) are manually placed topically on or inserted either into the body cavities that are in close proximity to a treatment site or directly into the tissue volume.

4.2.18 "Medical event" means an event that meets the criteria in RHA 4.117.1.

4.2.19 "Medical institution" means an organization in which more than one medical discipline is practiced.

4.2.20 "Medical use" means the intentional internal or external administration of radioactive material or the radiation from radioactive material to patients or human research subjects under the supervision of an authorized user.

4.2.21 "Medium dose-rate remote afterloader," as used in this part, means a brachytherapy device that remotely delivers a dose rate of greater than 2 gray (200 rads), but less than 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

4.2.22 "Mobile medical service" means the transportation of radioactive material to and its medical use at the client's address.

4.2.23 "*Ophthalmic physicist*" means an individual who-

4.2.23.1 Meets the requirements in RHA 4.52.1.2 and RHA 4.24; and

4.2.23.2 Is identified as an ophthalmic physicist on a-

4.2.23.2.1 Specific medical use license issued by the Nuclear Regulatory Commission or an Agreement State;

4.2.23.2.2 Permit issued by a Nuclear Regulatory Commission or Agreement State broad scope medical use licensee;

4.2.23.2.3 Medical use permit issued by a Nuclear Regulatory Commission master material licensee; or

4.2.23.2.4 Permit issued by a Nuclear Regulatory Commission master material licensee broad scope medical use permittee.

4.2.24 "Output" means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a brachytherapy source or a teletherapy, remote afterloader, or gamma stereotactic radiosurgery unit for specified set of exposure conditions.

4.2.25 "Patient intervention" means actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration.

4.2.26 "Pharmacist" means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice pharmacy.

4.2.27 "Physician" means a medical doctor or doctor of osteopathy licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine.

4.2.28 "Podiatrist" means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice podiatry.

4.2.29 "Positron Emission Tomography (PET) radionuclide production facility" means a facility operating a cyclotron or accelerator for the purpose of producing PET radionuclides.

4.2.30 "Preceptor" means an individual who provides, directs or verifies the training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, or a Radiation Safety Officer.

4.2.31 "Prescribed dosage" means the specified activity or range of activity of unsealed radioactive material as documented-

4.2.31.1 In a written directive; or

4.2.31.2 In accordance with the directions of the authorized user for procedures performed pursuant to RHA 4.35 and 4.37.

4.2.32 "Prescribed dose" means-

4.2.32.1 For gamma stereotactic radiosurgery, the total dose as documented in the written directive;

4.2.32.2 For teletherapy, the total dose and dose per fraction as documented in the written directive;

4.2.32.3 For manual brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or

4.2.32.4 For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

4.2.33 "Pulsed dose-rate remote afterloader," as used in this part, means a special type of remote afterloading brachytherapy device that uses a single source capable of delivering dose rates in the "high dose-rate" range, but-

4.2.33.1 Is approximately one-tenth of the activity of typical high dose-rate remote afterloader sources; and

4.2.33.2 Is used to simulate the radiobiology of a low dose-rate treatment by inserting the source for a given fraction of each hour.

4.2.34 "Radiation Safety Officer" means an individual who-

4.2.34.1 Meets the requirements in RHA 4.20.1 or 4.20.3 and RHA 4.24; or

4.2.34.2 Is identified as a Radiation Safety Officer on-

4.2.34.2.1 A specific medical use license issued by the NRC or Agreement State; or

4.2.34.2.2 A medical use permit issued by an NRC master material licensee.

4.2.35 "Sealed source" means any radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.

4.2.36 "Sealed Source and Device Registry" means the national registry that contains all the registration certificates, generated by both NRC and the Agreement States, that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product.

4.2.37 "Stereotactic radiosurgery" means the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a therapeutic dose to a tissue volume.

4.2.38 "Structured educational program" means an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.

4.2.39 "Teletherapy," as used in this part, means a method of radiation therapy in which collimated gamma rays are delivered at a distance from the patient or human research subject.

4.2.40 "Temporary job" means a location where mobile medical services are conducted other than those location(s) of use authorized on the license.

4.2.41 "Therapeutic dosage" means a dosage of unsealed radioactive material that is intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.

4.2.42 "Therapeutic dose" means a radiation dose delivered from a source containing radioactive material to a patient or human research subject for palliative or curative treatment.

4.2.43 "Treatment site" means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

4.2.44 "Type of use" means use of radioactive material under RHA 4.35, 4.37, 4.40, 4.46, 4.56 4.58 or 4.88.

4.2.45 "Unit dosage" means a dosage prepared for medical use for administration as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared.

4.2.46 "Written directive" means an authorized user's written order for the administration of radioactive material or radiation from radioactive material to a specific patient or human research subject, as specified in RHA 4.17.

History: Amended by SCSR 44–11, eff November 27, 2020 (errata); SCSR 45–5 Doc. No. 5036, eff May 28, 2021.

RHA 4.3. Maintenance of Records.

Each record required by this part must be legible throughout the specified retention period. The record may be the original, a reproduced copy, or a microform if the copy or microform is authenticated by authorized personnel and the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

RHA 4.4. Provisions for the Protection of Human Research Subjects.

4.4.1 A licensee may conduct research involving human research subjects only if it uses the radioactive materials specified on its license for the uses authorized on its license.

4.4.2 If the research is conducted, funded, supported, or regulated by another Federal agency that has implemented the Federal Policy for the Protection of Human Subjects (Federal Policy), the licensee shall, before conducting research—

4.4.2.1 Obtain review and approval of the research from an "Institutional Review Board," as defined and described in the Federal Policy; and

4.4.2.2 Obtain "informed consent," as defined and described in the Federal Policy, from the human research subject.

4.4.3 If the research will not be conducted, funded, supported, or regulated by another Federal agency that has implemented the Federal Policy, the licensee shall, before conducting research, apply for and receive a specific amendment to its South Carolina Radioactive Material medical use license. The amendment request must include a written commitment that the licensee will, before conducting research-

4.4.3.1 Obtain review and approval of the research from an "Institutional Review Board," as defined and described in the Federal Policy; and

4.4.3.2 Obtain "informed consent," as defined and described in the Federal Policy, from the human research subject.

4.4.4 Nothing in this section relieves licensees from complying with the other requirements in this part.

RHA 4.5. FDA, Other Federal, and State Requirements.

Nothing in this part relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs or devices.

RHA 4.6. License Required.

4.6.1 A person may manufacture, produce, acquire, receive, possess, prepare, use, or transfer byproduct material for medical use only in accordance with a specific license issued by the NRC or an Agreement State, or as allowed in RHA 4.6.2.1 or 4.6.2.2 of this section.

4.6.2 A specific license is not needed for an individual who—

4.6.2.1 Receives, possesses, uses, or transfers radioactive material in accordance with the regulations in this chapter under the supervision of an authorized user as provided in RHA 4.15, unless prohibited by license condition; or

4.6.2.2 Prepares unsealed radioactive material for medical use in accordance with the regulations in this chapter under the supervision of an authorized nuclear pharmacist or authorized user as provided in RHA 4.15, unless prohibited by license condition.

RHA 4.7. Application for License, Amendment, or Renewal.

4.7.1 An application must be signed by the applicant's or licensee's management.

4.7.2 An application for a license for medical use of radioactive material as described in RHA 4.35, 4.37, 4.40, 4.46, 4.56, 4.58 and 4.88 must be made by—

4.7.2.1 Filing an original of DHEC Form 0813, "Application for Radioactive Material License," that includes the facility diagram, equipment, and training and experience qualifications of the Radiation Safety Officer, Associate Radiation Safety Officer(s), authorized user(s), authorized medical physicist(s), ophthalmic physicist(s), and authorized nuclear pharmacist(s); and

4.7.2.2 Submitting procedures required by RHA 4.61, 4.67, 4.68 and 4.69, as applicable.

4.7.3 A request for a license amendment or renewal must be made by—

4.7.3.1 Submitting an original of either—

4.7.3.1.1 DHEC Form 0813, "Application for Radioactive Material License"; or

4.7.3.1.2 A letter containing all information required by DHEC Form 0813; and

4.7.3.2 Submitting procedures required by RHA 4.61, 4.67, 4.68 and 4.69, as applicable.

4.7.4 In addition to the requirements in RHA 4.7.2 and 4.7.3 of this section an application for a license or amendment for medical use of radioactive material as described in RHA 4.88 must also include:

4.7.4.1 Any additional aspects of the medical use of the material that are applicable to radiation safety that are not addressed in, or differ from, subparts A through C, L, and M of this part;

4.7.4.2 Identification of and commitment to follow the applicable radiation safety program requirements in subparts D through H of this part that are appropriate for the specific RHA 4.88 medical use;

4.7.4.3 Any additional specific information on —

4.7.4.3.1 Radiation safety precautions and instructions;

4.7.4.3.2 Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and

4.7.4.3.3 Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety; and

4.7.4.4 Any other information requested by the Department in its review of the application.

4.7.5 An applicant that satisfies the requirements specified in RHA 2.8.2 of this chapter may apply for a Type A specific license of broad scope.

HISTORY: Amended by SCSR 45–5 Doc. No. 5036, eff May 28, 2021.

RHA 4.8. License Amendments.

A licensee shall apply for and must receive a license amendment-

4.8.1 Before it receives, prepares, or uses radioactive material for a type of use that is permitted under this part, but that is not authorized on the licensee's current license issued under this part;

4.8.2 Before it permits anyone to work as an authorized user, authorized medical physicist, ophthalmic physicist, or authorized nuclear pharmacist under the license, except-

4.8.2.1 For an authorized user, an individual who meets the requirements in RHA 4.24, 4.36.1, 4.39.1, 4.43.1, 4.44.1.1, 4.45.1.1, 4.54.1.1, 4.57.1.1, and 4.74.1.1;

4.8.2.2 For an authorized nuclear pharmacist, an individual who meets the requirements in RHA 4.22.1 and RHA 4.24;

4.8.2.3 For an authorized medical physicist, an individual who meets the requirements in RHA 4.21.1 and RHA 4.24;

4.8.2.4 An individual who is identified as an authorized user, an authorized nuclear pharmacist, authorized medical physicist, or an ophthalmic physicist-

4.8.2.4.1 On an NRC or Agreement State license or other equivalent permit or license recognized by the Department that authorizes the use of radioactive material in medical use or in the practice of nuclear pharmacy;

4.8.2.4.2 On a license issued by an NRC or Agreement State specific license of broad scope that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy;

4.8.2.4.3 On a license issued by an NRC master material licensee that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy; or

4.8.2.4.4 By a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists.

4.8.3 Before it changes Radiation Safety Officers, except as provided in RHA 4.13.3;

4.8.4 Before it permits anyone to work as an Associate Radiation Safety Officer, or before the Radiation Safety Officer assigns duties and tasks to an Associate Radiation Safety Officer that differ from those for which this individual is authorized on the license;

4.8.5 Before it receives radioactive material in excess of the amount or in a different form, or receives a different radionuclide than is authorized on the license;

4.8.6 Before it adds to or changes the areas of use identified in the application or on the license, except for areas of use where radioactive material is used only in accordance with either RHA 4.35 or 4.37;

4.8.7 Before it changes the address(es) of use identified in the application or on the license;

4.8.8 Before it revises procedures required by RHA 4.61, 4.67, 4.68 and 4.69, as applicable, where such revision reduces radiation safety; and

4.8.9 Before it receives a sealed source from a different manufacturer or of a different model number than authorized by its license unless the sealed source is used for manual brachytherapy, is listed in the Sealed Source and Device Registry, and is in a quantity and for an isotope authorized by the license.

HISTORY: Amended by SCSR 45–5 Doc. No. 5036, eff May 28, 2021.

RHA 4.9. Notifications.

4.9.1 A licensee shall provide the Department, no later than 30 days after the date that the licensee permits an individual to work under the provisions of RHA 4.8.2 as an authorized user, authorized medical physicist, ophthalmic physicist, or authorized nuclear pharmacist-

4.9.1.1 A copy of the board certification and, as appropriate, verification of completion of:

4.9.1.1.1 Training for the authorized medical physicist under RHA 2.21.4;

4.9.1.1.2 Any additional case experience required in RHA 4.43.2.2.7 for an authorized user under RHA 4.40; or

4.9.1.1.3 Device specific training in RHA 4.74.1.5 for the authorized user under RHA 4.58; or

4.9.2 A copy of the Nuclear Regulatory Commission or Agreement State license, the permit issued by a Nuclear Regulatory Commission master material licensee, the permit issued by a Nuclear Regulatory Commission or Agreement State licensee of broad scope, the permit issued by a Nuclear Regulatory Commission master material license broad scope permittee, or documentation that only accelerator-produced radioactive materials, discrete sources of radium-226, or both, were used for medical use or in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the Nuclear Regulatory Commission for each individual whom the licensee permits to work under the provisions of this section.

4.9.2.1 A licensee shall notify the Department no later than 30 days after:

4.9.2.1.1 An authorized user, an authorized nuclear pharmacist, a Radiation Safety Officer, an Associate Radiation Safety Officer, an authorized medical physicist, or ophthalmic physicist permanently discontinues performance of duties under the license or has a name change;

4.9.2.1.2 The licensee permits an individual qualified to be a Radiation Safety Officer under RHA 4.20 and 4.24 to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer in accordance with RHA 4.13.3;

4.9.2.1.3 The licensee's mailing address changes;

4.9.2.1.4 The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in RHA 2.10.2.1 of this chapter;

4.9.2.1.5 The licensee has added to or changed the areas of use identified in the application or on the license where radioactive material is used in accordance with either RHA 4.35 or RHA 4.37 if the change does not include addition or relocation of either an area where PET radionuclides are produced or a PET radioactive drug delivery line from the PET radionuclide/PET radioactive drug production area; or

4.9.2.1.6 The licensee obtains a sealed source for use in manual brachytherapy from a different manufacturer or with a different model number than authorized by its license for which it did not require a license amendment as provided in RHA 4.8.9. The notification must include the manufacturer and model number of the sealed source, the isotope, and the quantity per sealed source.

4.9.3 The licensee shall send the documents required in this section to the appropriate address identified in RHA 1.13.

HISTORY: Amended by SCSR 45–5 Doc. No. 5036, eff May 28, 2021.

RHA 4.10. Exemptions Regarding "Type A" Specific Licenses of Broad Scope.

A licensee possessing a Type A specific license of broad scope for medical use, issued under Part II of this chapter, is exempt from—

4.10.1 The provisions of RHA 4.7.4 regarding the need to file an amendment to the license for medical use of radioactive material, as described in RHA 4.88;

4.10.2 The provisions of RHA 4.8.2;

4.10.3 The provisions of RHA 4.8.6 regarding additions to or changes in the areas of use at the addresses identified in the application or on the license;

4.10.4 The provisions of RHA 4.9.1;

4.10.5 The provisions of RHA 4.9.2.1.1 for an authorized user, an authorized nuclear pharmacist, authorized medical physicist, or an ophthalmic physicist;

4.10.6 The provisions of RHA 4.9.2.4 regarding additions to or changes in the areas of use identified in the application or on the license where radioactive material is used in accordance with either RHA 4.35 or 4.37.

4.10.7 The provisions of RHA 4.19.1.

HISTORY: Amended by SCSR 45–5 Doc. No. 5036, eff May 28, 2021.

RHA 4.11. License Issuance.

4.11.1 The Department shall issue a license for the medical use of radioactive material if—

4.11.1.1 The applicant has filed DHEC Form 0813 "Application for Radioactive Material License" in accordance with the instructions in RHA 4.7;

4.11.1.2 The Department finds the applicant equipped and committed to observe the safety standards established by the Department in this Part for the protection of the public health and safety; and

4.11.1.3 The applicant meets the requirements of Part II of this chapter.

4.11.2 The Department shall issue a license for mobile medical services if the applicant:

4.11.2.1 Meets the requirements in RHA 4.11.1 above; and

4.11.2.2 Assures that individuals or human research subjects to whom unsealed radioactive material or radiation from implants containing radioactive material will be administered may be released following treatment in accordance with RHA 4.32.

RHA 4.12. Specific Exemptions.

The Department may, upon application of any interested person or upon its own initiative, grant exemptions from the regulations in this part that it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

SUBPART B
General Administrative Requirements

RHA 4.13. Authority and Responsibilities for the Radiation Protection Program.

4.13.1 In addition to the radiation protection program requirements of RHA 3.4, a licensee's management shall approve in writing—

4.13.1.1 Requests for a license application, renewal, or amendment before submittal to the Department;

4.13.1.2 Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist, or other authorized medical physicist; and

4.13.1.3 Radiation protection program changes that do not require a license amendment and are permitted under RHA 4.14;

4.13.2 A licensee's management shall appoint a Radiation Safety Officer, who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements. A licensee's management may appoint, in writing, one or more Associate Radiation Safety Officers to support the Radiation Safety Officer. The Radiation Safety Officer, with written agreement of the licensee's management, must assign the specific duties and tasks to each Associate Radiation Safety Officer. These duties and tasks are restricted to the types of use for which the Associate Radiation Safety Officer is listed on a license. The Radiation Safety Officer may delegate duties and tasks to the Associate Radiation Safety Officer but shall not delegate the authority or responsibilities for implementing the radiation protection program.

4.13.3 For up to 60 days each year, a licensee may permit an individual qualified to be a Radiation Safety Officer, under RHA 4.20 and 4.24, to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer, as provided in RHA 4.13.7 of this section, if the licensee takes the actions required in RHA 4.13.2, 4.13.3, 4.13.7 and 4.13.8 of this section and notifies the Department in accordance with RHA 4.9.2.

4.13.4 A licensee may simultaneously appoint more than one temporary Radiation Safety Officer in accordance with RHA 4.13.3 of this section, if needed to ensure that the licensee has a temporary Radiation Safety Officer that satisfies the requirements to be a Radiation Safety Officer for each of the different types of uses of radioactive material permitted by the license.

4.13.5 A licensee shall establish the authority, duties, and responsibilities of the Radiation Safety Officer in writing.

4.13.6 Licensees that are authorized for two or more different types of uses of radioactive material under Subparts E, F, and H of this part, or two or more types of units under Subpart H of this part, shall establish a Radiation Safety Committee to oversee all uses of radioactive material permitted by the license. The Committee must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer. The Committee may include other members the licensee considers appropriate.

4.13.7 A licensee shall provide the Radiation Safety Officer sufficient authority, organizational freedom, time, resources, and management prerogative, to—

4.13.7.1 Identify radiation safety problems;

4.13.7.2 Initiate, recommend, or provide corrective actions;

4.13.7.3 Stop unsafe operations; and,

4.13.7.4 Verify implementation of corrective actions.

4.13.8 A licensee shall retain a record of actions taken under RHA 4.13.1, 4.13.2, and 4.13.5 of this section in accordance with 4.89.

History: Amended by SCSR 44–11, eff November 27, 2020 (errata); SCSR 45–5 Doc. No. 5036, eff May 28, 2021.

RHA 4.14. Radiation Protection Program Changes.

4.14.1 A licensee may revise its radiation protection program without Department approval if—

4.14.1.1 The revision does not require a license amendment under RHA 4.8;

4.14.1.2 The revision is in compliance with the regulations and the license;

4.14.1.3 The revision has been reviewed and approved by the Radiation Safety Officer and licensee management; and

4.14.1.4 The affected individuals are instructed on the revised program before the changes are implemented.

4.14.2 A licensee shall retain a record of each change in accordance with RHA 4.90.

RHA 4.15. Supervision.

4.15.1 A licensee that permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user, as allowed by RHA 4.6.2.1, shall—

4.15.1.1 In addition to the requirements in RHA 6.4 of this chapter, instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, regulations of this chapter, and license conditions with respect to the use of radioactive material; and

4.15.1.2 Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of radioactive material, written radiation protection procedures established by the licensee, written directive procedures, regulations of this Part and license conditions with respect to the medical use of radioactive material.

4.15.2 A licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by RHA 4.6.2.2, shall—

4.15.2.1 In addition to the requirements in RHA 6.4 of this chapter, instruct the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual's involvement with radioactive material; and

4.15.2.2 Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of radioactive material for medical use, written radiation protection procedures established by the licensee, the regulations of this Part, and license conditions.

4.15.3 A licensee that permits supervised activities under RHA 4.15.1 and 4.15.2 is responsible for the acts and omissions of the supervised individual.

RHA 4.17. Written Directives.

4.17.1 A written directive must be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 1.11 Megabequerels (MBq) (30 microcuries (uCi)), any therapeutic dosage of unsealed radioactive material or any therapeutic dose of radiation from radioactive material.

4.17.1.1 If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive must be documented as soon as possible in writing in the patient's record. A written directive must be prepared within 48 hours of the oral directive.

4.17.2 The written directive must contain the patient or human research subject's name and the following information—

4.17.2.1 For any administration of quantities greater than 1.11 MBq (30 uCi) of sodium iodide I-131: the dosage;

4.17.2.2 For an administration of a therapeutic dosage of unsealed radioactive material other than sodium iodide I-131: the radioactive drug, dosage, and route of administration;

4.17.2.3 For gamma stereotactic radiosurgery: the total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site;

4.17.2.4 For teletherapy: the total dose, dose per fraction, number of fractions, and treatment site;

4.17.2.5 For high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose;

4.17.2.6 For permanent implant brachytherapy:

4.17.2.6.1 Before implantation: The treatment site, the radionuclide, and the total source strength; and

4.17.2.6.2 After implantation but before the patient leaves the post-treatment recovery area: The treatment site, the number of sources implanted, the total source strength implanted, and the date; or

4.17.2.7 For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders:

4.17.2.7.1 Before implantation: The treatment site, radionuclide, and dose; and

4.17.2.7.2 After implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose), and date.

4.17.3 A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed radioactive material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

4.17.3.1 If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision must be documented as soon as possible in the patient's record. A revised written directive must be signed by the authorized user within 48 hours of the oral revision.

4.17.4 The licensee shall retain a copy of the written directive in accordance with RHA 4.91.

HISTORY: Amended by SCSR 45–5 Doc. No. 5036, eff May 28, 2021.

RHA 4.18. Procedures for Administrations Requiring a Written Directive.

4.18.1 For any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that:

4.18.1.1 The patient's or human research subject's identity is verified before each administration; and

4.18.1.2 Each administration is in accordance with the written directive.

4.18.2 At a minimum, the procedures required by RHA 4.18.1 must address the following items that are applicable to the licensee's use of radioactive material-

4.18.2.1 Verifying the identity of the patient or human research subject;

4.18.2.2 Verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive;

4.18.2.3 Checking both manual and computer-generated dose calculations;

4.18.2.4 Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by RHA 4.58 or RHA 4.88;

4.18.2.5 Determining if a medical event, as defined in RHA 4.117, has occurred; and

4.18.2.6 Determining, for permanent implant brachytherapy, within 60 calendar days from the date the implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation portion of the written directive, unless a written justification of patient unavailability is documented.

4.18.3 A licensee shall retain a copy of the procedures required under RHA 4.18.1 in accordance with RHA 4.92.

HISTORY: Amended by SCSR 45–5 Doc. No. 5036, eff May 28, 2021.

RHA 4.19. Suppliers for Sealed Sources or Devices for Medical Use.

For medical use, a licensee may only use—

4.19.1 Sealed sources or devices manufactured, labeled, packaged, and distributed in accordance with a license issued under Part II of these regulations and RHA 2.7.7 or equivalent requirements of NRC regulations (10 CFR Part 30 and 10 CFR 32.74);

4.19.2 Sealed sources or devices noncommercially transferred from a Part IV licensee or an Agreement State or NRC medical use licensee.

4.19.3 Teletherapy sources manufactured and distributed in accordance with a license issued under Part II of these regulations or the equivalent requirements of NRC regulations (10 CFR Part 30).

RHA 4.20. Training for Radiation Safety Officers and Associate Radiation Safety Officer

Except as provided in RHA 4.23, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer or an individual assigned duties and tasks as an Associate Radiation Safety Officer as provided in RHA 4.13 to be an individual who-

4.20.1 Is certified by a specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State and who meets the requirements in paragraphs 4.20.4 and 4.20.5 of this section. The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page.

4.20.1.1 To have its certification process recognized, a specialty board shall require all candidates for certification to:

4.20.1.1.1 Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;

4.20.1.1.2 Have 5 or more years of professional experience in health physics (graduate training may be substituted for no more than 2 years of the required experience) including at least 3 years in applied health physics; and

4.20.1.1.3 Pass an examination administered by diplomats of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or

4.20.1.2.1 Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

4.20.1.2.2 Have 2 years of full-time practical training and/or supervised experience in medical physics:

4.20.1.2.2.1 Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Nuclear Regulatory Commission or an Agreement State; or

4.20.1.2.2.2 In clinical nuclear medicine facilities providing diagnostic or therapeutic services under the direction of physicians who meet the requirements for authorized users in RHA 4.23, 4.39 or RHA 4.43; and

4.20.1.2.3 Pass an examination, administered by diplomats of the specialty board, that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or

4.20.2 Has completed a structured educational program consisting of both:

4.20.2.1 200 hours of classroom and laboratory training in the following areas-

4.20.2.1.1 Radiation physics and instrumentation;

4.20.2.1.2 Radiation protection;

4.20.2.1.3 Mathematics pertaining to the use and measurement of radioactivity;

4.20.2.1.4 Radiation biology; and

4.20.2.1.5 Radiation dosimetry; and

4.20.2.2 One year of full-time radiation safety experience under the supervision of the individual identified as the Radiation Safety Office on Nuclear Regulatory Commission or Agreement State license or on a permit issued by an Nuclear Regulatory Commission master material licensee that authorizes similar type(s) of use(s) of radioactive material. An Associate Radiation Safety Officer may provide supervision for those areas for which the Associate Radiation Safety Officer is authorized on a Nuclear Regulatory Commission or an Agreement State license or permit issued by a Nuclear Regulatory Commission master material licensee. The full-time radiation safety experience must involve the following-

4.20.2.2.1 Shipping, receiving, and performing related radiation surveys;

4.20.2.2.2 Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;

4.20.2.2.3 Securing and controlling radioactive material;

4.20.2.2.4 Using administrative controls to avoid mistakes in the administration of radioactive material;

4.20.2.2.5 Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

4.20.2.2.6 Using emergency procedures to control radioactive material; and

4.20.2.2.7 Disposing of radioactive material; and

4.20.2.3 This individual must obtain a written attestation, signed by a preceptor Radiation Safety Officer or Associate Radiation Safety Officer who has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual is seeking approval as a Radiation Safety Officer or an Associate Radiation Safety Officer. The written attestation must state that the individual has satisfactorily completed the requirements in paragraphs RHA 4.20.2 and RHA 4.20.4 of this section, and is able to independently fulfill the radiation safety-related duties as a Radiation Safety Officer or as an Associate Radiation Safety Officer for a medical use license; or

4.20.3 Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State under RHA 4.21.1, has experience with the radiation safety aspects of similar types of use of radioactive material for which the licensee seeks the approval of the individual as Radiation Safety Officer or an Associate Radiation Safety Officer, and meets the requirements in paragraph 4.20.4 of this section; or

4.20.3.1 Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on a Nuclear Regulatory Commission or an Agreement State license, a permit issued by a Nuclear Regulatory Commission master material licensee, a permit issued by a Nuclear Regulatory Commission or an Agreement State licensee of broad scope, or a permit issued by a Nuclear Regulatory Commission master material license broad scope permittee, has experience with the radiation safety aspects of similar types of use of radioactive material for which the licensee seeks the approval of the individual as the Radiation Safety Officer or Associate Radiation Safety Officer, and meets the requirements in paragraph 4.20.4 of this section; or

4.20.3.2 Has experience with the radiation safety aspects of the types of use of radioactive material for which the individual is seeking simultaneous approval both as the Radiation Safety Officer and the authorized user on the same new medical use license or new medical use permit issued by a Nuclear Regulatory Commission master material license. The individual must also meet the requirements in paragraph 4.20.4 of this section.

4.20.4 Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a Radiation Safety Officer, an Associate Radiation Safety

Officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

HISTORY: Amended by SCSR 45–5 Doc. No. 5036, eff May 28, 2021.

RHA 4.21. Training for an Authorized Medical Physicist.

Except as provided in RHA 4.23, the licensee shall require the authorized medical physicist to be an individual who-

4.21.1 Is certified by a specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State and who meets the requirements in paragraph 4.21.4 of this section. The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

4.21.1.1 Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university.

4.21.1.2 Have 2 years of full-time practical training and/or supervised experience in medical physics-

4.21.1.2.1 Under the supervision of a medical physicist who is certified in medical physics by a specialty board whose certification process has been recognized under this section by the Nuclear Regulatory Commission or an Agreement State; or

4.21.1.2.2 In clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements for authorized users in RHA 4.23, 4.54 or 4.74; and

4.21.1.3 Pass an examination, administered by diplomats of the specialty board, that assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery; or

4.21.2 Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and has completed 1 year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type(s) of use for which the individual is seeking authorization. This training and work experience must be conducted in clinical radiation facilities that provide high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services and must include:

4.21.2.1 Performing sealed source leak tests and inventories;

4.21.2.2 Performing decay corrections;

4.21.2.3 Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

4.21.2.4 Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

4.21.2.5 Has obtained written attestation that the individual has satisfactorily completed the requirements in RHA 4.21.2 and 4.21.3 of this section, and is able to independently fulfill the radiation safety-related duties as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in RHA 4.21 or 4.23, or equivalent Nuclear Regulatory Commission or Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status.

4.21.3 Has training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program

provided by the vendor or by training supervised by an authorized medical physicist authorized for the type(s) of use for which the individual is seeking authorization.

HISTORY: Amended by SCSR 45–5 Doc. No. 5036, eff May 28, 2021.

RHA 4.22. Training for an Authorized Nuclear Pharmacist.

Except as provided in RHA 4.23, the licensee shall require the authorized nuclear pharmacist to be a pharmacist who—

4.22.1 Is certified by a specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State. The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit webpage. To have its certification process recognized, a specialty board shall require all candidates for certification to:

4.22.1.1 Have graduated from a pharmacy program accredited by the American Council on Pharmaceutical Education (ACPE) or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;

4.22.1.2 Hold a current, active license to practice pharmacy;

4.22.1.3 Provide evidence of having acquired at least 4000 hours of training/experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2000 hours of the required training and experience; and

4.22.1.4 Pass an examination in nuclear pharmacy administered by diplomats of the specialty board, that assesses knowledge and competency in procurement, compounding, quality assurance, dispensing, distribution, health and safety, radiation safety, provision of information and consultation, monitoring patient outcomes, research and development; or

4.22.2 Has completed 700 hours in a structured educational program consisting of both:

4.22.2.1 200 hours of classroom and laboratory training in the following areas—

4.22.2.1.1 Radiation physics and instrumentation;

4.22.2.1.2 Radiation protection;

4.22.2.1.3 Mathematics pertaining to the use and measurement of radioactivity;

4.22.2.1.4 Chemistry of radioactive material for medical use; and

4.22.2.1.5 Radiation biology; and

4.22.2.2 Supervised practical experience in a nuclear pharmacy involving—

4.22.2.2.1 Shipping, receiving, and performing related radiation surveys;

4.22.2.2.2 Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;

4.22.2.2.3 Calculating, assaying, and safely preparing dosages for patients or human research subjects;

4.22.2.2.4 Using administrative controls to avoid medical events in the administration of radioactive material; and

4.22.2.2.5 Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

4.22.3 Has obtained written attestation signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in RHA 4.22.2 of this section and is able to independently fulfill the radiation safety-related duties as an authorized nuclear pharmacist.

History: Amended by SCSR 44–11, eff November 27, 2020 (errata); SCSR 45–5 Doc. No. 5036, eff May 28, 2021.

RHA 4.23. Training for Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized Medical Physicist, Authorized User, Nuclear Pharmacist, and Authorized Nuclear Pharmacist.

4.23.1 Training for Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, and Nuclear Pharmacist.

4.23.1.1 An individual identified on a Nuclear Regulatory Commission or an Agreement State license or a permit issued by a Nuclear Regulatory Commission or an Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope as a Radiation Safety Officer, a teletherapy or medical physicist, an authorized medical physicist, a nuclear pharmacist or an authorized nuclear pharmacist on or before January 14, 2019, need not comply with the training requirements of RHA 4.20, RHA 4.21, or RHA 4.22, respectively, except the Radiation Safety Officers and authorized medical physicists identified in this paragraph must meet the training requirements in RHA 4.20.4 or RHA 4.21.3, as appropriate, for any material or uses for which they were not authorized prior to this date.

4.23.1.2 Any individual certified by the American Board of Health Physics in Comprehensive Health Physics; American Board of Radiology; American Board of Nuclear Medicine; American Board of Science in Nuclear Medicine; Board of Pharmaceutical Specialties in Nuclear Pharmacy; American Board of Medical Physics in radiation oncology physics; Royal College of Physicians and Surgeons of Canada in nuclear medicine; American Osteopathic Board of Radiology; or American Osteopathic Board of Nuclear Medicine on or before October 24, 2005, need not comply with the training requirements of RHA 4.20 to be identified as a Radiation Safety Officer or as an Associate Radiation Safety Officer on a Nuclear Regulatory Commission or an Agreement State license or Nuclear Regulatory Commission master material license permit for those materials and uses that these individuals performed on or before October 24, 2005.

4.23.1.3 Any individual certified by the American Board of Radiology in therapeutic radiological physics, Roentgen ray and gamma ray physics, x-ray and radium physics, or radiological physics, or certified by the American Board of Medical Physics in radiation oncology physics, on or before October 24, 2005, need not comply with the training requirements for an authorized medical physicist described in RHA 4.21, for those materials and uses that these individuals performed on or before October 24, 2005.

4.23.1.4 A Radiation Safety Officer, a medical physicist, or a nuclear pharmacist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses or in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the Nuclear Regulatory Commission, need not comply with the training requirements of RHA 4.20, RHA 4.21, or RHA 4.22, respectively, when performing the same uses. A nuclear pharmacist, who prepared only radioactive drugs containing accelerator-produced radioactive materials, or a medical physicist, who used only accelerator-produced radioactive materials, at the locations and during the time period identified in this paragraph, qualifies as an authorized nuclear pharmacist or an authorized medical physicist, respectively, for those materials and uses performed before these dates, for the purposes of this chapter.

4.23.2 Training for Experienced Authorized User

4.23.2.1 Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material on a license issued by the Nuclear Regulatory Commission or an Agreement State, a permit issued by a Nuclear Regulatory Commission master material licensee, a permit issued by a Nuclear Regulatory Commission or an Agreement State broad scope licensee, or a permit issued by a Nuclear Regulatory Commission master material license broad scope permittee on or before January 14, 2019, who perform only those medical uses for which they were authorized on or before that date need not comply with the training requirements of subparts D through H of this part.

4.23.2.2 Physicians, dentists, or podiatrists not identified as authorized users for the medical use of radioactive material on a license issued by the Nuclear Regulatory Commission or an Agreement State, a permit issued by a Nuclear Regulatory Commission master material licensee, a permit issued by a Nuclear Regulatory Commission or an Agreement State broad scope licensee, or a permit issued by a Nuclear Regulatory Commission master material license of broad scope on or before October 24, 2005, need not comply with the training requirements of subparts D through H of this part for those materials and uses that these individuals performed on or before October 24, 2005, as follows:

4.23.2.2.1 For uses authorized under RHA 4.35 or RHA 4.37, or oral administration of sodium iodide I-131 requiring a written directive for imaging and localization purposes, a physician who was certified on or before October 24, 2005, in nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology by the American Board of Radiology; diagnostic radiology

or radiology by the American Osteopathic Board of Radiology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or American Osteopathic Board of Nuclear Medicine in nuclear medicine;

4.23.2.2.2 For uses authorized under RHA 4.40, a physician who was certified on or before October 24, 2005, by the American Board of Nuclear Medicine; the American Board of Radiology in radiology, therapeutic radiology, or radiation oncology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or the American Osteopathic Board of Radiology after 1984;

4.23.2.2.3 For uses authorized under RHA 4.46 or RHA 4.58, a physician who was certified on or before October 24, 2005, in radiology, therapeutic radiology or radiation oncology by the American Board of Radiology; radiation oncology by the American Osteopathic Board of Radiology; radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; and

4.23.2.2.4 For uses authorized under RHA 4.56, a physician who was certified on or before October 24, 2005, in radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or nuclear medicine by the Royal College of Physicians and Surgeons of Canada.

4.23.2.3 Physicians, dentists, or podiatrists who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses performed at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the Nuclear Regulatory Commission, need not comply with the training requirements of subparts D through H of this part when performing the same medical uses. A physician, dentist, or podiatrist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses at the locations and time period identified in this paragraph, qualifies as an authorized user for those materials and uses performed before these dates, for the purposes of this chapter.

HISTORY: Amended by SCSR 45–5 Doc. No. 5036, eff May 28, 2021.

RHA 4.24. Recentness of Training.

The training and experience specified in Subparts B, D, E, F, G, and H of this part must have been obtained within the 7 years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.

SUBPART C
General Technical Requirements

RHA 4.25. Possession, Use, and Calibration of Instruments Used to Measure the Activity of Unsealed Radioactive Material.

4.25.1 For direct measurements performed in accordance with RHA 4.27, a licensee shall possess and use instrumentation to measure the activity of unsealed radioactive material before it is administered to each patient or human research subject.

4.25.2 A licensee shall calibrate the instrumentation required in RHA 4.25.1 in accordance with nationally recognized standards or the manufacturer's instructions.

4.25.3 A licensee shall retain a record of each instrument calibration required by this section in accordance with RHA 4.93.

RHA 4.26. Calibration of Survey Instruments.

4.26.1 A licensee shall calibrate the survey instruments used to show compliance with this part and Part III before first use, annually, and following a repair that affects the calibration. A licensee shall—

4.26.1.1 Calibrate all scales with readings up to 10 mSv (1000 mrem) per hour with a radiation source;

4.26.1.2 Calibrate two separated readings on each scale or decade that will be used to show compliance; and

4.26.1.3 Conspicuously note on the instrument the date of calibration.

4.26.2 A licensee may not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is more than 20 percent.

4.26.3 A licensee shall retain a record of each survey instrument calibration in accordance with RHA 4.94.

RHA 4.27. Determination of Dosages of Unsealed Byproduct Material for Medical Use.

4.27.1 A licensee shall determine and record the activity of each dosage before medical use.

4.27.2 For a unit dosage, this determination must be made by—

4.27.2.1 Direct measurement of radioactivity; or

4.27.2.2 A decay correction, based on the activity or activity concentration determined by—

4.27.2.2.1 A manufacturer or preparer licensed under RHA 2.7.5 or equivalent NRC requirements;

4.27.2.2.2 An NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

4.27.2.2.3 A PET radioactive drug producer licensed under Part 2 of this Regulation or equivalent Agreement State requirements.

4.27.3 For other than unit dosages, this determination must be made by—

4.27.3.1 Direct measurement of radioactivity;

4.27.3.2 Combination of measurement of radioactivity and mathematical calculations; or

4.27.3.3 Combination of volumetric measurements and mathematical calculations, based on the measurement made by:

4.27.3.3.1 A manufacturer or preparer licensed under Part 2 of this Regulation or equivalent Agreement State requirements; or

4.27.3.3.2 A PET radioactive drug producer licensed under Part 2 of this Regulation or equivalent Agreement State requirements.

4.27.4 Unless otherwise directed by the authorized user, a licensee may not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent.

4.27.5 A licensee shall retain a record of the dosage determination required by this section in accordance with RHA 4.95.

RHA 4.28. Authorization for Calibration, Transmission, and Reference Sources.

Any person authorized by RHA 4.6 for medical use of radioactive material may receive, possess, and use any of the following radioactive material for check, calibration, transmission, and reference use.

4.28.1 Sealed sources, not exceeding 1.11 GBq (30 mCi) each, manufactured and distributed by a person licensed under RHA 2.7.7 of this chapter or equivalent NRC or Agreement State regulations.

4.28.2 Sealed sources, not exceeding 1.11 GBq (30 mCi) each, redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed under RHA 2.7.7 of this chapter or equivalent Nuclear Regulatory Commission or Agreement State regulations, providing the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions.

4.28.3 Any radioactive material with a half-life not longer than 120 days in individual amounts not to exceed 0.56 GBq (15 mCi).

4.28.4 Any radioactive material with a half-life longer than 120 days in individual amounts not to exceed the smaller of 7.4 MBq (200 uCi) or 1000 times the quantities in Appendix C, RHA 3.54, of Part III of these regulations.

4.28.5 Technetium-99m in amounts as needed.

4.28.6 Radioactive material in sealed sources authorized by this provision shall not be:

4.28.6.1 Used for medical use as defined in RHA 4.2 except in accordance with the requirements in RHA 4.56 or

4.28.6.2 Combined (i.e., bundled or aggregated) to create an activity greater than the maximum activity of any single sealed source authorized under this section.

4.28.6.3 A licensee using calibration, transmission, and reference sources in accordance with the requirements in this section need not list these sources on a specific medical use license.

HISTORY: Amended by SCSR 45–5 Doc. No. 5036, eff May 28, 2021.

RHA 4.29. Requirements for Possession of Sealed Sources and Brachytherapy Sources.

4.29.1 A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer.

4.29.2 A licensee in possession of a sealed source shall—

4.29.2.1 Test the source for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within 6 months before transfer to the licensee; and

4.29.2.2 Test the source for leakage at the intervals not to exceed 6 months or at other intervals approved by the NRC or an Agreement State in the Sealed Source and Device Registry.

4.29.3 To satisfy the leak test requirements of this section, the licensee shall measure the sample so that the leak test can detect the presence of 185 Bq (0.005 uCi) of radioactive material in the sample.

4.29.4 A licensee shall retain leak test records in accordance with RHA 4.96.1.

4.29.5 If the leak test reveals the presence of 185 Bq (0.005 uCi) or more of removable contamination, the licensee shall—

4.29.5.1 Immediately withdraw the sealed source from use and store, dispose, or cause it to be repaired in accordance with the requirements in Parts II and III of these regulations; and

4.29.5.2 File a report within 5 days of the leak test in accordance with RHA 4.119.

4.29.6 A licensee need not perform a leak test on the following sources:

4.29.6.1 Sources containing only radioactive material with a half-life of less than 30 days;

4.29.6.2 Sources containing only radioactive material as a gas;

4.29.6.3 Sources containing 3.7 MBq (100 uCi) or less of beta- or gamma-emitting material or 0.37 MBq (10 uCi) or less of alpha-emitting material;

4.29.6.4 Seeds of Iridium-192 encased in nylon ribbon; and

4.29.6.5 Sources stored and not being used. However, the licensee shall test each such source for leakage before any use or transfer unless it has been leak tested within 6 months before the date of use or transfer.

4.29.7 A licensee in possession of sealed sources or brachytherapy sources, except for gamma stereotactic radiosurgery sources, shall conduct a semi-annual physical inventory of all such sources in its possession. The licensee shall retain each inventory record in accordance with RHA 4.96.2.

RHA 4.30. Labeling of Vials and Syringes.

Each syringe and vial that contains unsealed radioactive material must be labeled to identify the radioactive drug. Each syringe shield and vial shield must also be labeled unless the label on the syringe or vial is visible when shielded.

RHA 4.31. Surveys of Ambient Radiation Exposure Rate.

4.31.1 In addition to the surveys required by Part III of this chapter, a licensee shall survey with a radiation detection survey instrument at the end of each day of use. A licensee shall survey all areas where unsealed radioactive material requiring a written directive was prepared for use or administered.

4.31.2 A licensee does not need to perform the surveys required by RHA 4.31.1 in an area(s) where patients or human research subjects are confined when they cannot be released under RHA 4.32.

4.31.3 A licensee shall retain a record of each survey in accordance with RHA 4.97.

RHA 4.32. Release of Individuals Containing Unsealed Radioactive Material or Implants Containing Radioactive Material.

4.32.1 A licensee may authorize the release from its control of any individual who has been administered unsealed radioactive material or implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem).[1]

4.32.2 A licensee shall provide the released individual, or the individual's parent or guardian, with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem). If the total effective dose equivalent to a nursing infant or child could exceed 1 mSv (0.1 rem) assuming there were no interruption of breast-feeding, the instructions must also include—

4.32.2.1 Guidance on the interruption or discontinuation of breast-feeding; and

4.32.2.2 Information on the potential consequences, if any, of failure to follow the guidance.

4.32.3 A licensee shall maintain a record of the basis for authorizing the release of an individual in accordance with RHA 4.98.1.

4.32.4 The licensee shall maintain a record of instructions provided to a breast-feeding female in accordance with RHA 4.98.2.

History: Amended by SCSR 44–11, eff November 27, 2020 (errata).

RHA 4.33. Provision of Mobile Medical Services.

4.33.1 A licensee providing mobile medical service shall—

4.33.1.1 Obtain a letter signed by the management of each client for which services are rendered that permits the use of radioactive material at the client's address and clearly delineates the authority and responsibility of the licensee and the client;

4.33.1.2 Check instruments used to measure the activity of unsealed radioactive material for proper function before medical use at each client's address or on each day of use, whichever is more frequent. At a minimum, the check for proper function required by this paragraph must include a constancy check;

4.33.1.3 Check survey instruments for proper operation with a dedicated check source before use at each client's address; and

4.33.1.4 Before leaving a client's address, survey all areas of use to ensure compliance with the requirements in Part III of these regulations.

4.33.2 A mobile medical service may not have radioactive material delivered from the manufacturer or the distributor to the client unless the client has a license allowing possession of the radioactive material. Radioactive material delivered to the client must be received and handled in conformance with the client's license.

4.33.3 A licensee providing mobile medical services shall retain the letter required in RHA 4.33.1.1 and the record of each survey required in RHA 4.33.1.4 in accordance with RHA 4.99.1 and 4.99.2 respectively.

RHA 4.34. Decay-in-Storage.

4.34.1 A licensee may hold radioactive material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if it—

1 The current revision of NUREG-1556, Vol. 9, "Consolidated Guidance About Medical Licenses" describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 5 mSv (0.5 rem).

4.34.1.1 Monitors radioactive material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and

4.34.1.2 Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee.

4.34.2 A licensee shall retain a record of each disposal permitted under RHA 4.34.1 in accordance with RHA 4.100.

SUBPART D
Unsealed Radioactive Material…Written Directive Not Required

RHA 4.35. Use of Unsealed Radioactive Material for Uptake, Dilution, and Excretion Studies for Which a Written Directive is not Required.

Except for quantities that require a written directive under RHA 4.17.2, a licensee may use any unsealed byproduct material prepared for medical use for uptake, dilution, or excretion studies that is—

4.35.1 Obtained from:

4.35.1.1 A manufacturer or preparer licensed under RHA 2.7.5 or equivalent Agreement State requirements; or

4.35.1.2 A PET radioactive drug producer licensed under Part 2 of this Regulation or equivalent Agreement State requirements; or

4.35.2 Excluding production of PET radionuclides, prepared by: an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in RHA 4.39 or 4.43 and 4.39.3.2.7, or an individual under the supervision of either as specified in RHA 4.15; or

4.35.3 Obtained from and prepared by an NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

4.35.4 Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

HISTORY: Amended by SCSR 45–5 Doc. No. 5036, eff May 28, 2021.

RHA 4.36. Training for Uptake, Dilution, and Excretion Studies.

Except as provided in RHA 4.23, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under RHA 4.35 to be a physician who-

4.36.1 Is certified by a medical specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State. The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

4.36.1.1 Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies that includes the topics listed in paragraphs 4.36.3 through 4.36.3.2.6 of this section; and

4.36.1.2 Pass an examination, administered by diplomats of the specialty board, that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

4.36.2 Is an authorized user under RHA 4.39 or 4.43 or equivalent NRC requirements; or 4.36.3-

4.36.3 Has completed 60 hours of training and experience, including a minimum of 8 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies. The training and experience must include-

4.36.3.1 Classroom and laboratory training in the following areas-

4.36.3.1.1 Radiation physics and instrumentation;

4.36.3.1.2 Radiation protection;

4.36.3.1.3 Mathematics pertaining to the use and measurement of radioactivity;

4.36.3.1.4 Chemistry of radioactive material for medical use; and

4.36.3.1.5 Radiation biology; and

4.36.3.2 Work experience, under the supervision of an authorized user who meets the requirements in RHA 4.23, 4.36, 4.39 or 4.43 or equivalent NRC requirements, involving-

4.36.3.2.1 Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

4.36.3.2.2 Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

4.36.3.2.3 Calculating, measuring, and safely preparing patient or human research subject dosages;

4.36.3.2.4 Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

4.36.3.2.5 Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

4.36.3.2.6 Administering dosages of radioactive drugs to patients or human research subjects; and

4.36.3.3 Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph 4.36.3 of this section and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under 4.35. The attestation must be obtained from either:

4.36.3.3.1 A preceptor authorized user who meets the requirements in RHA 4.23, 4.36, 4.39, or 4.43, or equivalent Agreement State requirements; or

4.36.3.3.2 A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in RHA 4.23, 4.36, 4.39, or 4.43, or equivalent Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraph 4.36.3 of this section.

History: Amended by SCSR 44–11, eff November 27, 2020 (errata); SCSR 45–5 Doc. No. 5036, eff May 28, 2021.

RHA 4.37. Use of Unsealed Byproduct Material for Imaging and Localization Studies for Which a Written Directive is not Required.

Except for quantities that require a written directive under RHA 4.17.2, a licensee may use any unsealed byproduct material prepared for medical use for imaging and localization studies that is—

4.37.1 Obtained from:

4.37.1.1 A manufacturer or preparer licensed under RHA 2.7.5 or equivalent Agreement State requirements; or

4.37.1.2 A PET radioactive drug producer licensed under Part 2 of this Regulation or equivalent Agreement State requirements; or

4.37.2 Excluding production of PET radionuclides, prepared by: an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in RHA 4.39 or 4.43 and 4.39.3.2.7, or an individual under the supervision of either as specified in RHA 4.15;

4.37.3 Obtained from and prepared by an NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

4.37.4 Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

RHA 4.38. Permissible Molybdenum-99, Strontium-82, and Strontium-85 Concentrations.

4.38.1 A licensee may not administer to humans a radiopharmaceutical that contains:

4.38.1.1 More than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m); or

4.38.1.2 More than 0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 chloride injection (0.02 microcurie of strontium-82 per millicurie of rubidium-82 chloride); or more than 0.2 kilobecquerel of strontium-85 per megabecquerel of rubidium-82 chloride injection (0.2 microcurie of strontium-85 per millicurie of rubidium-82).

4.38.2 A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration in each eluate from a generator to demonstrate compliance with RHA 4.38.1.

4.38.3 A licensee that uses a strontium-82/rubidium-82 generator for preparing a rubidium-82 radiopharmaceutical shall, before the first patient use of the day, measure the concentration of radionuclides strontium-82 and strontium-85 to demonstrate compliance with RHA 4.38.1.

4.38.4 If a licensee is required to measure the molybdenum-99 concentration, the licensee shall retain a record of each measurement in accordance with RHA 4.101.

4.38.5 The licensee shall report any measurement that exceeds the limits in RHA 4.38.1 of this section at the time of generator elution, in accordance with RHA 4.120.

HISTORY: Amended by SCSR 45–5 Doc. No. 5036, eff May 28, 2021.

RHA 4.39. Training for Imaging and Localization Studies.

Except as provided in RHA 4.23, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under RHA 4.37 to be a physician who-

4.39.1 Is certified by a medical specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State. The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit Web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

4.39.1.1 Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for imaging and localization studies that includes the topics listed in paragraphs RHA 4.39.3 through 4.39.3.2.7; and

4.39.1.2 Pass an examination, administered by diplomats of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

4.39.2 Is an authorized user under RHA 4.43 and meets the requirements in RHA 4.39.3.2.7 or equivalent NRC requirements; or

4.39.3 Has completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies. The training and experience must include, at a minimum,-

4.39.3.1 Classroom and laboratory training in the following areas-

4.39.3.1.1 Radiation physics and instrumentation;

4.39.3.1.2 Radiation protection;

4.39.3.1.3 Mathematics pertaining to the use and measurement of radioactivity;

4.39.3.1.4 Chemistry of radioactive material for medical use;

4.39.3.1.5 Radiation biology; and

4.39.3.2 Work experience, under the supervision of an authorized user who meets the requirements in RHA 4.23, 4.39 or 4.43 and 4.39.3.2.7 or equivalent NRC or Agreement State requirements. An authorized nuclear pharmacist who meets the requirements in RHA 4.22 or RHA 4.23 may provide the supervised work experience for paragraph 4.39.3.2.7 of this section. Work experience must involve-

4.39.3.2.1 Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

4.39.3.2.2 Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

4.39.3.2.3 Calculating, measuring, and safely preparing patient or human research subject dosages;

4.39.3.2.4 Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

4.39.3.2.5 Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;

4.39.3.2.6 Administering dosages of radioactive drugs to patients or human research subjects; and

4.39.3.2.7 Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

4.39.3.3 Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph 4.39.3 of this section and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under RHA 4.35 and 4.37. The attestation must be obtained from either:

4.39.3.3.1 A preceptor authorized user who meets the requirements in RHA 4.23, RHA 4.39, or RHA 4.43 and RHA 4.39.3.2.7, or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

4.39.3.3.2 A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in RHA 4.23, RHA 4.39, or RHA 4.43 and RHA 4.39.3.2.7, or equivalent Nuclear Regulatory Commission or Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraph 4.39.3 of this section.

History: Amended by SCSR 44–11, eff November 27, 2020 (errata); SCSR 45–5 Doc. No. 5036, eff May 28, 2021.

SUBPART E
Unsealed Radioactive Material—Written Directive Required

RHA 4.40. Use of Unsealed Radioactive Material for Which a Written Directive is Required.

A licensee may use any unsealed radioactive material identified in RHA 4.43.2.2.7 prepared for medical use and for which a written directive is required that is-

4.40.1 Obtained from:

4.40.1.1 A manufacturer or preparer licensed under RHA 2.7.5 or equivalent Agreement State requirements; or

4.40.1.2 A PET radioactive drug producer licensed under Part 2 of this Regulation or equivalent Agreement State requirements; or

4.40.2 Excluding production of PET radionuclides, prepared by: an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in RHA 4.39 or 4.43; or an individual under the supervision of either as specified in RHA 4.15; or

4.40.3 Obtained from and prepared by an NRC or Agreement State licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA; or

4.40.4 Prepared by the licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA.

HISTORY: Amended by SCSR 45–5 Doc. No. 5036, eff May 28, 2021.

RHA 4.41. Safety Instruction.

In addition to the requirements of RHA 6.4 of these regulations,

4.41.1 A licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who cannot be released under RHA 4.32. To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include—

4.41.1.1 Patient or human research subject control;

4.41.1.2 Visitor control, including—

4.41.1.2.1 Routine visitation to hospitalized individuals in accordance with RHA 3.13.1.1 of these regulations; and

4.41.1.2.2 Visitation authorized in accordance with RHA 3.13.3 of these regulations;

4.41.1.3 Contamination control;

4.41.1.4 Waste control; and

4.41.1.5 Notification of the Radiation Safety Officer, or his or her designee, and the authorized user if the patient or the human research subject has a medical emergency or dies.

4.41.2 A licensee shall retain a record of individuals receiving instruction in accordance with RHA 4.102.

RHA 4.42. Safety Precautions.

4.42.1 For each patient or human research subject who cannot be released under RHA 4.32, a licensee shall—

4.42.1.1 Quarter the patient or the human research subject either in—

4.42.1.1.1 A private room with a private sanitary facility; or

4.42.1.1.2 A room, with a private sanitary facility, with another individual who also has received therapy with unsealed radioactive material and who also cannot be released under RHA 4.32;

4.42.1.2 Visibly post the patient's or the human research subject's room with a "Radioactive Materials" sign.

4.42.1.3 Note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or the human research subject's room; and

4.42.1.4 Either monitor material and items removed from the patient's or the human research subject's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle the material and items as radioactive waste.

4.42.2 A licensee shall notify the Radiation Safety Officer, or his or her designee, and the authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

RHA 4.43. Training for Use of Unsealed Radioactive Material for Which a Written Directive is Required.

Except as provided in RHA 4.23, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under RHA 4.40 to be a physician who-

4.43.1 Is certified by a medical specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State and who meets the requirements in paragraphs 4.43.2.2.7 of this section. The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit Web page. To be recognized, a specialty board shall require all candidates for certification to:

4.43.1.1 Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must include 700 hours of training and experience as described in paragraphs 4.43.2.1 through

4.43.2.2.5 of this section. Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association; and

4.43.1.2 Pass an examination, administered by diplomats of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed radioactive material for which a written directive is required; or

4.43.2 Has completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive. The training and experience must include-

4.43.2.1 Classroom and laboratory training in the following areas-

4.43.2.1.1 Radiation physics and instrumentation;

4.43.2.1.2 Radiation protection;

4.43.2.1.3 Mathematics pertaining to the use and measurement of radioactivity;

4.43.2.1.4 Chemistry of radioactive material for medical use; and

4.43.2.1.5 Radiation biology; and

4.43.2.2 Work experience, under the supervision of an authorized user who meets the requirements in RHA 4.23, 4.43, or equivalent NRC requirements. A supervising authorized user, who meets the requirements in RHA 4.43.2, must also have experience in administering dosages in the same dosage category or categories (i.e., RHA 4.43.2.2.7) as the individual requesting authorized user status. The work experience must involve-

4.43.2.2.1 Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

4.43.2.2.2 Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

4.43.2.2.3 Calculating, measuring, and safely preparing patient or human research subject dosages;

4.43.2.2.4 Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

4.43.2.2.5 Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

4.43.2.2.6 [Reserved]

4.43.2.2.7 Administering dosages of radioactive drugs to patients or research subjects from the three categories in this paragraph. Radioactive drugs containing radionuclides in categories not included in this paragraph are regulated under RHA 4.88. This work experience must involve a minimum of three cases in each of the following categories for which the individual is requesting authorized user status—

4.43.2.2.7.1 Oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131, for which a written directive is required;

4.43.2.2.7.2 Oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; [2]

4.43.2.2.7.3 Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required; and

4.43.2.3 Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph 4.43.2 of this section and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under RHA 4.40 for

[2] Experience with at least three cases in RHA 4.43.2.2.7.2 also satisfies the requirement in RHA 4.43.2.2.7.1.

which the individual is requesting authorized user status. The attestation must be obtained from either:

4.43.2.3.1 A preceptor authorized user who meets the requirements in 4.23, 4.43, or equivalent Nuclear Regulatory Commission or Agreement State requirements and has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status; or

4.43.2.3.2 A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in 4.23, 4.43, or equivalent Nuclear Regulatory Commission or Agreement State requirements, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraph 4.43.2 of this section.

4.43.3 Training for the parenteral administration of unsealed byproduct material requiring a written directive.

4.43.3.1 Except as provided in RHA 4.23, the licensee shall require an authorized user for the parenteral administration requiring a written directive, to be a physician who-

4.43.3.1.1 Is an authorized user under RHA 4.43 uses listed in RHA 4.43.2.2.7.3 or equivalent NRC or Agreement State requirements; or

4.43.3.1.2 Is an authorized user under RHA 4.54, 4.74, or equivalent NRC or Agreement State requirements and who meets the requirements in RHA 4.43.3.2 of this section; or

4.43.3.1.3 Is certified by a medical specialty board whose certification process has been recognized by the NRC or an Agreement State under RHA 4.54 or 4.74, and who meets the requirements in RHA 4.43.3.2 of this section.

4.43.3.2 The Physician—

4.43.3.2.1 Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations, listed in RHA 4.43.2.2.7.3. The training must include-

4.43.3.2.1.1 Radiation physics and instrumentation;

4.43.3.2.1.2 Radiation protection;

4.43.3.2.1.3 Mathematics pertaining to the use and measurement of radioactivity;

4.43.3.2.1.4 Chemistry of radioactive material for medical use; and

4.43.3.2.1.5 Radiation biology; and

4.43.3.2.2 Has work experience, under the supervision of an authorized user who meets the requirements in RHA 4.23, 4.43, 4.43.3 or equivalent NRC or Agreement State requirements, in the parenteral administration listed in RHA 4.43.2.2.7.3. A supervising authorized user who meets the requirements in RHA 4.43, 4.43.3, or equivalent Nuclear Regulatory Commission or Agreement State requirements must have experience in administering dosages in the same category or categories as the individual requesting authorized user status. The work experience must involve-

4.43.3.2.2.1 Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;

4.43.3.2.2.2 Performing quality control procedures on instruments used to determine the activity of dosages, an performing checks for proper operation of survey meters;

4.43.3.2.2.3 Calculating, measuring, and safely preparing patient or human research subject dosages;

4.43.3.2.2.4 Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

4.43.3.2.2.5 Using procedures to contain spilled radioactive material safely, and using proper decontamination procedures; and

4.43.3.2.2.6 Administering dosages to patients or human research subjects, that include at least three cases of parenteral administrations as specified in RHA 4.43.2.2.7.3; and

4.43.3.3 Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs 4.43.3.2.1 and 4.43.3.2.2 of this section, and is able to independently fulfill the radiation safety-related duties as an authorized user for the parenteral administration of unsealed radioactive material requiring a written directive. The attestation must be obtained from either:

4.43.3.3.1 A preceptor authorized user who meets the requirements in RHA 4.23, RHA 4.43, RHA 4.43.3, or equivalent Nuclear Regulatory Commission or Agreement State requirements. A preceptor authorized user who meets the requirements in RHA 4.43, RHA 4.43.3, or equivalent Nuclear Regulatory Commission or Agreement State requirements, must have experience in administering dosages in the same category or categories as the individual requesting authorized user status; or

4.43.3.3.2 A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in RHA 4.23, RHA 4.43, RHA 4.43.3, or equivalent Nuclear Regulatory Commission or Agreement State requirements, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraphs 4.43.3.2.1 and 4.43.3.2.2 of this section.

HISTORY: Amended by SCSR 45–5 Doc. No. 5036, eff May 28, 2021.

RHA 4.44. Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities Less Than or Equal to 1.22 Gigabecquerels (33 Millicuries).

Except as provided in RHA 4.23, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries), to be a physician who-

4.44.1 Is certified by a medical specialty board whose certification process includes all of the requirements in paragraphs 4.44.1.3 and 4.44.1.4 of this section and whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State. The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit Web page; or

4.44.2 Is an authorized user under RHA 4.43, for uses listed in RHA 4.43.2.2.7.1 or 4.43.2.2.7.2, RHA 4.45, or equivalent NRC requirements; or

4.44.3 Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include-

4.44.3.1 Radiation physics and instrumentation;

4.44.3.2 Radiation protection;

4.44.3.3 Mathematics pertaining to the use and measurement of radioactivity;

4.44.3.4 Chemistry of radioactive material for medical use; and

4.44.3.5 Radiation biology; and

4.44.3.6 Has work experience, under the supervision of an authorized user who meets the requirements in RHA 4.23, 4.43, RHA 4.44, RHA 4.45, or equivalent NRC requirements. A supervising authorized user who meets the requirements in RHA 4.43.2 must have experience in administering dosages as specified in RHA 4.43.2.2.7.1 or 4.43.2.2.7.2. The work experience must involve-

4.44.3.6.1 Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

4.44.3.6.2 Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation for survey meters;

4.44.3.6.3 Calculating, measuring, and safely preparing patient or human research subject dosages;

4.44.3.6.4 Using administrative controls to prevent a medical event involving the use of radioactive material;

4.44.3.6.5 Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

4.44.3.6.6 Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of less than or equal to 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131; and

4.44.3.7 Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs 4.44.3 of this section, and is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 for medical uses authorized under RHA 4.40. The attestation must be obtained from either:

4.44.3.7.1 A preceptor authorized user who meets the requirements in RHA 4.23, RHA 4.43, RHA 4.44, RHA 4.45, or equivalent Nuclear Regulatory Commission or Agreement State requirements and has experience in administering dosages as specified in RHA 4.43.2.2.7.1 or RHA 4.43.2.2.7.2; or

4.44.3.7.2 A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in RHA 4.23, RHA 4.43, RHA 4.44, RHA 4.45, or equivalent Agreement State requirements, has experience in administering dosages as specified in RHA 4.43.2.2.7.1 or RHA 4.43.2.2.7.2, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraphs 4.44.1.3 and 4.44.1.4 of this section.

HISTORY: Amended by SCSR 45–5 Doc. No. 5036, eff May 28, 2021.

RHA 4.45. Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities Greater Than 1.22 Gigabecquerels (33 Millicuries).

Except as provided in RHA 4.23, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries), to be a physician who-

4.45.1 Is certified by a medical specialty board whose certification process includes all of the requirements in paragraphs 4.45.1.3 and 4.45.1.4 of this section, and whose certification has been recognized by the Nuclear Regulatory Commission or an Agreement State. The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit Web page; or

4.45.2 Is an authorized user under RHA 4.43.1, 4.43.2 for uses listed in RHA 4.43.2.2.7.2, or equivalent NRC requirements; or

4.45.3 Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include-

4.45.3.1 Radiation physics and instrumentation;

4.45.3.2 Radiation protection;

4.45.3.3 Mathematics pertaining to the use and measurement of radioactivity;

4.45.3.4 Chemistry of radioactive material for medical use; and

4.45.3.5 Radiation biology; and

4.45.3.6 Has work experience, under the supervision of an authorized user who meets the requirements in RHA 4.23, 4.43, 4.45, or equivalent NRC requirements. A supervising authorized user, who meets the requirements in RHA 4.43.2, must also have experience in administering dosages as specified in RHA 4.43.2.2.7.2. The work experience must involve-

4.45.3.6.1 Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

4.45.3.6.2 Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation for survey meters;

4.45.3.6.3 Calculating, measuring, and safely preparing patient or human research subject dosages;

4.45.3.6.4 Using administrative controls to prevent a medical event involving the use of radioactive material;

4.45.3.6.5 Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

4.45.3.6.6 Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of greater than 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131; and

4.45.3.7 Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs 4.45.3 of this section, and is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of greater than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 for medical uses authorized under RHA 4.40. The attestation must be obtained from either:

4.45.3.7.1 A preceptor authorized user who meets the requirements in RHA 4.23, 4.43, 4.45, or equivalent Nuclear Regulatory Commission or Agreement State requirements and has experience in administering dosages as specified in 4.43.2.2.7.2; or

4.45.3.7.2 A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in RHA 4.23, 4.43, 4.45, or equivalent Nuclear Regulatory Commission or Agreement State requirements, has experience in administering dosages as specified in 4.43.2.2.7.2, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraphs 4.45.3 of this section.

HISTORY: Amended by SCSR 45–5 Doc. No. 5036, eff May 28, 2021.

SUBPART F
Manual Brachytherapy

RHA 4.46. Use of Sources for Manual Brachytherapy.

4.46.1 A licensee must use only brachytherapy sources:

4.46.1.1 Approved in the Sealed Source and Device Registry for manual brachytherapy medical use. The manual brachytherapy sources may be used for manual brachytherapy uses that are not explicitly listed in the Sealed Source and Device Registry, but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry; or

4.46.1.2 In research to deliver therapeutic doses for medical use in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of RHA 4.19.1 are met.

HISTORY: Amended by SCSR 45–5 Doc. No. 5036, eff May 28, 2021.

RHA 4.47. Surveys After Source Implant and Removal.

4.47.1 Immediately after implanting sources in a patient or a human research subject, the licensee shall make a survey to locate and account for all sources that have not been implanted.

4.47.2 Immediately after removing the last temporary implant source from a patient or a human research subject, the licensee shall make a survey of the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed.

4.47.3 A licensee shall retain a record of the surveys required by RHA 4.47.1 and 4.47.2 in accordance with RHA 4.103.

RHA 4.48. Brachytherapy Sources Accountability.

4.48.1 A licensee shall maintain accountability at all times for all brachytherapy sources in storage or use.

4.48.2 As soon as possible after removing sources from a patient or a human research subject, a licensee shall return brachytherapy sources to a secure storage area.

4.48.3 A licensee shall maintain a record of the brachytherapy source accountability in accordance with RHA 4.104.

RHA 4.49. Safety Instruction.

4.49.1 In addition to the requirements of RHA 6.4 of these regulations, the licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who are receiving brachytherapy and cannot be released under RHA 4.32. To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include the—

4.49.1.1 Size and appearance of the brachytherapy sources;

4.49.1.2 Safe handling and shielding instructions;

4.49.1.3 Patient or human research subject control;

4.49.1.4 Visitor control, including both:

4.49.1.4.1 Routine visitation of hospitalized individuals in accordance with RHA 3.13.1.1 of these regulations; and

4.49.1.4.2 Visitation authorized in accordance with RHA 3.13.3 of these regulations; and

4.49.1.5 Notification of the Radiation Safety Officer, or his or her designee, and an authorized user if the patient or the human research subject has a medical emergency or dies.

4.49.2 A licensee shall retain a record of individuals receiving instruction in accordance with RHA 4.102.

RHA 4.50. Safety Precautions.

4.50.1 For each patient or human research subject who is receiving brachytherapy and cannot be released under RHA 4.32, a licensee shall—

4.50.1.1 Not quarter the patient or the human research subject in the same room as an individual who is not receiving brachytherapy;

4.50.1.2 Visibly post the patient's or human research subject's room with a "Radioactive Materials" sign; and

4.50.1.3 Note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room.

4.50.2 A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source—

4.50.2.1 Dislodged from the patient; and

4.50.2.2 Lodged within the patient following removal of the source applicators.

4.50.3 A licensee shall notify the Radiation Safety Officer, or his or her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

RHA 4.51. Calibration Measurements of Brachytherapy Sources.

4.51.1 Before the first medical use of a brachytherapy source on or after the effective date of these regulations, a licensee shall have—

4.51.1.1 Determined the source output or activity using a dosimetry system that meets the requirements of RHA 4.63.1;

4.51.1.2 Determined source positioning accuracy within applicators; and

4.51.1.3 Used published protocols currently accepted by nationally recognized bodies to meet the requirements of RHA 4.51.1.1 and 4.51.1.2.

4.51.2 A licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine that are made in accordance with RHA 4.51.1.

4.51.3 A licensee shall mathematically correct the outputs or activities determined in RHA 4.51.1 for physical decay at intervals consistent with 1 percent physical decay.

4.51.4 A licensee shall retain a record of each calibration in accordance with RHA 4.105.

RHA 4.52. Strontium-90 Sources for Ophthalmic Treatments.

4.52.1 Licensees who use strontium-90 for ophthalmic treatments must ensure that certain activities as specified in 4.52.2 of this section are performed by either:

4.52.1.1 An authorized medical physicist; or

4.52.1.2 An individual who:

4.52.1.2.1 Is identified as an ophthalmic physicist on a specific medical use license issued by the Nuclear Regulatory Commission or an Agreement State; permit issued by a Nuclear Regulatory Commission or Agreement State broad scope medical use licensee; medical use permit issued by a Nuclear Regulatory Commission master material licensee; or permit issued by a Nuclear Regulatory Commission master material licensee broad scope medical use permittee; and

4.52.1.2.2 Holds a master's or doctor's degree in physics, medical physics, other physical sciences, engineering, or applied mathematics from an accredited college or university; and

4.52.1.2.3 Has successfully completed 1 year of full-time training in medical physics and an additional year of full-time work experience under the supervision of a medical physicist; and

4.52.1.2.4 Has documented training in:

4.52.1.2.4.1 The creation, modification, and completion of written directives;

4.52.1.2.4.2 Procedures for administrations requiring a written directive; and

4.52.1.2.4.3 Performing the calibration measurements of brachytherapy sources as detailed in RHA 4.51.

4.52.2 The individuals who are identified in 4.52.1 of this section must:

4.52.2.1 Calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under RHA 4.51; and

4.52.2.2 Assist the licensee in developing, implementing, and maintaining written procedures to provide high confidence that the administration is in accordance with the written directive. These procedures must include the frequencies that the individual meeting the requirements in 4.52.1 of this section will observe treatments, review the treatment methodology, calculate treatment time for the prescribed dose, and review records to verify that the administrations were in accordance with the written directives.

4.52.3 Licensees must retain a record of the activity of each strontium-90 source in accordance with RHA 4.106.

HISTORY: Amended by SCSR 45–5 Doc. No. 5036, eff May 28, 2021.

RHA 4.53. Therapy-Related Computer Systems.

4.53.1 The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

4.53.1.1 The source-specific input parameters required by the dose calculation algorithm;

4.53.1.2 The accuracy of dose, dwell time, and treatment time calculations at representative points;

4.53.1.3 The accuracy of isodose plots and graphic displays; and

4.53.1.4 The accuracy of the software used to determine sealed source positions from radiographic images.

RHA 4.54. Training for Use of Manual Brachytherapy Sources.

Except as provided in RHA 4.23, the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under RHA 4.46 to be a physician who-

4.54.1 Is certified by a medical specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State. The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit Web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

4.54.1.1 Successfully complete a minimum of 3 years of residency training in a radiation oncology program approved by the Residency Review committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

4.54.1.2 Pass an examination, administered by diplomats of the specialty board, that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy; or

4.54.2 Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes-

4.54.2.1 200 hours of classroom and laboratory training in the following areas:

4.54.2.1.1 Radiation physics and instrumentation;

4.54.2.1.2 Radiation protection;

4.54.2.1.3 Mathematics pertaining to the use and measurement of radioactivity; and

4.54.2.1.4 Radiation biology; and

4.54.2.2 500 hours of work experience, under the supervision of an authorized user who meets the requirements in RHA 4.23, 4.54, or equivalent NRC or Agreement State requirements at a medical facility authorized to use radioactive material under RHA 4.46, involving-

4.54.2.2.1 Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

4.54.2.2.2 Checking survey meters for proper operation;

4.54.2.2.3 Preparing, implanting, and removing brachytherapy sources;

4.54.2.2.4 Maintaining running inventories of material on hand;

4.54.2.2.5 Using administrative controls to prevent a medical event involving the use of radioactive material;

4.54.2.2.6 Using emergency procedures to control radioactive material; and

4.54.2.3 Has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in RHA 4.23, 4.54 or equivalent NRC requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by RHA 4.54.2.2; and

4.54.2.4 Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs 4.54.2.1 and 4.54.2.2 of this section and is able to independently fulfill the radiation safety-related duties as an authorized user of manual brachytherapy sources for the medical uses authorized under RHA 4.46. The attestation must be obtained from either:

4.54.2.4.1 A preceptor authorized user who meets the requirements in RHA 4.23, RHA 4.54, or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

4.54.2.4.2 A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in RHA 4.23, RHA 4.54, or equivalent Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraphs 4.54.2.1 and 4.54.2.2 of this section.

HISTORY: Amended by SCSR 45–5 Doc. No. 5036, eff May 28, 2021.

RHA 4.55. Training for Ophthalmic Use of Strontium-90.

Except as provided in RHA 4.23, the licensee shall require the authorized user of strontium-90 for ophthalmic radiotherapy to be a physician who-

4.55.1 Is an authorized user under RHA 4.54 or equivalent NRC requirements; or

4.55.2 Has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training must include-

4.55.2.1 Radiation physics and instrumentation;

4.55.2.2 Radiation protection;

4.55.2.3 Mathematics pertaining to the use and measurement of radioactivity; and

4.55.2.4 Radiation biology; and

4.55.3 Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training must involve-

4.55.3.1 Examination of each individual to be treated;

4.55.3.2 Calculation of the dose to be administered;

4.55.3.3 Administration of the dose; and

4.55.3.4 Follow up and review of each individual's case history; and

4.55.4 Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in RHA 4.23, 4.54, 4.55, or equivalent NRC or Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs 4.55.2 and 4.55.3 of this section and is able to independently fulfill the radiation safety-related duties as an authorized user of strontium-90 for ophthalmic use.

HISTORY: Amended by SCSR 45–5 Doc. No. 5036, eff May 28, 2021.

SUBPART G
Sealed Sources for Diagnosis

RHA 4.56. Use of Sealed Sources and Medical Devices for Diagnosis.

4.56.1 A licensee must use only sealed sources that are not in medical devices for diagnostic medical uses if the sealed sources are approved in the Sealed Source and Device Registry for diagnostic medicine. The sealed sources may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

4.56.2 A licensee must only use medical devices containing sealed sources for diagnostic medical uses if both the sealed sources and medical devices are approved in the Sealed Source and Device Registry for diagnostic medical uses. The diagnostic medical devices may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

4.56.3 Sealed sources and devices for diagnostic medical uses may be used in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of RHA 4.19.1 are met.

HISTORY: Amended by SCSR 45–5 Doc. No. 5036, eff May 28, 2021.

RHA 4.57. Training for Use of Sealed Sources and Medical Devices for Diagnosis.

Except as provided in RHA 4.23, the licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized under RHA 4.56 to be a physician, dentist, or podiatrist who-

4.57.1 Is certified by a medical specialty board whose certification process includes all of the requirements in RHA 4.57.3 and 4.57.4 of this section and whose certification has been recognized by the Nuclear Regulatory Commission or an Agreement State. The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit Web page; or

4.57.2 Is an authorized user for uses listed in RHA 4.37 or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

4.57.3 Has had 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include-

4.57.3.1 Radiation physics and instrumentation;

4.57.3.2 Radiation protection;

4.57.3.3 Mathematics pertaining to the use and measurement of radioactivity;

4.57.3.4 Radiation biology; and

4.57.4 Has completed training in the use of the device for the uses requested.

HISTORY: Amended by SCSR 45–5 Doc. No. 5036, eff May 28, 2021.

SUBPART H
Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

RHA 4.58. Use of a Sealed Source in a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit.

4.58.1 A licensee must only use sealed sources:

4.58.1.1 Approved and as provided for in the Sealed Source and Device Registry in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units to deliver therapeutic doses for medical uses: or

4.58.1.2 In research involving photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of RHA 4.19.1 are met.

4.58.2 A licensee must use photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units:

4.58.2.1 Approved in the Sealed Source and Device Registry to deliver a therapeutic dose for medical use. These devices may be used for therapeutic medical treatments that are not explicitly provided for in the Sealed Source and Device Registry, but must be used in accordance with radiation safety conditions and limitations described in the Sealed Source and Device Registry; or

4.58.2.2 In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of RHA 4.19.1 are met.

HISTORY: Amended by SCSR 45–5 Doc. No. 5036, eff May 28, 2021.

RHA 4.59. Surveys of Patients and Human Research Subjects Treated With a Remote Afterloader Unit.

4.59.1 Before releasing a patient or a human research subject from licensee control, a licensee shall survey the patient or the human research subject and the remote afterloader unit with a portable

radiation detection survey instrument to confirm that the source(s) has been removed from the patient or human research subject and returned to the safe shielded position.

4.59.2 A licensee shall retain a record of these surveys in accordance with RHA 4.103.

RHA 4.60. Installation, Maintenance, Adjustment, and Repair.

4.60.1 Only a person specifically licensed by the NRC or an Agreement State shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source(s), reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

4.60.2 Except for low dose-rate remote afterloader units, only a person specifically licensed by the NRC or an Agreement State shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units.

4.60.3 For a low dose-rate remote afterloader unit, only a person specifically licensed by the NRC or an Agreement State or an authorized medical physicist shall install, replace, relocate, or remove a sealed source(s) contained in the unit.

4.60.4 A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units in accordance with RHA 4.107.

RHA 4.61. Safety Procedures and Instructions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.

4.61.1 A licensee shall—

4.61.1.1 Secure the unit, the console, the console keys, and the treatment room when not in use or unattended;

4.61.1.2 Permit only individuals approved by the authorized user, Radiation Safety Officer, or authorized medical physicist to be present in the treatment room during treatment with the source(s);

4.61.1.3 Prevent dual operation of more than one radiation producing device in a treatment room if applicable; and

4.61.1.4 Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source(s) in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. These procedures must include—

4.61.1.4.1 Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;

4.61.1.4.2 The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

4.61.1.4.3 The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

4.61.2 A copy of the procedures required by RHA 4.61.1.4 must be physically located at the unit console.

4.61.3 A licensee shall post instructions at the unit console to inform the operator of—

4.61.3.1 The location of the procedures required by RHA 4.61.1.4; and

4.61.3.2 The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

4.61.4 Training and Instructions.

4.61.4.1 Prior to the first use for patient treatment of a new unit or an existing unit with a manufacturer upgrade that affects the operation and safety of the unit, a licensee shall ensure that vendor operational and safety training is provided to all individuals who will operate the unit. The

vendor operational and safety training must be provided by the device manufacturer or by an individual certified by the device manufacturer to provide the operational and safety training.

4.61.4.2 A licensee shall provide operational and safety instructions initially and at least annually to all individuals who operate the unit at the facility, as appropriate to the individual's assigned duties. The instructions shall include instruction in-

4.61.4.2.1 The procedures identified in paragraph 4.61.1.4 of this section; and

4.61.4.2.2 The operating procedures for the unit.

4.61.5 A licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

4.61.6 A licensee shall retain a record of individuals receiving instruction required by RHA 4.61.4, in accordance with RHA 4.102.

4.61.7 A licensee shall retain a copy of the procedures required by RHA 4.61.1.4 and 4.61.4.2.2 of this section in accordance with RHA 4.108.

HISTORY: Amended by SCSR 45–5 Doc. No. 5036, eff May 28, 2021.

RHA 4.62. Safety Precautions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.

A licensee shall control access to the treatment room by a door at each entrance.*

4.62.2 A licensee shall equip each entrance to the treatment room with an electrical interlock system that will—

4.62.2.1 Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;

4.62.2.2 Cause the source(s) to be shielded when an entrance door is opened; and

4.62.2.3 Prevent the source(s) from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source(s) on-off control is reset at the console.

4.62.3 A licensee shall require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels.

4.62.4 Except for low-dose remote afterloader units, a licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation.

4.62.5 For licensed activities where sources are placed within the patient's or human research subject's body, a licensee shall only conduct treatments which allow for expeditious removal of a decoupled or jammed source.

4.62.6 In addition to the requirements specified in RHA 4.62.1 through 4.62.5, a licensee shall—

4.62.6.1 For medium dose-rate and pulsed dose-rate remote afterloader units, require—

4.62.6.1.1 An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit to be physically present during the initiation of all patient treatments involving the unit; and

4.62.6.1.2 An authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who has been trained to remove the source applicator(s) in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit.

4.62.6.2 For high dose-rate remote afterloader units, require—

4.62.6.2.1 An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and

4.62.6.2.2 An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency

* Paragraph designator omitted from original. Should probably be "4.62.1".

response for the unit, to be physically present during continuation of all patient treatments involving the unit.

4.62.6.3 For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit.

4.62.6.4 Notify the Radiation Safety Officer, or his/her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

4.62.7 A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source—

4.62.7.1 Remaining in the unshielded position; or

4.62.7.2 Lodged within the patient following completion of the treatment.

RHA 4.63. Dosimetry Equipment.

4.63.1 Except for low dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer, a licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions must be met.

4.63.1.1 The system must have been calibrated using a system or source traceable to the National Institute of Science and Technology (NIST) and published protocols accepted by nationally recognized bodies; or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration must have been performed within the previous 2 years and after any servicing that may have affected system calibration; or

4.63.1.2 The system must have been calibrated within the previous 4 years. Eighteen to thirty months after that calibration, the system must have been intercompared with another dosimetry system that was calibrated within the past 24 months by NIST or by a calibration laboratory accredited by the AAPM. The results of the intercomparison must indicate that the calibration factor of the licensee's system had not changed by more than 2 percent. The licensee may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee shall use a comparable unit with beam attenuators or collimators, as applicable, and sources of the same radionuclide as the source used at the licensee's facility.

4.63.2 The licensee shall have a dosimetry system available for use for spot-check output measurements, if applicable. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with RHA 4.63.1. This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in RHA 4.63.1

4.63.3 The licensee shall retain a record of each calibration, intercomparison, and comparison in accordance with RHA 4.109.

RHA 4.64. Full Calibration Measurements on Teletherapy Units.

4.64.1 A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit—

4.64.1.1 Before the first medical use of the unit; and

4.64.1.2 Before medical use under the following conditions:

4.64.1.2.1 Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

4.64.1.2.2 Following replacement of the source or following reinstallation of the teletherapy unit in a new location;

4.64.1.2.3 Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

4.64.1.3 At intervals not exceeding 1 year.

4.64.2 To satisfy the requirement of RHA 4.64.1, full calibration measurements must include determination of—

4.64.2.1 The output within +/-3 percent for the range of field sizes and for the distance or range of distances used for medical use;

4.64.2.2 The coincidence of the radiation field and the field indicated by the light beam localizing device;

4.64.2.3 The uniformity of the radiation field and its dependence on the orientation of the useful beam;

4.64.2.4 Timer accuracy and linearity over the range of use;

4.64.2.5 On-off error; and

4.64.2.6 The accuracy of all distance measuring and localization devices in medical use.

4.64.3 A licensee shall use the dosimetry system described in RHA 4.63.1 to measure the output for one set of exposure conditions. The remaining radiation measurements required in RHA 4.64.2.1 may be made using a dosimetry system that indicates relative dose rates.

4.64.4 A licensee shall make full calibration measurements required by RHA 4.64.1 in accordance with published protocols accepted by nationally recognized bodies.

4.64.5 A licensee shall mathematically correct the outputs determined in RHA 4.64.2.1 for physical decay for intervals not exceeding 1 month for cobalt-60, 6 months for cesium-137, or at intervals consistent with 1 percent decay for all other nuclides.

4.64.6 Full calibration measurements required by RHA 4.64.1 and physical decay corrections required by RHA 4.64.5 must be performed by the authorized medical physicist.

4.64.7 A licensee shall retain a record of each calibration in accordance with RHA 4.110.

RHA 4.65. Full Calibration Measurements on Remote Afterloader Units.

4.65.1 A licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit—

4.65.1.1 Before the first medical use of the unit;

4.65.1.2 Before medical use under the following conditions:

4.65.1.2.1 Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and

4.65.1.2.2 Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

4.65.1.3 At intervals not exceeding 1 quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds 75 days; and

4.65.1.4 At intervals not exceeding 1 year for low dose-rate remote afterloader units.

4.65.2 To satisfy the requirement of RHA 4.65.1, full calibration measurements must include, as applicable, determination of:

4.65.2.1 The output within 5 percent;

4.65.2.2 Source positioning accuracy to within 1 millimeter;

4.65.2.3 Source retraction with backup battery upon power failure;

4.65.2.4 Length of the source transfer tubes;

4.65.2.5 Timer accuracy and linearity over the typical range of use;

4.65.2.6 Length of the applicators; and

4.65.2.7 Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

4.65.3 A licensee shall use the dosimetry system described in RHA 4.63.1 to measure the output.

4.65.4 A licensee shall make full calibration measurements required by RHA 4.65.1 in accordance with published protocols accepted by nationally recognized bodies.

4.65.5 In addition to the requirements for full calibrations for low dose-rate remote afterloader units in RHA 4.65.2, a licensee shall perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding 1 quarter.

4.65.6 For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with RHA 4.65.1 through 4.65.5.

4.65.7 A licensee shall mathematically correct the outputs determined in RHA 4.65.2.1 for physical decay at intervals consistent with 1 percent physical decay.

4.65.8 Full calibration measurements required by RHA 4.65.1 and physical decay corrections required by RHA 4.65.7 must be performed by the authorized medical physicist.

4.65.9 A licensee shall retain a record of each calibration in accordance with RHA 4.110.

RHA 4.66. Full Calibration Measurements on Gamma Stereotactic Radiosurgery Units.

4.66.1 A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each unit—

4.66.1.1 Before the first medical use of the unit;

4.66.1.2 Before medical use under the following conditions—

4.66.1.2.1 Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

4.66.1.2.2 Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and

4.66.1.2.3 Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and

4.66.1.3 At intervals not exceeding 1 year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.

4.66.2 To satisfy the requirement of RHA 4.66.1, full calibration measurements must include determination of—

4.66.2.1 The output within 3 percent;

4.66.2.2 Relative helmet factors;

4.66.2.3 Isocenter coincidence;

4.66.2.4 Timer accuracy and linearity over the range of use;

4.66.2.5 On-off error;

4.66.2.6 Trunnion centricity;

4.66.2.7 Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

4.66.2.8 Helmet microswitches;

4.66.2.9 Emergency timing circuits; and

4.66.2.10 Stereotactic frames and localizing devices (trunnions).

4.66.3 A licensee shall use the dosimetry system described in RHA 4.63.1 to measure the output for one set of exposure conditions. The remaining radiation measurements required in RHA 4.66.2.1 may be made using a dosimetry system that indicates relative dose rates.

4.66.4 A licensee shall make full calibration measurements required by RHA 4.66.1 in accordance with published protocols accepted by nationally recognized bodies.

4.66.5 A licensee shall mathematically correct the outputs determined in RHA 4.66.2.1 at intervals not exceeding 1 month for cobalt-60 and at intervals consistent with 1 percent physical decay for all other radionuclides.

4.66.6 Full calibration measurements required by RHA 4.66.1 and physical decay corrections required by RHA 4.66.5 must be performed by the authorized medical physicist.

4.66.7 A license shall retain a record of each calibration in accordance with RHA 4.110.

RHA 4.67. Periodic Spot-Checks for Teletherapy Units.

4.67.1 A licensee authorized to use teletherapy units for medical use shall perform output spot-checks on each teletherapy unit once in each calendar month that include determination of—

4.67.1.1 Timer accuracy, and timer linearity over the range of use;

4.67.1.2 On-off error;

4.67.1.3 The coincidence of the radiation field and the field indicated by the light beam localizing device;

4.67.1.4 The accuracy of all distance measuring and localization devices used for medical use;

4.67.1.5 The output for one typical set of operating conditions measured with the dosimetry system described in RHA 4.63.2; and

4.67.1.6 The difference between the measurement made in RHA 4.67.1.5 and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

4.67.2 A licensee shall perform measurements required by RHA 4.67.1 in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot-check measurements.

4.67.3 A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

4.67.4 A licensee authorized to use a teletherapy unit for medical use shall perform safety spot-checks of each teletherapy facility once in each calendar month and after each source installation to assure proper operation of—

4.67.4.1 Electrical interlocks at each teletherapy room entrance;

4.67.4.2 Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);

4.67.4.3 Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;

4.67.4.4 Viewing and intercom systems;

4.67.4.5 Treatment room doors from inside and outside the treatment room; and

4.67.4.6 Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

4.67.5 If the results of the checks required in RHA 4.67.4 indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

4.67.6 A licensee shall retain a record of each spot-check required by RHA 4.67.1 and 4.67.4 and a copy of the procedures required by RHA 4.67.2, in accordance with RHA 4.111.

RHA 4.68. Periodic Spot-Checks for Remote Afterloader Units.

4.68.1 A licensee authorized to use a remote afterloader unit for medical use shall perform spot-checks of each remote afterloader facility and on each unit—

4.68.1.1 Before the first use of a high dose-rate, medium dose-rate, or pulsed dose-rate remote afterloader unit on a given day;

4.68.1.2 Before each patient treatment with a low dose-rate remote afterloader unit; and

4.68.1.3 After each source installation.

4.68.2 A licensee shall perform the measurements required by RHA 4.68.1 in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

4.68.3 A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

4.68.4 To satisfy the requirements of RHA 4.68.1, spot-checks must, at a minimum, assure proper operation of—

4.68.4.1 Electrical interlocks at each remote afterloader unit room entrance;

4.68.4.2 Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

4.68.4.3 Viewing and intercom systems in each high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader facility;

4.68.4.4 Emergency response equipment;

4.68.4.5 Radiation monitors used to indicate the source position;

4.68.4.6 Timer accuracy;

4.68.4.7 Clock (date and time) in the unit's computer; and

4.68.4.8 Decayed source(s) activity in the unit's computer.

4.68.5 If the results of the checks required in RHA 4.68.4 indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

4.68.6 A licensee shall retain a record of each check required by RHA 4.68.4 and a copy of the procedures required by RHA 4.68.2 in accordance with RHA 4.112.

RHA 4.69. Periodic Spot-Checks for Gamma Stereotactic Radiosurgery Units.

4.69.1 A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform spot-checks of each gamma stereotactic radiosurgery facility and on each unit—

4.69.1.1 Monthly;

4.69.1.2 Before the first use of the unit on a given day; and

4.69.1.3 After each source installation.

4.69.2 A licensee shall—

4.69.2.1 Perform the measurements required by RHA 4.69.1 in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

4.69.2.2 Have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

4.69.3 To satisfy the requirements of RHA 4.69.1.1, spot-checks must, at a minimum—

4.69.3.1 Assure proper operation of—

4.69.3.1.1 Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

4.69.3.1.2 Helmet microswitches;

4.69.3.1.3 Emergency timing circuits; and

4.69.3.1.4 Stereotactic frames and localizing devices (trunnions).

4.69.3.2 Determine—

4.69.3.2.1 The output for one typical set of operating conditions measured with the dosimetry system described in RHA 4.63.2;

4.69.3.2.2 The difference between the measurement made in RHA 4.69.3.2.1 and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay);

4.69.3.2.3 Source output against computer calculation;

4.69.3.2.4 Timer accuracy and linearity over the range of use;

4.69.3.2.5 On-off error; and

4.69.3.2.6 Trunnion centricity.

4.69.4 To satisfy the requirements of RHA 4.69.1.2 and 4.69.1.3, spot-checks must assure proper operation of—

4.69.4.1 Electrical interlocks at each gamma stereotactic radiosurgery room entrance;

4.69.4.2 Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;

4.69.4.3 Viewing and intercom systems;

4.69.4.4 Timer termination;

4.69.4.5 Radiation monitors used to indicate room exposures; and

4.69.4.6 Emergency off buttons.

4.69.5 A licensee shall arrange for the repair of any system identified in RHA 4.69.3 that is not operating properly as soon as possible.

4.69.6 If the results of the checks required in RHA 4.69.4 indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

4.69.7 A licensee shall retain a record of each check required by RHA 4.69.3 and 4.69.4 and a copy of the procedures required by RHA 4.69.2 in accordance with RHA 4.113.

RHA 4.70. Additional Technical Requirements for Mobile Remote Afterloader Units.

4.70.1 A licensee providing mobile remote afterloader service shall—

4.70.1.1 Check survey instruments before medical use at each address of use or on each day of use, whichever is more frequent; and

4.70.1.2 Account for all sources before departure from a client's address of use.

4.70.2 In addition to the periodic spot-checks required by RHA 4.68, a licensee authorized to use mobile afterloaders for medical use shall perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks must be made to verify the operation of—

4.70.2.1 Electrical interlocks on treatment area access points;

4.70.2.2 Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

4.70.2.3 Viewing and intercom systems;

4.70.2.4 Applicators, source transfer tubes, and transfer tube-applicator interfaces;

4.70.2.5 Radiation monitors used to indicate room exposures;

4.70.2.6 Source positioning (accuracy); and

4.70.2.7 Radiation monitors used to indicate whether the source has returned to a safe shielded position.

4.70.3 In addition to the requirements for checks in RHA 4.70.2, a licensee shall ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.

4.70.4 If the results of the checks required in RHA 4.70.2 indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

4.70.5 A licensee shall retain a record of each check required by RHA 4.70.2 in accordance with RHA 4.114.

RHA 4.71. Radiation Surveys.

4.71.1 In addition to the survey requirement in RHA 3.16, a person licensed under this subpart shall make surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position do not exceed the levels stated in the Sealed Source and Device Registry.

4.71.2 The licensee shall make the survey required by RHA 4.71.1 at installation of a new source and following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or compromise the radiation safety of the unit or the source(s).

4.71.3 A licensee shall retain a record of the radiation surveys required by RHA 4.71.1 in accordance with RHA 4.115. mechanical component that could expose the source, reduce the shielding around the source(s), or

RHA 4.72. Full-inspection Servicing for Teletherapy and Gamma Stereotactic Radiosurgery Units.

4.72.1 A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during each source replacement to assure proper functioning of the source exposure mechanism and other safety components. The interval between each full-inspection servicing shall not exceed 5 years for each teletherapy unit and shall not exceed 7 years for each gamma stereotactic radiosurgery unit.

4.72.2 This inspection and servicing may only be performed by persons specifically licensed to do so by the NRC or an Agreement State.

4.72.3 A licensee shall keep a record of the inspection and servicing in accordance with RHA 4.116.

HISTORY: Amended by SCSR 45–5 Doc. No. 5036, eff May 28, 2021.

RHA 4.73. Therapy-Related Computer Systems.

4.73.1 The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

4.73.1.1 The source-specific input parameters required by the dose calculation algorithm;

4.73.1.2 The accuracy of dose, dwell time, and treatment time calculations at representative points;

4.73.1.3 The accuracy of isodose plots and graphic displays;

4.73.1.4 The accuracy of the software used to determine sealed source positions from radiographic images; and

4.73.1.5 The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

RHA 4.74. Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.

Except as provided in RHA 4.23, the licensee shall require an authorized user of a sealed source for a use authorized under RHA 4.58 to be a physician who-

4.74.1 Is certified by a medical specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State and who meets the requirements in paragraph 4.74.3 of this section. The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit Web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

4.74.1.1 Successfully complete a minimum of 3 years of residency training in radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physician and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

4.74.1.2 Pass an examination, administered by diplomats of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders and external beam therapy; or

4.74.2 Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes-

4.74.2.1 200 hours of classroom and laboratory training in the following areas-

4.74.2.1.1 Radiation physics and instrumentation;

4.74.2.1.2 Radiation protection;

4.74.2.1.3 Mathematics pertaining to the use and measurement of radioactivity; and

4.74.2.1.4 Radiation biology; and

4.74.2.2 500 hours of work experience, under the supervision of an authorized user who meets the requirements in RHA 4.23, 4.74, or equivalent NRC or Agreement State requirements at a medical facility that is authorized to use radioactive materials in RHA 4.58, involving-

4.74.2.2.1 Reviewing full calibration measurements and periodic spot-checks;

4.74.2.2.2 Preparing treatment plans and calculating treatment doses and times;

4.74.2.2.3 Using administrative controls to prevent a medical event involving the use of radioactive material;

4.74.2.2.4 Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;

4.74.2.2.5 Checking and using survey meters; and

4.74.2.2.6 Selecting the proper dose and how it is to be administered; and

4.74.2.3 Has completed 3 years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in RHA 4.23, 4.74, or equivalent NRC or Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by RHA 4.74.2.2; and

4.74.2.4 Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs 4.74.2.1, 4.74.2.2, 4.74.2.3, and 4.74.3 of this section; and is able to independently fulfill the radiation safety-related duties as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The attestation must be obtained from either:

4.74.2.4.1 A preceptor authorized user who meets the requirements in RHA 4.23, 4.74, or equivalent Nuclear Regulatory Commission or Agreement State requirements for the type(s) of therapeutic medical unit for which the individual is requesting authorized user status; or

4.74.2.4.2 A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in RHA 4.23, 4.74, or equivalent Nuclear Regulatory Commission or Agreement State requirements, for the type(s) of therapeutic medical unit for which the individual is requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraphs 4.74.2.1, 4.74.2.2, and 4.74.2.3 of this section.

4.74.3 Has received training in device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type(s) of use for which the individual is seeking authorization.

HISTORY: Amended by SCSR 45–5 Doc. No. 5036, eff May 28, 2021.

SUBPART K
Other Medical Uses of Radioactive Material or Radiation From Radioactive Material

RHA 4.88. Other Medical Uses of Radioactive Material or Radiation From Radioactive Material.

4.88.1 A licensee may use radioactive material or a radiation source approved for medical use which is not specifically addressed in subparts D through H of this part if—

4.88.1.1 The applicant or licensee has submitted the information required by RHA 4.7.2 through 4.7.4; and the applicant or licensee has received written approval from the Department or the NRC in a license or license amendment and uses the material in accordance with the regulations and specific conditions the Department or the NRC considers necessary for the medical use of the material.

SUBPART L
Records

RHA 4.89. Records of Authority and Responsibilities for Radiation Protection Programs.

4.89.1 A licensee shall retain a record of actions taken by the licensee's management in accordance with RHA 4.13.1 for 5 years. The record must include a summary of the actions taken and a signature of licensee management.

4.89.2 The licensee shall retain a copy of both authority, duties, and responsibilities of the Radiation Safety Officer as required by RHA 4.13.5, and a signed copy of each Radiation Safety Officer's agreement to be responsible for implementing the radiation safety program, as required by RHA 4.13.2, for the duration of the license. The records must include the signature of the Radiation Safety Officer and licensee management.

4.89.3. For each Associate Radiation Safety Officer appointed under RHA 4.13.2, the licensee shall retain, for 5 years after the Associate Radiation Safety Officer is removed from the license, a copy of the written document appointing the Associate Radiation Safety Officer signed by the licensee's management.

HISTORY: Amended by SCSR 45–5 Doc. No. 5036, eff May 28, 2021.

RHA 4.90. Records of Radiation Protection Program Changes.

A licensee shall retain a record of each radiation protection program change made in accordance with RHA 4.14.1 for 5 years. The record must include a copy of the old and new procedures; the effective date of the change; and the signature of the licensee management that reviewed and approved the change.

RHA 4.91. Records of Written Directives.

A licensee shall retain a copy of each written directive as required by RHA 4.17 for 3 years.

RHA 4.92. Records For Procedures For Administrations Requiring a Written Directive.

A licensee shall retain a copy of the procedures required by RHA 4.18.1 for the duration of the license.

RHA 4.93. Records of Calibrations of Instruments Used to Measure the Activity of Unsealed Radioactive Material.

A licensee shall maintain a record of instrument calibrations required by RHA 4.25 for 3 years. The records must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

RHA 4.94. Records of Radiation Survey Instrument Calibrations.

A licensee shall maintain a record of radiation survey instrument calibrations required by RHA 4.26 for 3 years. The record must include the model and serial number of the instrument, the date of the

calibration, the results of the calibration, and the name of the individual who performed the calibration.

RHA 4.95. Records of Dosages of Unsealed Radioactive Material For Medical Use.

4.95.1 A licensee shall maintain a record of dosage determinations required by RHA 4.27 for 3 years.

4.95.2 The record must contain—

4.95.2.1 The radiopharmaceutical;

4.95.2.2 The patient's or human research subject's name, or identification number if one has been assigned;

4.95.2.3 The prescribed dosage, the determined dosage, or a notation that the total activity is less than 1.1 MBq (30 uCi);

4.95.2.4 The date and time of the dosage determination; and

4.95.2.5 The name of the individual who determined the dosage.

RHA 4.96. Records of Leaks Tests and Inventory of sealed Sources and Brachytherapy Sources.

4.96.1 A licensee shall retain records of leak tests required by RHA 4.29.2 for 3 years. The records must include the model number, and serial number if one has been assigned, of each source tested; the identity of each source by radionuclide and its estimated activity; the results of the test; the date of the test; and the name of the individual who performed the test.

4.96.2 A licensee shall retain records of the semi-annual physical inventory of sealed sources and brachytherapy sources required by RHA 4.29.7 for 3 years. The inventory records must contain the model number of each source, and serial number if one has been assigned, the identity of each source by radionuclide and its nominal activity, the location of each source, and the name of the individual who performed the inventory.

RHA 4.97. Records of Surveys For Ambient Radiation Exposure Rate.

A licensee shall retain a record of each survey required by RHA 4.31 for 3 years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

RHA 4.98. Records of the Release of Individuals Containing Unsealed Radioactive Material or Implants Containing Radioactive Material.

4.98.1 A licensee shall retain a record of the basis for authorizing the release of an individual in accordance with RHA 4.32, if the total effective dose equivalent is calculated by—

4.98.1.1 Using the retained activity rather than the activity administered;

4.98.1.2 Using an occupancy factor less than 0.25 at 1 meter;

4.98.1.3 Using the biological or effective half-life; or

4.98.1.4 Considering the shielding by tissue.

4.98.2 A licensee shall retain a record that the instructions required by RHA 4.32.2 were provided to a breast-feeding female if the radiation dose to the infant or child from continued breast-feeing could result in a total effective dose equivalent exceeding 5 mSv (0.5 rem).

4.98.3 The records required by RHA 4.98.1 and 4.98.2 must be retained for 3 years after the date of release of the individual.

RHA 4.99. Records of Mobile Medical Services.

4.99.1 A licensee shall retain a copy of each letter that permits the use of radioactive material at a client's address, as required by RHA 4.33.1.1. Each letter must clearly delineate the authority and responsibility of the licensee and the client and must be retained for 3 years after the last provision of service.

4.99.2 A licensee shall retain the record of each survey required by RHA 4.33.1.4 for 3 years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

RHA 4.100. Records of Decay-in-Storage.

A licensee shall maintain records of the disposal of licensed materials, as required by RHA 4.34, for 3 years. The record must include the date of the disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the survey.

RHA 4.101. Records of Molybdenum-99 Concentrations.

A licensee shall maintain a record of the molybdenum-99 concentration tests required by RHA 4.38.2 for 3 years. The record must include, for each measured elution of technetium-99m, the ratio of the measures expressed as kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (or microcuries of molybdenum per millicurie of technetium), the time and date of the measurement, and the name of the individual who made the measurement.

RHA 4.102. Records of Safety Instruction.

A licensee shall maintain a record of safety instructions required by RHA 4.41, 4.49, and the operational and safety instructions required by RHA 4.61 for 3 years. The record must include a list of the topics covered, the date of the instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

HISTORY: Amended by SCSR 45–5 Doc. No. 5036, eff May 28, 2021.

RHA 4.103. Records of Surveys After Source Implant and Removal.

A licensee shall maintain a record of the surveys required by RHA 4.47 and 4.59 for 3 years. Each record must include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey.

RHA 4.104. Records of Brachytherapy Source Accountability.

4.104.1 A licensee shall maintain a record of brachytherapy source accountability required by RHA 4.48 for 3 years.

4.104.2 For temporary implants, the record must include—

4.104.2.1 The number and activity of sources removed from storage, the time and date they were removed from storage, the name of the individual who removed them from storage, and the location of use; and

4.104.2.2 The number and activity of sources returned to storage, the time and date they were returned to storage, and the name of the individual who returned them to storage.

4.104.3 For permanent implants, the record must include—

4.104.3.1 The number and activity of sources removed from storage, the date they were removed from storage, and the name of the individual who removed them from storage;

4.104.3.2 The number and activity of sources not implanted, the date they were returned to storage, and the name of the individual who returned them to storage; and

4.104.3.3 The number and activity of sources permanently implanted in the patient or human research subject.

RHA 4.105. Records of Calibration Measurements of Brachytherapy Sources.

4.105.1 A licensee shall maintain a record of the calibrations of brachytherapy sources required by RHA 4.51 for 3 years after the last use of the source.

4.105.2 The record must include—

4.105.2.1 The date of the calibration;

4.105.2.2 The manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source;

4.105.2.3 The source output or activity;

4.105.2.4 The source positioning accuracy within the applicators; and

4.105.2.5 The signature of the authorized medical physicist.

RHA 4.106. Records of Decay of Strontium-90 Sources for Ophthalmic Treatments.

4.106.1 A licensee shall maintain a record of the activity of a strontium-90 source required by RHA 4.52 for the life of the source.

4.106.2 The record must include—

4.106.2.1 The date and initial activity of the source as determined under RHA 4.51; and

4.106.2.2 For each decay calculation, the date and the source activity as determined under RHA 4.52.

RHA 4.107. Records of Installation, Maintenance, Adjustment, and Repair of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic and Radiosurgery Units.

A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units as required by RHA 4.60 for 3 years. For each installation, maintenance, adjustment and repair, the record must include the date, description of the service, and name(s) of the individual(s) who performed the work.

RHA 4.108. Records of Safety Procedures.

A licensee shall retain a copy of the procedures required by RHA 4.61.1.4 and 4.61.4.2 until the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery unit.

RHA 4.109. Records of Dosimetry Equipment Used with Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.

4.109.1 A licensee shall retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment done in accordance with RHA 4.63 for the duration of the license.

4.109.2 For each calibration, intercomparison, or comparison, the record must include—

4.109.2.1 The date;

4.109.2.2 The manufacturer's name, model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by RHA 4.63.1 and 4.63.2;

4.109.2.3 The correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison; and

4.109.2.4 The names of the individuals who performed the calibration, intercomparison, or comparison.

RHA 4.110. Records of Teletherapy, Remote Afterloader, and Gamma Stereotactic Radiosurgery Full Calibrations.

4.110.1 A licensee shall maintain a record of the teletherapy unit, remote afterloader unit, and gamma stereotactic radiosurgery unit full calibrations required by RHA 4.64, 4.65 and 4.66 for 3 years.

4.110.2 The record must include—

4.110.2.1 The date of the calibration;

4.110.2.2 The manufacturer's name, model number, and serial number of the teletherapy, remote afterloader, and gamma stereotactic radiosurgery unit(s), the source(s), and the instruments used to calibrate the unit(s);

4.110.2.3 The results and an assessment of the full calibrations;

4.110.2.4 The results of the autoradiograph required for low dose-rate remote afterloader units; and

4.110.2.5 The signature of the authorized medical physicist who performed the full calibration.

RHA 4.111. Records of Periodic Spot-Checks for Teletherapy Units.

4.111.1 A licensee shall retain a record of each periodic spot-check for teletherapy units required by RHA 4.67 for 3 years.

4.111.2 The record must include—

4.111.2.1 The date of the spot-check;

4.111.2.2 The manufacturer's name, model number, and serial number of the teletherapy unit, source and instrument used to measure the output of the teletherapy unit;

4.111.2.3 An assessment of timer linearity and constancy;

4.111.2.4 The calculated on-off error;

4.111.2.5 A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;

4.111.2.6 The determined accuracy of each distance measuring and localization device;

4.111.2.7 The difference between the anticipated output and the measured output;

4.111.2.8 Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each source exposure indicator light, and the viewing and intercom system and doors; and

4.111.2.9 The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

4.111.3 A licensee shall retain a copy of the procedures required by RHA 4.67.2 until the licensee no longer possesses the teletherapy unit.

RHA 4.112. Records of Periodic Spot-checks for Remote Afterloader Units.

4.112.1 A licensee shall retain a record of each spot-check for remote afterloader units required by RHA 4.68 for 3 years.

4.112.2 The record must include, as applicable—

4.112.2.1 The date of the spot-check;

4.112.2.2 The manufacturer's name, model number, and serial number for the remote afterloader unit and source;

4.112.2.3 An assessment of timer accuracy;

4.112.2.4 Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, and clock and decayed source activity in the unit's computer; and

4.112.2.5 The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

4.112.3 A licensee shall retain a copy of the procedures required by RHA 4.68.2 until the licensee no longer possesses the remote afterloader unit.

RHA 4.113. Records of Periodic Spot-checks for Gamma Stereotactic Radiosurgery Units.

4.113.1 A licensee shall retain a record of each spot-check for gamma stereotactic radiosurgery units required by RHA 4.69 for 3 years.

4.113.2 The record must include—

4.113.2.1 The date of the spot-check;

4.113.2.2 The manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit;

4.113.2.3 An assessment of timer linearity and accuracy;

4.113.2.4 The calculated on-off error;

4.113.2.5 A determination of trunnion centricity;

4.113.2.6 The difference between the anticipated output and the measured output;

4.113.2.7 An assessment of source output against computer calculations;

4.113.2.8 Notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, and stereotactic frames and localizing devices (trunnions); and

4.113.2.9 The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

4.113.3 A licensee shall retain a copy of the procedures required by RHA 4.69.2 until the licensee no longer possesses the gamma stereotactic radiosurgery unit.

RHA 4.114. Records of Additional Technical Requirements for Mobile Remote Afterloader Units.

4.114.1 A licensee shall retain a record of each check for mobile remote afterloader units required by RHA 4.70 for 3 years.

4.114.2 The record must include—

4.114.2.1 The date of the check;

4.114.2.2 The manufacturer's name, model number, and serial number of the remote afterloader unit;

4.114.2.3 Notations accounting for all sources before the licensee departs from a facility;

4.114.2.4 Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators, source transfer tubes, and transfer tube applicator interfaces, and source positioning accuracy; and

4.114.2.5 The signature of the individual who performed the check.

RHA 4.115. Records of Surveys of Therapeutic Treatment Units.

4.115.1 A licensee shall maintain a record of radiation surveys of treatment units made in accordance with RHA 4.71 for the duration of use of the unit.

4.115.2 The record must include—

4.115.2.1 The date of the measurements;

4.115.2.2 The manufacturer's name, model number and serial number of the treatment unit, source, and instrument used to measure radiation levels;

4.115.2.3 Each dose rate measured around the source while the unit is in the off position and the average of all measurements; and

4.115.2.4 The signature of the individual who performed the test.

RHA 4.116. Records of Full-inspection Servicing for Teletherapy and Gamma Stereotactic Radiosurgery Units.

4.116.1 A licensee shall maintain a record of the full-inspection and servicing for teletherapy and gamma stereotactic radiosurgery units required by RHA 4.72 for the duration of use of the unit.

4.116.2 The record must contain—

4.116.2.1 The inspector's radioactive materials license number;

4.116.2.2 The date of inspection;

4.116.2.3 The manufacturer's name and model number and serial number of both the treatment unit and source;

4.116.2.4 A list of components inspected and serviced, and the type of service; and

4.116.2.5 The signature of the inspector.

HISTORY: Amended by SCSR 45–5 Doc. No. 5036, eff May 28, 2021.

SUBPART M
Reports

RHA 4.117. Report and Notification of a Medical Event.

4.117.1 A licensee shall report any event as a medical event, except for an event that results from patient intervention, in which

4.117.1.1 The administration of radioactive material or radiation from radioactive material, except permanent implant brachytherapy, results in -

4.117.1.1.1 A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and

4.117.1.1.1.1 The total dose delivered differs from the prescribed dose by 20 percent or more; or

4.117.1.1.1.2 The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

4.117.1.1.1.3 The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

4.117.1.1.2 A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following-

4.117.1.1.2.1 An administration of a wrong radioactive drug containing radioactive material; or

4.117.1.1.2.2 An administration of a radioactive drug containing radioactive material by the wrong route of administration; or

4.117.1.1.2.3 An administration of a dose or dosage to the wrong individual or human research subject; or

4.117.1.1.2.4 An administration of a dose or dosage delivered by the wrong mode of treatment; or

4.117.1.1.2.5 A leaking sealed source.

4.117.1.1.3 A dose to the skin or an organ or tissue other than the treatment site that exceeds by:

4.117.1.1.3.1 0.5 Sv (50 rem) or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration; and

4.117.1.1.3.2 50 percent or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration.

4.117.1.2 For permanent implant brachytherapy, the administration of radioactive material or radiation from radioactive material (excluding sources that were implanted in the correct site but migrated outside the treatment site) that results in-

4.117.1.2.1 The total source strength administered differing by 20 percent or more from the total source strength documented in the post-implantation portion of the written directive;

4.117.1.2.2 The total source strength administered outside of the treatment site exceeding 20 percent of the total source strength documented in the post-implantation portion of the written directive; or

4.117.1.2.3 An administration that includes any of the following:

4.117.1.2.3.1 The wrong radionuclide;

4.117.1.2.3.2 The wrong individual or human research subject;

4.117.1.2.3.3 Sealed source(s) implanted directly into a location discontiguous from the treatment site, as documented in the post-implantation portion of the written directive; or

4.117.1.2.3.4 A leaking sealed source resulting in a dose that exceeds 0.5 Sv (50 rem) to an organ or tissue.

4.117.2 A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of radioactive material or radiation from radioactive material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

4.117.3 The licensee shall notify by telephone the SC DHEC Bureau of Radiological Health [3] no later than the next calendar day after discovery of the medical event.

4.117.4 The licensee shall submit a written report to the Bureau of Radiological Health within 15 days after discovery of the medical event.

4.117.4.1 The written report must include—

4.117.4.1.1 The licensee's name;

4.117.4.1.2 The name of the prescribing physician;

4.117.4.1.3 A brief description of the event;

4.117.4.1.4 Why the event occurred;

4.117.4.1.5 The effect, if any, on the individual(s) who received the administration;

4.117.4.1.6 What actions, if any, have been taken or are planned to prevent recurrence; and

4.117.4.1.7 Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

4.117.4.2 The report may not contain the individual's name or any other information that could lead to identification of the individual.

4.117.5 The licensee shall provide notification of the event to the referring physician and also notify the individual who is the subject of the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of this paragraph, the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

4.117.6 Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event, or to that individual's responsible relatives or guardians.

4.117.7 A licensee shall:

4.117.7.1 Annotate a copy of the report provided to the Bureau of Radiological Health with the:

4.117.7.1.1 Name of the individual who is the subject of the event; and

4.117.7.1.2 Identification number or if no other identification number is available, the social security number of the individual who is the subject of the event; and

4.117.7.2 Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

HISTORY: Amended by SCSR 45–5 Doc. No. 5036, eff May 28, 2021.

RHA 4.118. Report and Notification of a Dose to an Embryo/Fetus or a Nursing Child.

4.118.1 A licensee shall report any dose to an embryo/fetus that is greater than 50 mSv (5 rem) dose equivalent that is a result of an administration of radioactive material or radiation from

[3] The commercial telephone number of the Bureau of Radiological Health is (803) 545–4400.

radioactive material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.

4.118.2 A licensee shall report any dose to a nursing child that is a result of an administration of radioactive material to a breast-feeding individual that—

4.118.2.1 Is greater than 50 mSv (5 rem) total effective dose equivalent; or

4.118.2.2 Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

4.118.3 The licensee shall notify by telephone the SC DHEC Bureau of Radiological Health no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in RHA 4.118.1 or 4.118.2.

4.118.4 The licensee shall submit a written report to the Bureau of Radiological Health within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in RHA 4.118.1 or 4.118.2.

4.118.4.1 The written report must include—

4.118.4.1.1 The licensee's name;

4.118.4.1.2 The name of the prescribing physician;

4.118.4.1.3 A brief description of the event;

4.118.4.1.4 Why the event occurred;

4.118.4.1.5 The effect, if any, on the embryo/fetus or the nursing child;

4.118.4.1.6 What actions, if any, have been taken or are planned to prevent recurrence; and

4.118.4.1.7 Certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.

4.118.4.2 The report must not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

4.118.5 The licensee shall provide notification of the event to the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of an event that would require reporting under RHA 4.118.1 or 4.118.2, unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this paragraph, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

4.118.6 A licensee shall:

4.118.6.1 Annotate a copy of the report provided to the Bureau of Radiological Health with the:

4.118.6.1.1 Name of the pregnant individual or the nursing child who is the subject of the event; and

4.118.6.1.2 Identification number or if no other identification number is available, the social security number of the individual who is the subject of the event; and

4.118.6.2 Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

HISTORY: Amended by SCSR 45–5 Doc. No. 5036, eff May 28, 2021.

RHA 4.119. Report of a Leaking Source.

A licensee shall file a report within 5 days if a leak test required by RHA 4.29 reveals the presence of 185 Bq (0.005 uCi) or more of removable contamination. The report must be filed with SC DHEC,

Bureau of Radiological Health. The written report must include the model number and serial number if assigned, of the leaking source; the radionuclide and its estimated activity; the results of the test; the date of the test; and the action taken.

RHA 4.120. Report and Notification for an Eluate Exceeding Permissible Molybdenum-99, Strontium-82, and Strontium-85 Concentrations.

4.120.1 The licensee shall notify by telephone the Department and the distributor of the generator within 7 calendar days after discovery that an eluate exceeded the permissible concentration listed in 4.38.1 at the time of generator elution. The telephone report to the Department must include the manufacturer, model number, and serial number (or lot number) of the generator; the results of the measurement; the date of the measurement; whether dosages were administered to patients or human research subjects, when the distributor was notified, and the action taken.

4.120.2 By an appropriate method listed in RHA 1.13 of this chapter, the licensee shall submit a written report to the Department within 30 calendar days after discovery of an eluate exceeding the permissible concentration at the time of generator elution. The written report must include the action taken by the licensee; the patient dose assessment; the methodology used to make this dose assessment if the eluate was administered to patients or human research subjects; and the probable cause and an assessment of failure in the licensee's equipment, procedures or training that contributed to the excessive readings if an error occurred in the licensee's breakthrough determination; and the information in the telephone report as required by 4.120.1 of this section.

HISTORY: Added by SCSR 45–5 Doc. No. 5036, eff May 28, 2021.

PART V
Special Requirements for Industrial Radiographic Operations

RHA 5.1. Purpose.

This part prescribes requirements for the issuance of licenses for the use of sealed sources containing radioactive material and radiation safety requirements for persons using these sealed sources in industrial radiography. The provisions and requirements of this part are in addition to, and not in substitution for, other requirements of these regulations. In particular, the requirements and provisions of Parts I, II, III, and VI of these regulations apply to applications and licenses subject to this part.

RHA 5.2. Scope.

The regulations in this Part apply to all licensees using sources of radioactive material for industrial radiography; provided, however, that nothing in this Part shall apply to uses of sources of radioactive material in the health professions.

RHA 5.3. Definitions.

As used in this part:

5.3.1 *ALARA* (acronym for "as low as is reasonably achievable") means making every reasonable effort to maintain exposures to radiation as far below the dose limits specified in Part III, Title A as is practical consistent with the purpose for which the licensed activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed materials in the public interest.

5.3.2 *Annual refresher safety training* means a review conducted or provided by the licensee for its employees on radiation safety aspects of industrial radiography. The review may include, as appropriate, the results of internal inspections, new procedures or equipment, new or revised regulations, accidents or errors that have been observed, and should also provide opportunities for employees to ask safety questions.

5.3.3 *Associated equipments* means equipment that is used in conjunction with a radiographic exposure device to make radiographic exposures that drives, guides, or comes in contact with the

source, (e.g., guide tube, control tube, control (drive) cable, removable source stop, J tube and collimator when it is used as an exposure head.

5.3.4 *Becquerel (Bq)* means one disintegration per second.

5.3.5 *Certifying Entity* means an independent certifying organization meeting the requirements in Appendix A, 10 CFR Part 34 or an Agreement State meeting the requirements in appendix A, Parts II and III of 10 CFR Part 34.

5.3.6 *Collimator* means a radiation shield that is placed on the end of the guide tube or directly onto a radiographic exposure device to restrict the size of the radiation beam when the sealed source is cranked into position to make a radiographic exposure.

5.3.7 *Control (drive) cable* means the cable that is connected to the source assembly and used to drive the source to and from the exposure location.

5.3.8 *Control drive mechanism* means a device that enables the source assembly to be moved to and from the exposure device.

5.3.9 *Control tube* means a protective sheath for guiding the control cable. The control tube connects the control drive mechanism to the radiographic exposure device.

5.3.10 *Exposure head* means a device that locates the gamma radiography sealed source in the selected working position. (An exposure head is also known as a source stop.)

5.3.11 *Field station* means a facility where licensed material may be stored or used and from which equipment is dispatched.

5.3.12 *Gray* means the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 Joule/kilogram. It is also equal to 100 rads.

5.3.13 Guide tube (Projection sheath) means a flexible or rigid tube (i.e., J tube) for guiding the source assembly and the attached control cable from the exposure device to the exposure head. The guide tube may also include the connections necessary for attachment to the exposure device and to the exposure head.

5.3.14 *Hands-on experience* means experience in all of those areas considered to be directly involved in the radiography process.

5.3.15 *Independent certifying organization* means an independent organization that meets all of the criteria of Appendix A, 10 CFR Part 34.

5.3.16 *Industrial radiography (radiography)* means an examination of the structure of materials by nondestructive methods, utilizing ionizing radiation to make radiographic images.

5.3.17 *Lay-barge radiography* means industrial radiography performed on any water vessel used for laying pipe.

5.3.18 *Offshore platform radiography* means industrial radiography conducted from a platform over a body of water.

5.3.19 *Permanent radiographic installation* means an enclosed shielded room, cell, or vault, not located at a temporary jobsite, in which radiography is performed.

5.3.20 *Practical Examination* means a demonstration through practical application of the safety rules and principles in industrial radiography including use of all appropriate equipment and procedures.

5.3.21 *Radiation Safety Officer for industrial radiography* means an individual with the responsibility for the overall radiation safety program on behalf of the licensee and who meets the requirements of RHA 5.22.

5.3.22 *Radiographer* means any individual who performs or who, in attendance at the site where the sealed source or sources are being used, personally supervises industrial radiographic operations and who is responsible to the licensee for assuring compliance with the requirements of the Department's regulations and the conditions of the license.

5.3.23 *Radiographer certification* means written approval received from a certifying entity stating that an individual has satisfactorily met certain established radiation safety, testing and experience criteria.

5.3.24 *Radiographer's assistant* means any individual who under the direct supervision of a radiographer, uses radiographic exposure devices, sealed sources or related handling tools, or radiation survey instruments in industrial radiography.

5.3.25 *Radiographic exposure device* (also called a camera, or a projector) means any instrument containing a sealed source fastened or contained therein, in which the sealed source or shielding thereof may be moved, or otherwise changed, from a shielded to unshielded position for purposes of making a radiographic exposure.

5.3.26 *Radiographic operations* means all activities associated with the presence of radioactive sources in a radiographic exposure device during use of the device or transport (except when being transported by a common or contract transport), to include surveys to confirm the adequacy of boundaries, setting up equipment and any activity inside restricted area boundaries.

5.3.27 *S-tube* means a tube through which the radioactive source travels when inside a radiographic exposure device.

5.3.28 *Sealed source* means any radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.

5.3.29 *Shielded position* means the location within the radiographic exposure device or source changer where the sealed source is secured and restricted from movement.

5.3.30 *Sievert* means the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sieverts is equal to the absorbed dose in grays multiplied by the quality factor (1 Sv = 100 rems).

5.3.31 *Source assembly* means an assembly that consists of the sealed source and a connector that attaches the source to the control cable. The source assembly may also include a stop ball used to secure the source in the shielded position.

5.3.32 *Source changer* means a device designed and used for replacement of sealed sources in radiographic exposure devices, including those also used for transporting and storage of sealed sources.

5.3.33 *Storage area* means any location, facility, or vehicle which is used to store or to secure a radiographic exposure device, a storage container, or a sealed source when it is not in use and which is locked or has a physical barrier to prevent accidental exposure, tampering with, or unauthorized removal of the device, container, or source.

5.3.34 *Storage container* means a container in which sealed sources are secured and stored.

5.3.35 *Temporary jobsite* means a location where radiographic operations are conducted and where licensed material may be stored other than those location(s) of use authorized on the license.

5.3.36 *Underwater radiography* means industrial radiography performed when the radiographic exposure device and/or related equipment are beneath the surface of the water.

History: Amended by SCSR 44–11, eff November 27, 2020 (errata).

RHA 5.4. Issuance of Specific Licenses for use of Sealed Sources in Radiography.

An application for a specific license for use of sealed sources in industrial radiography will be approved if:

5.4.1 The applicant satisfies the general requirements specified in RHA 2.6 of these regulations.

5.4.2 The applicant submits an adequate program for training radiographers and radiographers' assistants that meets the requirements of RHA 5.12.

5.4.3 The applicant submits procedures for verifying and documenting the certification status of radiographers and for ensuring that the certification of individuals acting as radiographers remains valid.

5.4.4 The applicant submits written operating and emergency procedures as described in RHA 5.13.

5.4.5 The applicant submits a description of a program for inspections of the job performance of each radiographer and radiographers' assistant at intervals not to exceed 6 months as described in RHA 5.12.5.

5.4.6 The applicant submits a description of the applicant's overall organizational structure as it applies to the radiation safety responsibilities in industrial radiography, including specified delegation of authority and responsibility.

5.4.7 The applicant identifies and lists the qualifications of the individual(s) designated as the RSO (RHA 5.22) and potential designees responsible for ensuring that the licensee's radiation safety program is implemented in accordance with approved procedures.

5.4.8 If an applicant intends to perform leak testing of sealed sources or exposure devices containing depleted uranium (DU) shielding, the applicant must describe the procedures for performing and the qualifications of the person(s) authorized to do the leak testing. If the applicant intends to analyze its own wipe samples, the application must include a description of the procedures to be followed. The description must include the following:

5.4.8.1 Instruments to be used;

5.4.8.2 Methods of performing the analysis; and

5.4.8.3 Pertinent experience of the person who will analyze the wipe samples.

5.4.9 If the applicant intends to perform "in-house" calibrations of survey instruments the applicant must describe methods to be used and the relevant experience of the person(s) who will perform the calibrations. All calibrations must be performed according to the procedures described and at the intervals prescribed in RHA 5.8.

5.4.10 The applicant identifies and describes the location(s) of all field stations and permanent radiographic installations.

5.4.11 The applicant identifies the locations where all records required by this part and other parts of this regulation will be maintained.

RHA 5.5. Limits on External Radiation Levels from Storage Containers and Source Changers.

The maximum exposure rate limits for storage containers and source changers are 200 millirem (2 millisieverts) per hour at any exterior surface, and 10 millirem (0.1 millisieverts) per hour at 1 meter from any exterior surface with the sealed source in the shielded position.

RHA 5.6. Performance and Locking Requirements for Radiography Equipment.

Equipment used in industrial radiographic operations must meet the following minimum criteria:

5.6.1 Each radiographic exposure device, source assembly or sealed source, and all associated equipment must meet the requirements specified in American National Standard N432–1980 "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography," (published as NBS Handbook 136 issued January 1981). This publication has been approved for incorporation by reference by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. This publication may be purchased from the American National Standards Institute, Inc., 25 West 43rd Street, New York, New York 10036; Telephone (212) 642–4900. Copies of the document are available for inspection at the Nuclear Regulatory Commission library, 11545 Rockville Pike, Rockville, Maryland, 20852. A copy of the document is also on file at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202)741–6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

Engineering analyses may be submitted by an applicant or licensee to demonstrate the applicability of previously performed testing on similar individual radiography equipment components. Upon review, the Department may find this an acceptable alternative to actual testing of the component pursuant to the referenced standard.

5.6.2 In addition to the requirements specified in RHA 5.6.1, the following requirements apply to radiographic exposure devices, source changers, source assemblies and sealed sources.

5.6.2.1 Each radiographic exposure device must have attached to it by the user, a durable, legible, clearly visible label bearing the:

(i) Chemical symbol and mass number of the radionuclide in the device;

(ii) Activity and the date on which this activity was last measured;

(iii) Model number and serial number of the sealed source;

(iv) Manufacturer of the sealed source; and

(v) Licensee's name, address, and telephone number

5.6.2.2 Radiographic exposure devices intended for use as Type B transport containers must meet the applicable requirements of 10 CFR Part 71.

5.6.2.3 Modification of radiographic exposure devices, source changers, and source assemblies and associated equipment is prohibited, unless the design of any replacement component, including source holder, source assembly, controls or guide tubes would not compromise the design safety features of the system.

5.6.3 In addition to the requirements specified in RHA 5.6.1 and RHA 5.6.2, the following requirements apply to radiographic exposure devices, source assemblies and associated equipment that allow the source to be moved out of the device for radiographic operations or to source changers.

5.6.3.1 The coupling between the source assembly and the control cable must be designed in such a manner that the source assembly will not become disconnected if cranked outside the guide tube. The coupling must be such that it cannot be unintentionally disconnected under normal and reasonably foreseeable abnormal conditions.

5.6.3.2 The device must automatically secure the source assembly when it is cranked back into the fully shielded position within the device. This securing system may only be released by means of a deliberate operation on the exposure device.

5.6.3.3 The outlet fittings, lock box, and drive cable fittings on each radiographic exposure device must be equipped with safety plugs or covers which must be installed during storage and transportation to protect the source assembly from water, mud, sand or other foreign matter.

5.6.3.4 Each sealed source or source assembly must have attached to it or engraved in it, a durable, legible, visible label with the words: "**Danger-Radioactive**." The label must not interfere with the safe operations of the exposure device or associated equipment.

5.6.3.5 The guide tube must be able to withstand a crushing test that closely approximates the crushing forces that are likely to be encountered during use, and a kinking resistance test that closely approximates the kinking forces likely to be encountered during use.

5.6.3.6 Guide tubes must be used when moving the source out of the device.

5.6.3.7 An exposure head or similar device designed to prevent the source assembly from passing out of the end of the guide tube must be attached to the outermost end of the guide tube during industrial radiographic operations.

5.6.3.8 The guide tube exposure head connection must be able to withstand the tensile test for control units specified in ANSI N432-1980.

5.6.3.9 Source changers must provide a system for assuring that the source will not be accidentally withdrawn from the changer when connecting or disconnecting the drive cable to or from a source assembly.

5.6.4 All radiographic exposure devices and associated equipment in use after January 10, 1996, must comply with the requirements of the above sections.

5.6.5 Each radiographic exposure device must have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. The exposure device and/or its container must be kept locked (and if a keyed-lock, with the key removed at all times) when not under the direct surveillance of a radiographer or a radiographer's assistant except at permanent radiographic installations as stated in RHA 5.15. In addition, during radiographic operations the sealed source assembly must be secured in the shielded position each time the source is returned to that position.

5.6.6 Each sealed source storage container and source changer must have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. Storage containers and source changers must be kept locked (and if a keyed-lock, with the key removed at all times) when containing sealed sources except when under the direct surveillance of a radiographer or a radiographer's assistant.

5.6.7 Notwithstanding RHA 5.6.1 of this section, equipment used in industrial radiographic operations need not comply with section 8. 9. 2 (c) of the Endurance Test in American National Standards Institute N432-1980, if the prototype equipment has been tested using a torque value representative of the torque that an individual using the radiography equipment can realistically exert on the lever or crankshaft of the drive mechanism.

HISTORY: Amended by State Register Volume 38, Issue No. 10, Doc. No. 4462, eff October 24, 2014; SCSR 42–2 Doc. No. 4791, eff February 23, 2018; SCSR 42–4 Doc. No. 2519, eff April 27, 2018 (errata).

RHA 5.7. Labeling, Storage, and Transportation.

5.7.1 The licensee may not use a source changer or a container to store licensed material unless the source changer or the storage container has securely attached to it a durable, legible, and clearly visible label bearing the standard trefoil radiation caution symbol conventional colors, i.e., magenta, purple or black on a yellow background, having a minimum diameter of 25 mm, and the wording

CAUTION*

RADIOACTIVE MATERIAL

NOTIFY CIVIL AUTHORITIES (or NAME OF COMPANY)

*_____ or DANGER

5.7.2 The licensee may not transport licensed material unless the material is packaged, and the package is labeled, marked, and accompanied with appropriate shipping papers in accordance with regulations set out in 10 CFR part 71.

5.7.3 Locked radiographic exposure devices and storage containers must be physically secured to prevent tampering or removal by unauthorized personnel. The licensee shall store licensed material in a manner which will minimize danger from explosion or fire.

5.7.4 The licensee shall lock and physically secure the transport package containing licensed material in the transporting vehicle to prevent accidental loss tampering, or unauthorized removal of the licensed material from the vehicle.

RHA 5.8. Radiation Survey Instruments.

5.8.1 The licensee shall keep sufficient calibrated and operable radiation survey instruments at each location where radioactive material is present to make the radiation surveys required by this part and by Part III. Instrumentation required by this section must be capable of measuring a range from 2 millirems (0.02 millisieverts) per hour through 1 rem (0.01 sievert) per hour.

5.8.2 The licensee shall have each radiation survey instrument required under RHA 5.8.1 calibrated:

5.8.2.1 At intervals not to exceed 6 months and after instrument servicing, except for battery changes;

5.8.2.2 For linear scale instruments, at two points located approximately one-third and two-thirds of full-scale on each scale; for logarithmic scale instruments, at mid-range of each decade, and at two points of at least one decade; and for digital instruments, at 3 points between 2 and 1000 millirems (0.02 and 10 millisieverts) per hour; and

5.8.2.3 So that an accuracy within plus or minus 20 percent of the calibration source can be demonstrated at each point checked.

5.8.3 Each licensee shall maintain records of the calibrations of its radiation survey instruments and retain each record for 3 years after it is made.

RHA 5.9. Leak Testing, Repair, Tagging, Opening, Modification and Replacement of Sealed Sources.

5.9.1 The replacement of any sealed source fastened to or contained in a radiographic exposure device and leak testing, repair, tagging, opening, or any other modification of any sealed source shall be performed only by persons specifically authorized to do so by the Department in accordance with RHA 5.4 the U.S. Nuclear Regulatory Commission, or any Agreement State.

5.9.2 Each licensee who uses a sealed source shall have the source tested for leakage at intervals not to exceed 6 months. The leak testing of the source must be performed using a method approved by

the Nuclear Regulatory Commission or by an Agreement State. The wipe sample should be taken from the nearest accessible point to the sealed source where contamination might accumulate. The wipe sample must be analyzed for radioactive contamination. The analysis must be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample and must be performed by a person specifically authorized by the Commission or an Agreement State to perform the analysis.

5.9.3 Each licensee shall maintain records of leak test results for sealed sources and for devices containing DU. The results must be stated in units of microcuries (becquerels). The licensee shall retain each record for 3 years after it is made or until the source in storage is removed.

5.9.4 Any test conducted pursuant to RHA 5.9.2 which reveals the presence of 0.005 microcuries (185 Bq) or more of removable radioactive material shall be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the equipment involved from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with regulations of the Department. Within five days after obtaining results of the leak test, the licensee shall file a report with the Department describing the equipment involved, the test results and the corrective action taken.

5.9.5 Each exposure device using depleted uranium (DU) shielding and an "S" tube configuration must be tested for DU contamination at intervals not to exceed 12 months. The analysis must be capable of detecting the presence of .005 microcuries (185 Bq) of radioactive material on the test sample and must be performed by a person specifically authorized by the Department or an Agreement State to perform the analysis. Should such testing reveal the presence of .005 microcuries (185 Bq) or more of removable DU contamination, the exposure device must be removed from use until an evaluation of the wear on the S-tube has been made. Should the evaluation reveal that the S-tube is worn through, the device may not be used again. DU shielded devices do not have to be tested for DU contamination while in storage and not in use. Before using or transferring such a device however, the device must be tested for DU contamination if the interval of storage exceeded 12 months. A record of the DU leak-test must be made in accordance with RHA 5.9.3. Licensees will have until May 26, 2001, to comply with the DU leak-testing requirements of this paragraph.

5.9.6 Unless a sealed source is accompanied by a certificate from the transferor that shows that it has been leak tested within 6 months before the transfer, it may not be used by the licensee until tested for leakage. Sealed sources that are in storage and not in use do not require leak testing, but must be tested before use or transfer to another person if the interval of storage exceeds 6 months.

RHA 5.10. Quarterly Inventory and Receipt/Transfer Records.

5.10.1 Each licensee shall conduct a quarterly physical inventory to account for all sealed sources and for devices containing depleted uranium received and possessed under this license.

5.10.2 The licensee shall maintain records of the quarterly inventory and retain each record for 3 years after it is made.

5.10.3 The record must include the date of the inventory, name of the individual conducting the inventory, radionuclide, number of becquerels (curies) or mass (for DU) in each device, location of sealed source and/or devices, and manufacturer, model, and serial number of each sealed source and/or device, as appropriate.

5.10.4 Each licensee shall maintain records showing the receipts and transfers of sealed sources and devices using DU for shielding and retain each record for 3 years after it is made.

5.10.5 These records must include the date, the name of the individual making the record, radionuclide, number of curies (becquerels) or mass (for DU), and manufacturer, model, and serial number of each sealed source and/or device, as appropriate.

RHA 5.11. Utilization Logs.

5.11.1 Each licensee shall maintain utilization logs showing for each sealed source the following information:

5.11.1.1 A description, including the make, model, and serial number of the radiographic exposure device or transport or storage container in which the sealed source is located;

5.11.1.2 The identity and signature of the radiographer to whom assigned; and

5.11.1.3 The plant or site where used and dates of use, including the dates removed and returned to storage.

5.11.2 The licensee shall retain the logs required by RHA 5.11.1 for 3 years after the log is made.

RHA 5.12. Training.

5.12.1 The licensee may not permit any individual to act as a radiographer until the individual:

5.12.1.1 Has received training in the subjects in RHA 5.12.7, in addition to a minimum of 2 months of on-the-job training, and is certified through a radiographer certification program by a certifying entity in accordance with the criteria specified in Appendix A. RHA 5.26. (An independent organization that would like to be recognized as a certifying entity shall submit its request to the Director, Office of Nuclear Materials Safety and Safeguards, US Nuclear Regulatory Commission, Washington, DC 20555–0001) or

5.12.1.2 The licensee may, until May 26, 2002, allow an individual who has not met the requirements of RHA 5.12.1.1 to act as a radiographer after the individual has received training in the subjects outlined in RHA 5.12.7 and demonstrated an understanding of these subjects by successful completion of a written examination that was previously submitted to and approved by the Department.

5.12.2 In addition, the licensee may not permit any individual to act as a radiographer until the individual:

5.12.2.1 Has received copies of and instruction in the requirements described in Department regulations contained in this part; in RHA 6.7, and 2.1.2; in the applicable sections of parts III and VI; in applicable DOT regulations as referenced in 10 CFR part 71, in the specific license(s) under which the radiographer will perform industrial radiography, and the licensee's operating and emergency procedures;

5.12.2.2 Has demonstrated understanding of the licensee's license and operating and emergency procedures by successful completion of a written or oral examination covering this material.

5.12.2.3 Has received training in the use of the licensee's radiographic exposure devices, sealed sources, in the daily inspection of devices and associated equipment, and in the use of radiation survey instruments.

5.12.2.4 Has demonstrated understanding of the use of radiographic exposure devices, sources, survey instruments and associated equipment described in RHA 5.12.2.1 and 5.12.2.3 by successful completion of a practical examination covering this material.

5.12.3 The licensee may not permit any individual to act as a radiographer's assistant until the individual:

5.12.3.1 Has received copies of and instruction in the requirements described in Department regulations contained in this part, in RHA 6.7 and 2.1.2, in the applicable sections of parts III and VI, in applicable DOT regulations as referenced in 10 CFR part 71, in the specific license(s) under which the radiographer's assistant will perform industrial radiography, and the licensee's operating and emergency procedures;

5.12.3.2 Has developed competence to use, under the personal supervision of the radiographer, the radiographic exposure devices, sealed sources, associated equipment, and radiation survey instruments that the assistant will use; and

5.12.3.3 Has demonstrated understanding of the instructions provided under RHA 5.12.3.1 of this section by successfully completing a written test on the subjects covered and has demonstrated competence in the use of hardware described in 5.12.3.2 of this section by successfully completion of a practical examination on the use of such hardware.

5.12.4 The licensee shall provide annual refresher safety training for each radiographer and radiographer's assistant at intervals not to exceed 12 months.

5.12.5 Except as provided in RHA 5.12.5.4, the RSO or designee shall conduct an inspection program of the job performance of each radiographer and radiographer's assistant to ensure that the Department's regulations, license requirements, and the applicant's operating and emergency procedures are followed. The inspection program must:

5.12.5.1 Include observation of the performance of each radiographer and radiographer's assistant during an actual industrial radiographic operation, at intervals not to exceed 6 months; and

5.12.5.2 Provide that, if a radiographer or a radiographer's assistant has not participated in an industrial radiographic operation for more than 6 months since the last inspection, the radiographer must demonstrate knowledge of the training requirements of RHA 5.12.2.3 and the radiographer's assistant must re-demonstrate knowledge of the training requirements of RHA 5.12.3.2 by a practical examination before these individuals can next participate in a radiographic operation.

5.12.5.3 The Department may consider alternatives in those situations where the individual serves as both radiographer and RSO.

5.12.5.4 In those operations where a single individual serves as both radiographer and RSO, and performs all radiography operations, an inspection program is not required.

5.12.6 The licensee shall maintain records of the above training to include certification documents, written and practical examinations, refresher safety training and inspections of job performance in accordance with RHA 5.12.10.

5.12.7 The licensee shall include the following subjects required in RHA 5.12.1 of this section:

5.12.7.1 Fundamentals of radiation safety including:

5.12.7.1.1 Characteristics of gamma radiation;

5.12.7.1.2 Units of radiation dose and quantity of radioactivity;

5.12.7.1.3 Hazards of exposure to radiation;

5.12.7.1.4 Levels of radiation from licensed material; and

5.12.7.1.5 Methods of controlling radiation dose (time, distance, and shielding);

5.12.7.2 Radiation detection instruments including:

5.12.7.2.1 Use, operation, calibration, and limitations of radiation survey instruments;

5.12.7.2.2 Survey techniques; and

5.12.7.2.3 Use of personnel monitoring equipment;

5.12.7.3 Equipment to be used including:

5.12.7.3.1 Operation and control of radiographic exposure equipment, remote handling equipment, and storage containers, including pictures or models of source assemblies (pigtails).

5.12.7.3.2 Storage, control, and disposal of licensed material; and

5.12.7.3.3 Inspection and maintenance of equipment.

5.12.7.4 The requirements of pertinent Federal and State regulations; and

5.12.7.5 Case histories of accidents in radiography.

5.12.8 Licensees will have until May 26, 2001, to comply with the additional training requirements specified in RHA 5.12.2.1 and RHA 5.12.3.1.

5.12.9 Licensees will have until May 26, 2002, to comply with the certification requirements specified in RHA 5.12.1.1. Records of radiographer certification maintained in accordance with RHA 5.12.10.1 provide appropriate affirmation of certification requirements specified in RHA 5.12.1.1.

5.12.10 Each licensee shall maintain the following records (of training and certification) for 3 years after the record is made:

5.12.10.1 Records of training of each radiographer and each radiographer's assistant. The record must include radiographer certification documents and verification of certification status, copies of written tests, dates of oral and practical examinations, and names of individuals conducting and receiving the oral and practical examinations; and

5.12.10.2 Records of annual refresher safety training and semi-annual inspections of job performance for each radiographer and each radiographer's assistant. The records must list the topics discussed during the refresher safety training, the dates the annual refresher safety training was conducted, and names of the instructors and attendees. For inspections of job performance, the

records must also include a list showing the items checked and any non-compliances observed by the RSO.

RHA 5.13. Operating and Emergency Procedures.

The licensee's operating and emergency procedures shall include instructions in at least the following:

5.13.1 The handling and use of sources of radiation to be employed such that no person is likely to be exposed to radiation doses in excess of the limits established in these regulations;

5.13.2 Methods and occasions for conducting radiation surveys;

5.13.3 Methods for controlling access to radiographic areas;

5.13.4 Methods and occasions for locking and securing radiographic exposure devices, transport and storage containers and sealed sources;

5.13.5 Personnel monitoring and the use of personnel monitoring equipment, including steps that must be taken immediately by radiography personnel in the event a pocket dosimeter is found to be off-scale or an alarm rate meter alarms unexpectedly.

5.13.6 Transporting sources of radiation to field locations, including packing of sources of radiation in the vehicles, posting of sources of radiation in the vehicles, posting of vehicles, and control of sources of radiation during transportation;

5.13.7 Minimizing exposure of individuals in the event of an accident;

5.13.8 The procedure for notifying proper persons in the event of an accident;

5.13.9 Maintenance of records; and

5.13.10 The inspection, maintenance, and operability checks of radiographic exposure devices, survey instruments, transport containers, and storage containers;

5.13.11 The procedure(s) for identifying and reporting defects and noncompliance, as required by Part VI of these regulations.

5.13.12 Source recovery procedure if licensee will perform source recovery;

5.13.13 Each licensee shall maintain a copy of current operating and emergency procedures until the Department terminates the license. Superseded material must be retained for 3 years after the change is made. Location of these documents shall be in accordance with RHA 5.24.

RHA 5.14. Personnel Monitoring Control.

5.14.1 The licensee may not permit any individual to act as a radiographer or a radiographer's assistant unless, at all times during radiographic operations, each individual wears, on the trunk of the body, a direct reading dosimeter, an operating alarm rate meter and a personnel dosimeter. At permanent radiography facilities where other appropriate alarming or warning devices are in routine use, the wearing of an alarming rate meter is not required. Pocket dosimeters must have a range from zero to at least 200 milliroentgens and must be recharged at the start of each shift. Electronic personal dosimeters may only be used in place of ion-chamber pocket dosimeters. Each personnel dosimeter must be assigned to and worn by only one individual. Film badges must be replaced at least monthly and all other personnel dosimeters that require replacement must be replaced at least quarterly. All personnel dosimeters must be evaluated at least quarterly or promptly after replacement, whichever is more frequent.

5.14.2 Pocket dosimeters or electronic personal dosimeters must be read and exposures recorded at the beginning and end of each shift. The licensee shall retain each record of these exposures in accordance with RHA 5.14.7.1.

5.14.3 Pocket dosimeters or electronic personal dosimeters shall be checked at periods not to exceed one year for correct response to radiation. Acceptable dosimeters shall read within plus or minus 20 percent of the true radiation exposure. Records must be maintained in accordance with RHA 5.14.7.1.

5.14.4 If an individual's pocket chamber is found to be off scale, or if his or her electronic personal dosimeter reads greater than 2 millisieverts (200 millirems), and the possibility of radiation exposure cannot be ruled out as the cause, the individual's personnel dosimeter must be sent for processing within 24 hours. For personnel dosimeters that do not require processing, evaluation of the dosimeter

must be started within 24 hours. In addition, the individual may not resume work associated with licensed material use until a determination of the individual's radiation exposure has been made. This determination must be made by the RSO or the RSO's designee. The results of this determination must be included in records to be maintained by the licensee until the Department terminates the license.

If the personnel dosimeter that is required by RHA 5.14.1 is lost or damaged, the worker shall cease work immediately until a replacement personnel dosimeter meeting the requirements is provided and the exposure is calculated for the time period from issuance to loss or damage of the personnel dosimeter. The results of the calculated exposure and the time period for which the personnel dosimeter was lost or damaged must be included in the records to be maintained until the Department terminates the license.

5.14.5 Dosimetry results must be retained in accordance with RHA 5.14.7.

5.14.6 Each alarm rate meter must:

5.14.6.1 Be checked to ensure that the alarm functions properly (sounds) prior to use at the start of each shift;

5.14.6.2 Be set to give an alarm signal at a preset dose rate of 500 mR/hr.;

5.14.6.3 Require special means to change the preset alarm function; and

5.14.6.4 Be calibrated at periods not to exceed one year for correct response to radiation: Acceptable rate meters must alarm within plus or minus 20 percent of the true radiation dose rate. Records of these calibrations must be maintained in accordance with RHA 5.14.7.2.

5.14.7 Each licensee shall maintain the following exposure records specified in RHA 5.14:

5.14.7.1 Direct reading dosimeter readings and yearly operability checks required by RHA 5.14.2 and 5.14.3 for 3 years after the record is made.

5.14.7.2 Records of alarm ratemeter calibrations for 3 years after the record is made.

5.14.7.3 Personnel dosimeter results must be retained until the Department terminates the license.

5.14.7.4 Records of estimates of exposures as a result of: off-scale personal direct reading dosimeters, or lost or damaged personnel dosimeters until the Department terminates the license.

HISTORY: Amended by SCSR 45–5 Doc. No. 5036, eff May 28, 2021.

RHA 5.15. Surveillance.

During each radiographic operation the radiographer, or the other individual present, as required by RHA 5.21, shall maintain continuous direct visual surveillance of the operation to protect against unauthorized entry into a high radiation area, as defined in Part III, except at permanent radiographic installations where all entryways are locked and the requirements of RHA 5.20 are met.

RHA 5.16. Posting.

Areas in which radiography is being performed shall be conspicuously posted as required by 3.8.2.1. and 3.8.2.2.

5.16.1 No radiographic operation shall be conducted unless a sufficient number of adequately calibrated and operable radiation survey instruments are available and used at each site where radiographic exposures are made.

5.16.2 A physical radiation survey with a radiation survey instrument shall be made after each radiographic exposure to determine that the sealed source has been returned to its shielded position. The entire circumference of the radiographic exposure device shall be surveyed. If the radiographic exposure device has a source guide tube, the survey shall include the guide tube.

5.16.3 A physical radiation survey shall be made to determine that each sealed source is in its shielded condition prior to securing the radiographic exposure device or storage container as specified in RHA 5.5.

5.16.4 Records shall be kept of the surveys requied by 5.16.3 and maintained for inspection by the Department.

RHA 5.17. Radiation Surveys and Survey Records.

The licensee shall ensure that:

5.17.1 A sufficient number of adequately calibrated and operable radiation survey instruments are available at the location of its radiographic operations whenever radiographic operations are being performed, and at the storage area, as defined in RHA 5.3.33 whenever a radiographic exposure device, a storage container, or source is being placed in storage.

5.17.2 A survey with a calibrated and operable radiation survey instrument is made after each exposure to determine that the sealed source has been returned to its shielded position. The entire circumference of the radiographic exposure device must be surveyed. If the radiographic exposure device has a source guide tube, the survey must include the guide tube. The survey must determine that the sealed source has returned to its shielded position before exchanging films, repositioning the exposure head, or dismantling equipment.

5.17.3 A survey with a calibrated and operable radiation survey instrument is made at any time a source is exchanged and whenever a radiographic exposure device is placed in a storage area as defined in RHA 5.3.33 to determine that the sealed source is in its shielded position. The entire circumference of the radiographic exposure device must be surveyed.

5.17.4 A record of the storage survey required in RHA 5.17.3 is made and is retained for three years for inspection by the Department when that storage survey is the last one performed in the work day.

RHA 5.18. Supervision of Radiographer's Assistant.

Whenever a radiographer's assistant uses radiographic exposure devices, uses sealed sources or related source handling tools or conducts radiation surveys required by RHA 5.17 to determine that the sealed source has been returned to the shielded position after an exposure, he shall be under the personal supervision of a radiographer. The personal supervision shall include:

5.18.1 The radiographer's personal presence at the site where the sealed sources are being used;

5.18.2 The ability of the radiographer to give immediate assistance if required; and

5.18.3 The radiographer's watching the assistant's performance of the operations referred to in this section.

RHA 5.19. Inspection and Maintenance of Radiographic Exposure Devices, Transport and Storage Containers, Associated Equipment, Source Changers and Survey Instruments.

5.19.1 The licensee shall perform visual and operability checks on survey meters, radiographic exposure devices, transport and storage containers, associated equipment and source changers before use on each day the equipment is to be used to ensure that the equipment is in good working condition, that the sources are adequately shielded, and that required labeling is present. Survey instrument operability must be performed using check sources or other appropriate means. If equipment problems are found, the equipment must be removed from service until repaired.

5.19.2 Each licensee shall have written procedures for:

5.19.2.1 Inspection and routine maintenance of radiographic exposure devices, source changers, associated equipment, transport and storage containers, and survey instruments at intervals not to exceed 3 months or before the first use thereafter to ensure the proper functioning of components important to safety. Replacement components shall meet design specifications. If equipment problems are found, the equipment must be removed from service until repaired.

5.19.2.2 Inspection and maintenance necessary to maintain the Type B packaging used to transport radioactive materials. The inspection and maintenance program must include procedures to assure that Type B packages are shipped and maintained in accordance with the certificate of compliance or other approval.

5.19.3 Records of equipment problems and of any maintenance performed under paragraphs 5.19.1 and 5.19.2 of this section must be made in accordance with the following:

5.19.3.1 Each licensee shall maintain records of equipment problems found in daily checks and quarterly inspections of radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments; and retain each record for 3 years after it is made.

5.19.3.2 The record must include the date of check or inspection, name of inspector, equipment involved, any problems found, and what repair and/or maintenance, if any, was done.

RHA 5.20. Permanent Radiographic Installation.

5.20.1 Each entrance that is used for personnel access to the high radiation area in a permanent radiographic installation must have either:

5.20.1.1 An entrance control of the type described in RHA 3.18.1.1 that reduces the radiation level upon entry into the area, or

5.20.1.2 Both conspicuous visible and audible warning signals to warn of the presence of radiation. The visible signal must be actuated by radiation whenever the source is exposed. The audible signal must be actuated when an attempt is made to enter the installation while the source is exposed.

5.20.2 The alarm system must be tested for proper operation with a radiation source each day before the installation is used for radiographic operations. The test must include a check of both the visible and audible signals. Entrance control devices that reduce the radiation level upon entry (designated in RHA 5.20.1.1) must be tested monthly. If an entrance control device or an alarm is operating improperly, it must be immediately labeled as defective and repaired within 7 calendar days. The facility may continue to be used during this 7-day period, provided the licensee implements the continuous surveillance requirements of RHA 5.15 and uses an alarming rate meter.

5.20.3 Each licensee shall maintain records of alarm system and entrance control device tests required under RHA 5.20.2 and retain each record for 3 years after it is made.

RHA 5.21. Conducting Industrial Radiographic Operations.

5.21.1 Whenever radiography is performed at a location other than a permanent radiographic installation, the radiographer must be accompanied by at least one other qualified radiographer or an individual who has at a minimum met the requirements of RHA 5.12.3. The additional qualified individual shall observe the operations and be capable of providing immediate assistance to prevent unauthorized entry. Radiography may not be performed if only one qualified individual is present.

5.21.2 All radiographic operations conducted at locations of use authorized on the license must be conducted in a permanent radiographic installation, unless specifically authorized by the Department.

5.21.3 A licensee may conduct lay-barge, offshore platform, or underwater radiography only if procedures have been approved by the Department, by an Agreement State, or by the Nuclear Regulatory Commission.

5.21.4 Licensees will have until May 26, 2001, to meet the requirements for having two qualified individuals present at locations other than a permanent radiographic installation as specified in RHA 5.21.1.

RHA 5.22. Radiation Safety Officer for Industrial Radiography.

The RSO shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's program.

5.22.1 The minimum qualifications, training, and experience for RSOs for industrial radiography are as follows:

5.22.1.1 Completion of the training and testing requirements of RHA 5.12.1;

5.22.1.2 2000 hours of hands-on experience as a qualified radiographer in industrial radiographic operations; and

5.22.1.3 Formal training in the establishment and maintenance of a radiation protection program.

5.22.2 The Department will consider alternatives when the RSO has appropriate training and/or experience in the field of ionizing radiation, and in addition, has adequate formal training with respect to the establishment and maintenance of a radiation safety protection program.

5.22.3 The specific duties and authorities of the RSO include, but are not limited to:

5.22.3.1 Establishing and overseeing all operating, emergency, and ALARA procedures as required by Part III of these regulations, and reviewing them regularly to ensure that the

procedures in use conform to current Part III procedures, conform to other Departmental regulations and to the license conditions.

5.22.3.2 Overseeing and approving all phases of the training program for radiographic personnel, ensuring and appropriate and effective radiation protection practices are taught.

5.22.3.3 Ensuring that required radiation surveys and leak tests are performed and documented in accordance with the regulations, including any corrective measures when levels of radiation exceed established limits;

5.22.3.4 Ensuring that personnel monitoring devices are calibrated and used properly by occupationally-exposed personnel, that records are kept of the monitoring results, and that timely notifications are made as required by RHA 3.46 of this regulation; and

5.22.3.5 Ensuring that operations are conducted safely and to assume control for instituting corrective actions including stopping of operations when necessary.

5.22.4 Licensees will have until May 26, 2002, to meet the requirements of RHA 5.22.1 or 5.22.2.

RHA 5.23. Form of Records.

Each record required by this part must be legible throughout the specified retention period. The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of reproducing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, must include all pertinent information, such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

RHA 5.24. Location of Documents and Records.

5.24.1 Each licensee shall maintain copies of records required by this part and other applicable parts of this regulation at the location specified in RHA 5.4.11.

5.24.2 Each licensee shall also maintain copies of the following documents and records sufficient to demonstrate compliance at each applicable field station and each temporary jobsite:

5.24.2.1 The license authorizing the use of licensed material;

5.24.2.2 A copy of parts II, III and V of Radioactive Materials Regulation 61–63. Title A.

5.24.2.3 Utilization records for each radiographic exposure device dispatched from that location as required by RHA 5.11;

5.24.2.4 Records of equipment problems identified in daily checks of equipment as required by RHA 5.19.3.1;

5.24.2.5 Records of alarm system and entrance control checks required by RHA 5.20.3 if applicable;

5.24.2.6 Records of direct reading dosimeters such as pocket dosimeter and or electronic personal dosimeters readings as required by RHA 5.14;

5.24.2.7 Operating and emergency procedures required by 5.13.13;

5.24.2.8 Evidence of the latest calibration of the radiation survey instruments in use at the site, as required by RHA 5.8.3;

5.24.2.9 Evidence of the latest calibrations of alarm rate meters and operability checks of pocket dosimeters and/or electronic personal dosimeters as required by RHA 5.14;

5.24.2.10 Latest survey records required by RHA 5.17.4;

5.24.2.11 The shipping papers for the transportation of radioactive materials required by RHA 2.22; and

5.24.2.12 When operating under reciprocity pursuant to RHA 2.21, a copy of the NRC or Agreement State license authorizing the use of licensed materials.

RHA 5.25. Reporting Requirements.

5.25.1 In addition to the reporting requirements specified in RHA 2.32, each licensee shall provide a written report to the S.C. Department of Health & Environmental Control, Bureau of Radiological Health, 2600 Bull Street, Columbia, S.C. 29201 within 30 days of the occurrence of any of the following incidents involving radiographic equipment.

5.25.1.1 Unintentional disconnection of the source assembly from the control cable.

5.25.1.2 Inability to retract the source assembly to its fully shielded position and secure it in this position.

5.25.1.3 Failure of any component (critical to safe operation of the device) to properly perform its intended function.

5.25.2 The licensee shall include the following information in each report submitted under RHA 5.25.1 of this section:

5.25.2.1 A description of the equipment problem.

5.25.2.2 Cause of each incident, if known.

5.25.2.3 Manufacturer and model number of equipment involved in the incident.

5.25.2.4 Corrective actions taken or planned to prevent recurrence.

5.25.2.7 Qualifications of personnel involved in the incident.[1]

5.25.3 Reports of overexposure submitted under RHA 3.46 which involve failure of safety components of radiography equipment must also include the information specified in RHA 5.25.2 of this section.

[1] So in original. State Register Volume 24, Issue No. 5 eff May 26, 2000 revised RHA 5.25 but did not promulgate either 5.25.2.5 or 5.25.2.6.

Editor's Note

Scrivener errors corrected in 2012.

RHA 5.26. Appendix A. Radiographer Certification.

5.26.1 Requirements for an Independent Certifying Organization. An independent certifying organization shall:

5.26.1.1 Be an organization such as a society or association, whose members participate in, or have an interest in, the fields of industrial radiography;

5.26.1.2 Make its membership available to the general public nationwide that is not restricted because of race, color, religion, sex, age, national origin or disability;

5.26.1.3 Have a certification program open to nonmembers, as well as members;

5.26.1.4 Be an incorporated, nationally recognized organization, that is involved in setting national standards of practice within its fields of expertise;

5.26.1.5 Have an adequate staff, a viable system for financing its operations, and a policy-and decision-making review board;

5.26.1.6 Have a set of written organizational by-laws and policies that provide adequate assurance of lack of conflict of interest and a system for monitoring and enforcing those by-laws and policies;

5.26.1.7 Have a committee, whose members can carry out their responsibilities impartially, to review and approve the certification guidelines and procedures, and to advise the organization's staff in implementing the certification program;

5.26.1.8 Have a committee, whose members can carry out their responsibilities impartially, to review complaints against certified individuals and to determine appropriate sanctions;

5.26.1.9 Have written procedures describing all aspects of its certification program, maintain records of the current status of each individual's certification and the administration of its certification program;

5.26.1.10 Have procedures to ensure that certified individuals are provided due process with respect to the administration of its certification program, including the process of becoming certified and any sanctions imposed against certified individuals;

5.26.1.11 Have procedures for proctoring examinations, including qualifications for proctors. These procedures must ensure that the individuals proctoring each examination are not employed by the same company or corporation (or a wholly-owned subsidiary of such company or corporation) as any of the examinees;

5.26.1.12 Exchange information about certified individuals with the Department and other independent certifying organizations and/or Agreement States and allow periodic review of its certification program and related records; and

5.26.1.13 Provide a description to the Nuclear Regulatory Commission of its procedures for choosing examination sites and for providing an appropriate examination environment.

5.26.2 Requirements for Certification Programs. All certification programs must:

5.26.2.1 Require applicants for certification to:

5.26.2.1.1 Receive training in the topics set forth in RHA 5.12.7 or equivalent Agreement State regulations, and

5.26.2.1.2 Satisfactorily complete a written examination covering these topics;

5.26.2.2 Require applicants for certification to provide documentation that demonstrates that the applicant has:

5.26.2.2.1 Received training in the topics set forth in RHA 5.12.7 or equivalent Agreement State regulations;

5.26.2.2.2 Satisfactorily completed a minimum period of on-the-job training; and

5.26.2.2.3 Has received verification by an Agreement State or a NRC licensee that the applicant has demonstrated the capability of independently working as a radiographer;

5.26.2.3 Include procedures to ensure that all examination questions are protected from disclosure;

5.26.2.4 Include procedures for denying an application, revoking, suspending, and reinstating a certificate;

5.26.2.5 Provide a certification period of not less than 3 years nor more than 5 years;

5.26.2.6 Include procedures for renewing certifications and, if the procedures allow renewals without examination, require evidence of recent full-time employment and annual refresher training.

5.26.2.7 Provide a timely response to inquiries, by telephone or letter, from members of the public, about an individual's certification status.

5.26.3 Requirements for Written Examinations. All examinations must be:

5.26.3.1 Designed to test an individual's knowledge and understanding of the topics listed in RHA 5.12.7 or equivalent Agreement State requirements or NRC requirements;

5.26.3.2 Written in a multiple-choice format;

5.26.3.3 Have test items drawn from a question bank containing psychometrically valid questions based on the material in RHA 5.12.7.

PART VI
NOTICES, INSTRUCTIONS, AND REPORTS TO WORKERS; INSPECTIONS

RHA 6.1. Purpose and Scope.

This part establishes requirements for notices, instructions, and reports by licensees to individuals participating in licensed activities and options available to such individuals in connection with Department inspections of licensees to ascertain compliance with the provisions of the Act and regulations, orders, and licenses issued thereunder regarding radiological working conditions. The regulations in this Part apply to all persons who receive, possess, use, own or transfer material licensed by the Department pursuant to the regulations in Parts II and III.

RHA 6.2. Definitions.

6.2.1 "Worker" means an individual engaged in activities licensed by the Department and controlled by a licensee, but does not include the licensee.

RHA 6.3. Posting of Notices to Workers.

6.3.1 Each licensee shall post current copies of the following documents; (1) the regulations in this Part and in Part III; (2) the license conditions or documents incorporated into the license by reference and amendments thereto; (3) the operating procedures applicable to licensed activities; (4) any notice of violation involving radiological working conditions, proposed imposition of civil penalty, or order issued pursuant to Part II and any response from the licensee.

6.3.2 If posting of a document specified in paragraph 6.2.1 (1), (2) or (3) of this section is not practicable, the licensee may post a notice which describes the document and states where it may be examined.

6.3.3 Department Form SC-RHA-20, "Notice to Employees" shall be prominently posted by each licensee wherever individuals work in or frequent any portion of a restricted area.

6.3.4 Documents, notices or forms posted pursuant to this section shall appear in a sufficient number of places to permit individuals engaged in licensed activities to observe them on the way to or from any particular licensed activity location to which the document applies, shall be conspicuous, and shall be replaced if defaced or altered.

6.3.5 Department documents posted pursuant to paragraph 6.2.1 (4) of this section shall be posted within 2 working days after receipt of the documents from the Department; the licensee's response, if any, shall be posted within 2 working days after dispatch from the licensee. Such documents shall remain posted for a minimum of 5 working days or until action correcting the violation has been completed, whichever is later.

RHA 6.4. Instructions to Workers.

6.4.1 All individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 100 mrem (1 mSv) shall be:

6.4.1.1 Kept informed of the storage, transfer, or use of radiation and/or radioactive materials:

6.4.1.2 Instructed in the health protection problems associated with exposure to radiation and/or radioactive material, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed;

6.4.1.3 Instructed in, and instructed to observe, to the extent within the worker's control, the applicable provisions of Department regulations and licenses for the protection of personnel to radiation and/or radioactive material;

6.4.1.4 Instructed of their responsibility to report promptly to the licensee any condition which may lead to or cause a violation of Department regulations and licenses or unnecessary exposure to radiation and/or radioactive material;

6.4.1.5 Instructed in the appropriate response to warnings made in the event of an unusual occurrence or malfunction that may involve exposure to radiation and/or radioactive material; and

6.4.1.6 Shall be advised as to the radiation exposure reports which workers may request pursuant to Section RHA 6.4.

6.4.2 In determining those individuals subject to the requirements of 6.3.1, licensees must take into consideration assigned activities during normal and abnormal situations involving exposure to radiation and/or radioactive material which can reasonably be expected to occur during the life of a licensed facility. The extent of these instructions must be commensurate with potential radiological health protection problems present in the work place.

RHA 6.5. Notification and Reports to Individuals.

6.5.1 Radiation exposure data for an individual, and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body of an individual, shall be reported to the individual as specified in this section. The information reported shall include data and results obtained pursuant to Department regulations, orders, or license conditions, as shown in records maintained by the licensee pursuant to Department regulations. Each notification and report shall; be in writing, include appropriate identifying data such as the name of the licensee, the name of the individual, the individual's social security number; include the individual's exposure information; and contain the following statement; "This report is furnished to you under the provisions of the South

Carolina Department of Health and Environmental Control's 'Radiation Control Regulations.' You should preserve this report for future reference."

6.5.2 Each licensee shall make dose information available to workers as shown in records maintained by the licensee pursuant to paragraphs 3.36.2 and 3.39. The licensee shall provide an annual report to each individual monitored pursuant to RHA 3.17 of the dose received in that monitoring year if:

6.5.2.1 The individual's occupational dose exceeds 100 mrem TEDE or 100 mrem to any individual organ or tissue; or

6.5.2.2 The individual requests his or her annual dose report.

6.5.3.1 At the request of a worker formerly engaged in licensed activities controlled by the licensee, each licensee shall furnish to the worker a report of the worker's exposure to radiation and/or radioactive material:

6.5.3.1.1 As shown in records maintained by the licensee pursuant to RHA 3.39 for each year the worker was required to be monitored under the provisions of RHA 3.17; and

6.5.3.1.2 For each year the worker was required to be monitored under the monitoring requirements in effect prior to January 1, 1994.

6.5.3.2 This report must be furnished within 30 days from the time the request is made, or within 30 days after the exposure of the individual has been determined by the licensee, whichever is later. This report must cover the period of time that the worker's activities involved exposure to radiation from radioactive materials licensed by the Department and must include the dates and locations of licensed activities in which the worker participated during this period.

6.5.4 When a licensee is required pursuant to RHA 3.45, 3.46, 3.47, and 3.49 to report to the Department any exposure of an individual to radiation or radioactive material, or an identified member of the public, to radiation or radioactive material, the licensee shall also provide the individual a report on his or her exposure data included in the report to the Department. This report shall be transmitted no later than the transmittal to the Department.

6.5.5 At the request of a worker who is terminating employment with the licensee that involved exposure to radiation or radioactive materials, during the calendar quarter or the current year, each licensee shall provide at termination to each worker, or to the worker's designee, a written report regarding the radiation dose received by that worker from operations of the licensee during the current year or fraction thereof. If the most recent individual monitoring results are not available at that time, a written estimate of the dose must be provided together with a clear indication that this is an estimate.

RHA 6.6. Presence of Representatives of Licensees and Workers During Inspections.

6.6.1 Each licensee shall afford to the Department at all reasonable times opportunity to inspect materials, activities, facilities, premises, and records pursuant to these regulations.

6.6.2 During an inspection, Department inspectors may consult privately with workers as specified in RHA 6.5. The licensee or licensee's representative may accompany Department inspectors during other phases of an inspection.

6.6.3 If, at any time of inspection, an individual has been authorized by the workers to represent them during Department inspections, the licensee shall notify the inspectors of such authorization and shall give the workers' representative an opportunity to accompany the inspectors during the inspection of physical working conditions.

6.6.4 Each workers' representative shall be routinely engaged in licensed activities under control of the licensee and shall have received instructions as specified in Section RHA 6.4.

6.6.5 Different representatives of licensees and workers may accompany the inspectors during different phases of an inspection if there is no resulting interference with the conduct of the inspection. However, only one workers' representative at a time may accompany the inspector.

6.6.6 With the approval of the licensee and the workers' representative, an individual who is not routinely engaged in licensed activities under control of the licensee, for example, a consultant to the licensee or to the workers' representative, shall be afforded the opportunity to accompany Department inspectors during the inspection of physical working conditions.

6.6.7 Notwithstanding the other provisions of this section, Department inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection. With regard to areas containing proprietary information, the workers' representative for that area shall be an individual previously authorized by the licensee to enter that area.

RHA 6.7. Consultation with Workers During Inspections.

6.7.1 Department inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of Department regulations and licenses to the extent the inspectors deem necessary for the conduct of an effective and thorough inspection.

6.7.2 During the course of an inspection any worker may bring privately to the attention of the inspectors, either orally or in writing, any past or present condition which he has reason to believe may have contributed to or caused any violation of the Act, these regulations, or license condition, or any unnecessary exposure of an individual to radiation from licensed radioactive material under the licensee's control. Any such notice in writing shall comply with the requirements of paragraph 6.8.1.

6.7.3 The provisions of paragraph 6.7.2 of this section shall not be interpreted as authorization to disregard instructions pursuant to Section RHA 6.4.

RHA 6.8. Requests by Workers for Inspections.

6.8.1 Any worker or representative of workers who believes that a violation of the Act, these regulations, or license conditions exists or has occurred in license activities with regard to radiological working conditions in which the worker is engaged, may request an inspection by giving notice of the alleged violation to the Department. Any such notice shall be in writing, shall set forth the specific grounds for the notice, and shall be signed by the worker or representative of workers. A copy shall be provided to the licensee by the Department no later than at the time of inspection except that, upon the request of the worker giving such notice, his name and the name of individuals referred to therein shall not appear in such copy or on any record published, released, or made available by the Department, except for good cause shown.

6.8.2 If, upon receipt of such notice, the Department determines that the complaint meets the requirements set forth in paragraph 6.8.1 of this section, and that there are reasonable grounds to believe that the alleged violation exists or has occurred, he shall cause an inspection to be made as soon as practicable, to determine if such alleged violation exists or has occurred. Inspections pursuant to this Section need not be limited to matters referred to in the complaint.

RHA 6.9. Inspections Not Warranted; Informal Review.

6.9.1 If the Department determines, with respect to a complaint under RHA 6.8, that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, he shall notify the complainant in writing of such determination. The complainant may obtain review of such determination by submitting a written statement of position with the Commissioner for the South Carolina Department of Health & Environmental Control who will provide the licensee with a copy of such statement by certified mail, excluding, at the request of the complainant, the name of the complainant. The licensee may submit an opposing written statement of position with the Department who will provide the complainant with a copy of such statement by certified mail. Upon the request of the complainant, the Department may hold an informal conference in which the complainant and the licensee may orally present their views. An informal conference may also be held at the request of the licensee, but disclosure of the identity of the complainant will be made only following receipt of written authorization from the complainant. After considering all written and oral views presented, the Commissioner for the South Carolina Department of Health & Environmental Control shall affirm, modify, or reverse the determination of the Department and furnish the complainant and the licensee a written notification of his decision and the reason therefor.

6.9.2 If the Department determines that an inspection is not warranted because the requirements of Section 6.8.1 have not been met, he shall notify the complainant in writing of such determination. Such determination shall be without prejudice to the filing of a new complaint meeting the requirements of Section 6.8.1.

RHA 6.10. Employee Protection.

Employment discrimination by a licensee (or a holder of a certificate of compliance) or a contractor or subcontractor of a licensee (or a holder of a certificate of compliance) against an employee for engaging in protected activities under this Regulation is prohibited.

RHA 6.11. Discrimination Prohibited.

No person shall on the ground of sex be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity licensed by this Department. This provision will be enforced through Department provisions and rules similar to those already established, with respect to racial and other discrimination, under Title 1, Chapter 13 of the South Carolina Code. This remedy is not exclusive, however, and will not prejudice or cut off any other legal remedies available to a discriminatee.

PART VII

Licensing Requirements for Land Disposal of Radioactive Waste

RHA 7.1. Purpose and Scope.

7.1.1 The regulations in this Part establish procedures, criteria, and terms and conditions upon which the Department issues licenses for the land disposal of wastes received from other persons. (Applicability of the requirements in this part to Department licenses for waste disposal facilities in effect on the effective date of this regulation will be determined on a case-by-case basis and implemented through terms and conditions of the license or by orders issued by the Department). The requirements of this part are in addition to, and not in substitution for, other applicable requirements of these regulations.

7.1.2 The regulations in this Part do not apply to disposal of byproduct material as defined in definition (2) of "Byproduct material" in 1.2 of these regulations in quantities greater than 10,000 kilograms containing more than 5 millicuries of radium-226 or disposal of radioactive material as provided for in Part III of these regulations.

7.1.3 This Part establishes procedural requirements and performance objectives applicable to any method of land disposal. It establishes specific technical requirements for near-surface disposal of radioactive waste which involves disposal in the uppermost portion of the earth.

RHA 7.2. Definitions.

As used in this part:

7.2.1 "Active maintenance" means any significant activity needed during the period of institutional control to maintain a reasonable assurance that the performance objectives in 7.18 and 7.19 are met. Such active maintenance includes ongoing activities such as the pumping and treatment of water from a disposal unit or one-time measures such as replacement of a disposal unit cover. Active maintenance does not include custodial activities such as repair of fencing, repair or replacement of monitoring equipment, revegetation, minor additions to soil cover, minor repair of disposal unit covers, and general disposal site upkeep such as mowing grass.

7.2.2 "Buffer zone" means a portion of the disposal site that is controlled by the licensee and lies under the disposal units and between the disposal units and the boundary of the site.

7.2.3 "Chelating agent" means amine polycarboxylic acids, hydroxycarboxylic acids, gluconic acid, and polycarboxylic acids.

7.2.4 "Commencement of construction" means any clearing of land, excavation, or other substantial action that would adversely affect the environment of a land disposal facility. The term does not mean disposal site exploration, necessary roads for disposal site exploration, borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the suitability of the disposal site or the protection of environmental values.

7.2.5 "Custodial agency" means an agency of the government designated to act on behalf of the government owner of the disposal site.

7.2.6 "Disposal" means the isolation of wastes from the biosphere inhabited by man and his food chains by emplacement in a land disposal facility.

7.2.7 "Disposal site" means that portion of a land disposal facility which is used for disposal of waste. It consists of disposal units and a buffer zone.

7.2.8 "Disposal unit" means a discrete portion of the disposal site into which waste is placed for disposal. For near-surface disposal, the unit is usually a vault or a trench.

7.2.9 "Engineered barrier" means a man-made structure or device that is intended to improve the land disposal facility's ability to meet the performance objectives in this part. This shall include above or below grade vaults or equivalent structures.

7.2.10 "Explosive material" means any chemical compound, mixture, or device which produces a substantial instantaneous release of gas and heat spontaneously or by contact with sparks or flame.

7.2.11 "Hazardous Waste" means the waste designed as hazardous by U.S. Environmental Protection Agency regulations in 40 CFR Part 261 and waste designed as hazardous by Regulation R. 61-79.261.

7.2.12 "Hydrogeologic unit" means any soil or rock unit or zone which by virtue of its porosity or permeability, or lack thereof, has a distinct influence on the storage or movement of groundwater.

7.2.13 "Inadvertent intruder" means a person who might occupy the disposal site after closure and engage in normal activities, such as agriculture, dwelling construction, or other pursuits in which an individual might be unknowingly exposed to radiation from the waste.

7.2.14 "Intruder barrier" means a sufficient depth of cover over the waste that inhibits contact with waste and helps to ensure that radiation exposures to an inadvertent intruder will meet the performance objectives set forth in this part or engineered structures that provide equivalent protection to the inadvertent intruder.

7.2.15 "Land Disposal Facility" means the land, buildings and structures, and equipment which are intended to be used for the disposal of radioactive wastes. For the purpose of this part, a "geologic repository" as defined in 10 CFR Part 60 is not considered a land disposal facility.

7.2.16 "Monitoring" means observing and making measurements to provide data to evaluate the performance and characteristics of the disposal site.

7.2.17 "Near-surface disposal facility" means a land disposal facility in which waste is disposed of within approximately the upper 30 meters of the earth's surface.

7.2.18 "Pyrophoric liquid" means any liquid that ignites spontaneously in dry or moist air at or below 130′F (54.4′C). A "pyrophoric solid" is any solid material, other than one classed as an explosive, which under normal conditions, is liable to cause fires through friction, retained heat from manufacturing or processing, or which can be ignited readily and, when ignited, burns so vigorously and persistently as to create a serious transportation, handling, or disposal hazard. Included are spontaneously combustible and water-reactive materials.

7.2.19 "Site closure and stabilization" means those actions that are taken upon completion of operations that prepare the disposal site for custodial care and that assure that the disposal site will remain stable and will not need ongoing active maintenance.

7.2.20 "Stability" means structural stability.

7.2.21 "Surveillance" means monitoring and observation of the disposal site for purposes of visual detection of need for maintenance, custodial care, evidence of intrusion, and compliance with other license and regulatory requirements.

7.2.22 "Waste" means those low-level radioactive wastes containing source, special nuclear, or byproduct material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level radioactive waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in Section 1.2.6, paragraphs 2, 3, and 4 of this Regulation.

RHA 7.3. License Required.

7.3.1 No person may receive, possess, and dispose of waste received from other persons at a land disposal facility unless authorized by a license issued by the Department pursuant to this part, and Part II of these regulations.

7.3.2 Each person shall file an application with the Department pursuant to 2.5 of these regulations and obtain a license as provided in this part before commencement of construction of a land disposal facility. Failure to comply with this requirement may be grounds for denial of a license.

RHA 7.4. Content of Application.

In addition to the requirements set forth in 2.6 of these regulations, an application to receive from others, possess, and dispose of wastes shall consist of general information, specific technical information, institutional information, and financial information as set forth in 7.5 through 7.9.

RHA 7.5. General Information.

The general information shall include each of the following:

7.5.1 Identity of the applicant including:

7.5.1.1 The full name, address, telephone number, and description of the business or occupation of the applicant;

7.5.1.2 If the applicant is a partnership, the name and address of each partner and the principal location where the partnership does business;

7.5.1.3 If the applicant is a corporation or an unincorporated association (1) state where it is incorporated or organized and the principal location where it does business and (2) the names and addresses of its directors and principal officers; and

7.5.1.4 If the applicant is acting as an agent or representative of another person in filing the application, all information required under 7.5.1 must be supplied with respect to the other person.

7.5.2 Qualifications of the applicant:

7.5.2.1 The organizational structure of the applicant, both offsite and onsite, including a description of lines of authority and assignments of responsibilities, whether in the form of administrative directives, contract provisions, or otherwise;

7.5.2.2 The technical qualifications, including training and experience, of the applicant and members of the applicant's staff to engage in the proposed activities. Minimum training and experience requirements for personnel filling key positions described in 7.5.2.1 must be provided;

7.5.2.3 A description of the applicant's personnel training program; and

7.5.2.4 The plan to maintain an adequate complement of trained personnel to carry out waste receipt, handling, and disposal operations in a safe manner.

7.5.3 A description of:

7.5.3.1 The location of the proposed disposal site;

7.5.3.2 The general character of the proposed activities;

7.5.3.3 The types and quantities of waste to be received, possessed, and disposed of;

7.5.3.4 Plans for use of the land disposal facility for purposes other than disposal of wastes; and

7.5.3.5 The proposed facilities and equipment.

7.5.4 Proposed schedules for construction, receipt of waste, and first emplacement of waste at the proposed land disposal facility.

RHA 7.6. Specific Technical Information.

The specific technical information shall include the following information needed for demonstration that the performance objectives and the applicable technical requirements of this part will be met:

7.6.1 A description of the natural and demographic disposal site characteristics as determined by disposal site selection and characterization activities. The description shall include geologic, geochemical, geotechnical, hydrologic, ecologic, archaelogic, meteorologic, climatologic, and biotic features of the disposal site and vicinity.

7.6.2 A description of the design features of the land disposal facility and the disposal units. For near-surface disposal, the description shall include a complete description of the engineered barriers;

those design features related to infiltration of water; integrity of covers for disposal units, design of covers for disposal units; structural stability of engineered barriers, backfill, wastes and covers; contact of wastes with standing water; disposal site drainage; disposal site closure and stabilization; elimination to the extent practicable of long-term disposal site maintenance; inadvertent intrusion; occupational exposures; disposal site monitoring; and adequacy of the size of the buffer zone for monitoring and potential mitigative measures.

7.6.3 A description of the principal design criteria and their relationship to the performance objectives.

7.6.4 A description of the design basis natural events or phenomena and their relationship to the principal design criteria.

7.6.5 A description of codes and standards which the applicant has applied to the design and which will apply to construction of the land disposal facilities.

7.6.6 A description of the construction and operation of the land disposal facility. The description shall include as a minimum the methods of construction of disposal units; waste emplacement; the procedures for and areas of waste segregation; types of intruder barriers; onsite traffic and drainage systems; survey control program; methods and areas of waste storage; and methods to control surface water and groundwater access to the wastes. The description shall also include a description of the methods to be employed in the handling and disposal of wastes containing chelating agents or other non-radiological substances that might affect meeting the performance objectives of this part.

7.6.7 A description of the disposal site closure plan, including those design features which are intended to facilitate disposal site closure and to eliminate the need for ongoing active maintenance.

7.6.8 An identification of the known natural resources at the disposal site, whose exploitation could result in inadvertent intrusion into the wastes after removal of active institutional control.

7.6.9 A description of the kind, amount, classification and specification of the radioactive material proposed to be received, possessed, and disposed of at the land disposal facility.

7.6.10 A description of the quality control program for the determination of natural disposal site characteristics and for quality control during the design, construction, operation, and closure of the land disposal facility and the receipt, handling, and emplacement of waste. Audits and managerial controls must be included.

7.6.11 A description of the radiation safety program for control and monitoring of radioactive effluents to ensure compliance with the performance objective in 7.18 and occupational radiation exposure to ensure compliance with the requirements of Part III of these regulations and to control contamination of personnel, vehicles, equipment, buildings, and the disposal site. Both routine operations and accidents shall be addressed. The program description must include procedures, instrumentation, facilities, and equipment.

7.6.12 A description of the environmental monitoring program to provide data to evaluate potential health and environmental impacts and the plan for taking corrective measures if migration is indicated.

7.6.13 A description of the administrative procedures that the applicant will apply to control activities at the land disposal facility.

7.6.14 A description of the facility electronic recordkeeping system as required in RHA 7.32.

RHA 7.7. Technical Analyses.

The specific technical information shall also include the following analyses needed to demonstrate that the performance objectives of this part will be met:

7.7.1 Pathways analyzed in demonstrating protection of the general population from releases of radioactivity shall include air, soil, groundwater, surface water, plant uptake, and exhumation by burrowing animals. The analyses shall clearly identify and differentiate between the roles performed by the natural disposal site characteristics and design features in isolating and segregating the wastes. The analyses shall clearly demonstrate that there is reasonable assurance that the exposures to humans from the release of radioactivity will not exceed the limits set forth in 7.18.

7.7.2 Analyses of the protection of individuals from inadvertent intrusion shall include demonstration that there is reasonable assurance the waste classification and segregation requirements will be met and that adequate barriers to inadvertent intrusion will be provided.

7.7.3 Analyses of the protection of individuals during operations shall include assessments of expected exposures due to routine operations and likely accidents during handling, storage, and disposal of waste. The analyses shall provide reasonable assurance that exposures will be controlled to meet the requirements of Part III of these regulations.

7.7.4 Analyses of the long-term stability of the disposal site and the need for ongoing active maintenance after closure shall be based upon analyses of active natural processes such as erosion, mass wasting, slope failure, settlement of wastes and backfill, infiltration through covers over disposal areas and adjacent soils, and surface drainage of the disposal site. The analyses shall provide reasonable assurance that there will not be a need for ongoing active maintenance of the disposal site following closure.

RHA 7.8. Institutional Information.

The institutional information submitted by the applicant shall include:

7.8.1 A certification by the federal or state agency which owns the disposal site that the federal or state agency is prepared to accept transfer of the license when the provisions of 7.15 are met and will assume responsibility for institutional control after site closure and postclosure observation and maintenance.

7.8.2 Where the proposed disposal site is on land not owned by the federal or a state government, the applicant shall submit evidence that arrangements have been made for assumption of ownership in fee by the federal or a state agency before the Department issues a license.

RHA 7.9. Financial Information.

The financial information shall be sufficient to demonstrate that the financial qualifications of the applicant are adequate to carry out the activities for which the license is sought and meet other financial assurance requirements of this part.

RHA 7.10. Requirements for Issuance of a License.

A license for the receipt, possession, and disposal of waste containing or contaminated with radioactive material will be issued by the Department upon finding that:

7.10.1 The issuance of the license will not constitute an unreasonable risk to the health and safety of the public;

7.10.2 The applicant is qualified by reason of training and experience to carry out the disposal operations requested in a manner that protects health and minimizes danger to life or property;

7.10.3 The applicant's proposed disposal site, disposal design, land disposal facility operations, including equipment, facilities, and procedures, disposal site closure, and postclosure institutional control are adequate to protect the public health and safety in that they provide reasonable assurance that the general population will be protected from releases of radioactivity as specified in the performance objective in 7.18;

7.10.4 The applicant's proposed disposal site, disposal site design, land disposal facility operations, including equipment, facilities, and procedures, disposal site closure, and postclosure institutional control are adequate to protect the public health and safety in that they will provide reasonable assurance that individual inadvertent intruders are protected in accordance with the performance objective in 7.19;

7.10.5 The applicant's proposed land disposal facility operations, including equipment, facilities, and procedures, are adequate to protect the public health and safety in that they will provide reasonable assurance that the standards for radiation protection set out in Part III of these regulations will be met;

7.10.6 The applicant's proposed disposal site, disposal site design, land disposal facility operations, disposal site closure, and postclosure institutional control are adequate to protect the public health and safety in that they will provide reasonable assurance that long-term stability of the

disposed waste and the disposal site will be achieved and will eliminate to the extent practicable the need for ongoing active maintenance of the disposal site following closure;

7.10.7 The applicant's demonstration provides reasonable assurance that the applicable technical requirements of this part will be met;

7.10.8 The applicant's proposal for institutional control provides reasonable assurance that such control will be provided for the length of time found necessary to ensure the findings in 7.10.3 through 7.10.6 and that the institutional control meets the requirements of 7.27; and

7.10.9 The financial or surety arrangements meet the requirements of this part.

7.10.10 The applicant's Quality Assurance Plan describing the methods and procedures used to ensure that the disposal units are constructed in accordance with the approved designs and applicable standards and that the waste complies with the requirements of this regulation and the license.

RHA 7.11. Conditions of Licenses.

7.11.1 A license issued under this part, or any right thereunder, may not be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of the license to any person, unless the Department finds, after securing full information, that the transfer is in accordance with the provisions of the Act and gives its consent in writing in the form of a license amendment.

7.11.2 The licensee shall submit written statements under oath upon request of the Department, at any time before termination of the license, to enable the Department to determine whether the license should be modified, suspended, or revoked.

7.11.3 The license will be transferred only on the full implementation of the final closure plan as approved by the Department including postclosure observation and maintenance.

7.11.4 The licensee shall be subject to the provisions of the Act now or hereafter in effect, and to all rules, regulations, and orders of the Department. The terms and conditions of the license are subject to amendment, revision, or modification, by reason of amendments to, or by reason of rules, regulations, and orders issued in accordance with the terms of the Act.

7.11.5 Each person licensed by the Department pursuant to the regulations in this part shall confine possession and use of materials to the locations and purposes authorized in the license.

7.11.6 The licensee shall not dispose of waste until the Department has inspected the land disposal facility and thereafter, each disposal unit or trench, and has found it to be in conformance with the description, design, and construction described in the application for a license.

7.11.7 The Department may incorporate in any license at the time of issuance, or thereafter, by appropriate rule, regulation or order, additional requirements and conditions with respect to the licensee's receipt, possession, and disposal of waste as it deems appropriate or necessary in order to:

7.11.7.1 Protect health or to minimize danger to life or property;

7.11.7.2 Require reports and the keeping of records, and to provide for inspections of activities under the license that may be necessary or appropriate to effectuate the purposes of the Act and regulations thereunder.

7.11.8 The authority to dispose of wastes expires on the date stated in the license. Any expiration date on a license applies only to the above ground activities and to the authority to dispose of waste. Failure to renew the license shall not relieve the licensee of responsibility for implementing site closure, postclosure observation, and transfer of the license to the site owner.

7.11.9 The disposal facility shall incorporate engineered barriers for all waste classifications. The engineered barriers shall be designed and constructed to complement and improve the ability of the disposal facility to meet the performance objectives in this part.

7.11.10 The engineered barriers shall be designed and constructed of materials having physical and chemical properties so as to provide reasonable assurance that the barriers will maintain their functional integrity under all foreseeable conditions for at least the institutional control period. No reliance may be placed on the engineered barriers beyond the institutional control period.

7.11.11 The disposal units and the incorporated engineered barriers shall be designed and constructed to meet the following objectives:

7.11.11.1 to minimize the migration of water onto the disposal units.

7.11.11.2 to minimize the migration of waste or waste contaminated water out of the disposal units.

7.11.11.3 detection of water and other liquids in the disposal units.

7.11.11.4 temporary collection and retention of water and other liquids for a time sufficient to allow for the detection and removal or other remedial measures without the contamination of groundwater or the surrounding soil.

7.11.11.5 facilitation of remedial methods without disturbing other disposal units.

7.11.11.6 reasonable assurance that the waste will be isolated for at least the institutional control period.

7.11.11.7 prevention of contact between the waste and the surrounding earth, except for earthen materials which may be used for backfilling within the disposal units.

7.11.12 The licensee shall insure that the waste received for disposal has been reduced in volume to the maximum extent practicable using the existing technology.

RHA 7.12. Application for Renewal or Closure.

7.12.1 An application for renewal or an application for closure under 7.13 must be filed at least 90 days prior to license expiration.

7.12.2 Applications for renewal of a license must be filed in accordance with 7.4 through 7.9. Applications for closure must be filed in accordance with 7.13. Information contained in previous applications, statements, or reports filed with the Department under the license may be incorporated by reference if the references are clear and specific.

7.12.3 In any case in which a licensee has filed an application in proper form for renewal of a license, the license does not expire until the Department has taken final action on the application for renewal.

7.12.4 In determining whether a license will be renewed, the Department will apply the criteria set forth in 7.10.

RHA 7.13. Contents of Application for Site Closure and Stabilization.

7.13.1 Prior to final closure of the disposal site, or as otherwise directed by the Department, the applicant shall submit an application to amend the license for closure. This closure application shall include a final revision and specific details of the disposal site closure plan included as part of the license application submitted under 7.6.7 that includes each of the following:

7.13.1.1 Any additional geologic, hydrologic, or other data pertinent to the long-term containment of emplaced wastes obtained during the operational period.

7.13.1.2 The results of tests, experiments, or any other analyses relating to backfill of excavated areas, closure and sealing, waste migration and interaction with emplacement media, or any other tests, experiments, or analysis pertinent to the long-term containment of emplaced waste within the disposal site.

7.13.1.3 Any proposed revision of plans for:

7.13.1.3.1 Decontamination and/or dismantlement of surface facilities;

7.13.1.3.2 Backfilling of excavated areas; or

7.13.1.3.3 Stabilization of the disposal site for postclosure care.

7.13.1.4 Any significant new information regarding the environmental impact of closure activities and long-term performance of the disposal site.

7.13.2 Upon review and consideration of an application to amend the license for closure submitted in accordance with 7.13.1, the Department shall issue an amendment authorizing closure if there is reasonable assurance that the long-term performance objectives of this part will be met.

RHA 7.14. Postclosure Observation and Maintenance.

The licensee shall observe, monitor, and carry out necessary maintenance and repairs at the disposal site until the site closure is complete and the license is transferred by the Department in accordance with 7.15. Responsibility for the disposal site must be maintained by the licensee for 5 years. A shorter or longer time period for postclosure observation and maintenance may be established and approved as part of the site closure plan, based on site-specific conditions.

RHA 7.15. Transfer of License.

Following closure and the period of postclosure observation and maintenance, the licensee may apply for an amendment to transfer the license to the disposal site owner. The license shall be transferred when the Department finds:

7.15.1 That the closure of the disposal site has been made in conformance with the licensee's disposal site closure plan, as amended and approved as part of the license;

7.15.2 That reasonable assurance has been provided by the licensee that the performance objectives of this part are met;

7.15.3 That any funds for care and records required by RHA 7.32.4 and 7.32.5 have been transferred to the disposal site owner;

7.15.4 That the postclosure monitoring program is operational for implementation by the disposal site owner; and

7.15.5 That the federal or state agency which will assume responsibility for institutional control of the disposal site is prepared to assume responsibility and ensure that the institutional requirements found necessary under 7.10.8 will be met.

RHA 7.16. Termination of License.

7.16.1 Following any period of institutional control needed to meet the requirements found necessary under 7.10, the licensee may apply for an amendment to terminate the license.

7.16.2 This application will be reviewed in accordance with the provisions of 2.19 of these regulations.

7.16.3 A license shall be terminated only when the Department finds:

7.16.3.1 That the institutional control requirements found necessary under 7.10.8 have been met;

7.16.3.2 That any additional requirements resulting from new information developed during the institutional control period have been met; and

7.16.3.3 That permanent monuments or markers warning against intrusion have been installed.

7.16.3.4 That the records required by RHA 7.32.4 and 7.32.5 have been sent to the party responsible for institutional control of the disposal site and a copy has been sent to the Department immediately prior to license termination.

RHA 7.17. General Requirements.

Land disposal facilities shall be sited, designed, operated, closed, and controlled after closure so that reasonable assurance exists that exposures to individuals are within the requirements established in the performance objectives in 7.18 through 7.21.

RHA 7.18. Protection of the General Population from Releases of Radioactivity.

Concentrations of radioactive material which may be released to the general environment in groundwater, surface water, air, soil, plants, or animals shall not result in an annual dose exceeding an equivalent of 25 millirems (0.25 mSv) to the whole body, 75 millirems (0.75 mSv) to the thyroid, and 25 millirems (0.25 mSv) to any other organ of any member of the public. Reasonable effort should be made to maintain releases of radioactivity in effluents to the general environment as low as is reasonably achievable.

RHA 7.19. Protection of Individuals from Inadvertent Intrusion.

Design, operation, and closure of the land disposal facility shall ensure protection of any individual inadvertently intruding into the disposal site and occupying the site or contacting the waste at any time after active institutional controls over the disposal site are removed.

RHA 7.20. Protection of Individuals During Operations.

Operations at the land disposal facility shall be conducted in compliance with the standards for radiation protection set out in Part III of these regulations, except for releases of radioactivity in effluents from the land disposal facility, which shall be governed by 7.18. Every reasonable effort should be made to maintain radiation exposures as low as is reasonably achievable.

RHA 7.21. Stability of the Disposal Site After Closure.

The disposal facility shall be sited, designed, used, operated, and closed to achieve long-term stability of the disposal site and to eliminate, to the extent practicable, the need for ongoing active maintenance of the disposal site following closure so that only surveillance, monitoring, or minor custodial care are required. Engineered barriers shall be used to ensure that the stability requirements are met.

RHA 7.22. Disposal Site Suitability Requirements for Land Disposal.

7.22.1 Disposal Site Suitability for Near-Surface Disposal. The primary emphasis in disposal site suitability is given to isolation of wastes, and to disposal site features that ensure that the long-term performance objectives are met.

7.22.1.1 The disposal site shall be capable of being characterized, modeled, analyzed and monitored;

7.22.1.2 Within the region where the facility is to be located, a disposal site should be selected so that projected population growth and future developments are not likely to affect the ability of the disposal facility to meet the performance objectives of this part.

7.22.1.3 Areas shall be avoided having known natural resources which, if exploited, would result in failure to meet the performance objectives of this part.

7.22.1.4 The disposal site shall be generally well drained and free of areas of flooding or frequent ponding. Waste disposal shall not take place in a 100-year flood plain, coastal high-hazard area or wetland, as defined in Executive Order 11988, "Floodplain Management Guidelines." the zone of fluctuation of the water table.

7.22.1.5 Upstream drainage areas shall be minimized to decrease the amount of runoff which could erode or inundate waste disposal units.

7.22.1.6 The disposal site shall provide sufficient depth to the water table that groundwater intrusion, perennial or otherwise, into the waste will not occur. The Department will consider an exception to this requirement to allow disposal below the water table if it can be conclusively shown that disposal site characteristics will result in molecular diffusion being the predominant means of radionuclide movement and the rate of movement will result in the performance objectives being met. In no case will waste disposal be permitted in the zone of fluctuation of the water table.

7.22.1.7 The hydrogeologic unit used for disposal shall not discharge groundwater to the surface within the disposal site.

7.22.1.8 Areas shall be avoided where tectonic processes such as faulting, folding, seismic activity or vulcanism may occur with such frequency and extent to significantly affect the ability of the disposal site to meet the performance objectives of this part or may preclude defensible modeling and prediction of longterm impacts.

7.22.1.9 Areas shall be avoided where surface geologic processes such as mass wasting, erosion, slumping, landsliding, or weathering occur with such frequency and extent to significantly affect the ability of the disposal site to meet the performance objectives of this part, or may prelcude defensible modeling and prediction of long-term impacts.

7.22.1.10 The disposal site must not be located where nearby facilities or activities could adversely impact the ability of the site to meet the performance objectives of this part or significantly mask the environmental monitoring program.

RHA 7.23. Disposal Site Design for Near–Surface Disposal.

7.23.1 Site design features shall be directed toward long-term isolation and avoidance of the need for continuing active maintenance after site closure.

7.23.2 The disposal site design and operation shall be compatible with the disposal site closure and stabilization plan and lead to disposal site closure that provides reasonable assurance that the performance objectives will be met.

7.23.3 The disposal site shall be designed to complement and improve, where appropriate, the ability of the disposal site's natural characteristics to assure that the performance objectives will be met.

7.23.4 Covers shall be designed to minimize to the extent practicable water infiltration, to direct percolating or surface water away from the disposed waste, and to resist degradation by surface geologic processes and biotic activity.

7.23.5 Surface features shall direct surface water drainage away from disposal units at velocities and gradients which will not result in erosion that will require ongoing active maintenance in the future.

7.23.6 The disposal site shall be designed to minimize to the extent practicable the contact of water with waste during storage, the contact of standing water with waste during disposal, and the contact of percolating or standing water with wastes after disposal.

RHA 7.24. Near–Surface Disposal Facility Operation and Disposal Site Closure.

7.24.1 Wastes designated as Class A pursuant to 3.25.1 of these regulations shall be segregated from other wastes by placing in disposal units which are sufficiently separated from disposal units for the other waste classes so that any interaction between Class A wastes and other wastes will not result in the failure to meet the performance objectives of this part. This segregation is not necessary for Class A wastes if they meet the stability requirements in 3.25.2.2 of these regulations.

7.24.2 Waste designated as Class C pursuant to 3.25.1 of these regulations shall be disposed of so that the top of the waste is a minimum of 5 meters below the top surface of the cover or must be disposed of with intruder barriers that are designed to protect against an inadvertent intrusion for at least 500 years.

7.24.3 Except as provided in 7.24.12, only waste classified as Class A, B, or C shall be acceptable for near-surface disposal. All waste shall be disposed of in accordance with requirements of 7.24.4 through 7.24.11.

7.24.4 Wastes shall be emplaced in a manner that maintains the package integrity during emplacement, minimizes the void spaces between packages, and permits the void spaces to be filled.

7.24.5 Void spaces between waste packages shall be filled with earth or other material to reduce future subsidence within the fill.

7.24.6 Waste shall be placed and covered in a manner that limits the radiation dose rate at the surface of the cover to levels that at a minimum will permit the licensee to comply with all provisions of 3.4 of these regulations at the time the license is transferred pursuant to 7.15.

7.24.7 The boundaries and locations of each disposal unit shall be accurately located and mapped by means of a land survey. Nearsurface disposal units shall be marked in such a way that the boundaries of each unit can be easily defined. Three (3) permanent survey marker control points, referenced to U.S. Geological Survey (USGS) or National Geodetic Survey (NGS) survey control stations, shall be established on the site to facilitate surveys. The USGS or NGS control stations shall provide horizontal and vertical controls as checked against USGS or NGS record files.

7.24.8 A buffer zone of land shall be maintained between any buried waste and the disposal site boundary and beneath the disposed waste. The buffer zone shall be of adequate dimensions to carry out environmental monitoring activities specified in 7.25.4 and take mitigative measures if needed.

7.24.9 Closure and stabilization measures as set forth in the approved site closure plan shall be carried out as each disposal unit is filled and covered.

7.24.10 Active waste disposal operations shall not have an adverse effect on completed closure and stabilization measures.

7.24.11 Only wastes containing or contaminated with radioactive material shall be disposed of at the disposal site.

7.24.12 Proposals for disposal of waste that is not generally acceptable for near-surface disposal because the waste form and disposal methods must be different and, in general, more stringent than those specified for Class C waste, may be submitted to the Department for approval.

RHA 7.25. Environmental Monitoring.

7.25.1 At the time a license application is submitted, the applicant shall have conducted a preoperational monitoring program to provide basic environmental data on the disposal site characteristics. The applicant shall obtain information about the ecology, meteorology, climate, hydrology, geology, geochemistry and seismology of the disposal site. For those characteristics that are subject to seasonal variation, data must cover at least a twelve month period.

7.25.2 During the land disposal facility site construction and operation, the licensee shall maintain an environmental monitoring program. Measurements and observations must be made and recorded to provide data to evaluate the potential health and environmental impacts during both the construction and the operation of the facility and to enable the evaluation of long-term effects and the need for mitigative measures. The monitoring system must be capable of providing early warning of releases of waste from the disposal site before they leave the site boundary.

7.25.3 After the disposal site is closed, the licensee responsible for post-operational surveillance of the disposal site shall maintain a monitoring system based on the operating history and the closure and stabilization of the disposal site. The monitoring system must be capable of providing early warning of releases of waste from the disposal site before they leave the site boundary.

7.25.4 The licensee shall have plans for taking corrective measures if the environmental monitoring program detects migration of waste which would indicate that the performance objectives may not be met.

RHA 7.26. Alternative Requirements for Design and Operations.

The Department may, upon request or on its own initiative, authorize provisions other than those set forth in 7.23 through 7.25 for the segregation and disposal of waste and for the design and operation of a land disposal facility on a specific basis, if it finds reasonable assurance of compliance with the performance objectives of this part.

RHA 7.27. Institutional Requirements.

7.27.1 Land Ownership. Disposal of waste received from other persons may be permitted only on land owned in fee by the federal or a state government.

7.27.2 Institutional Control. The land owner or custodial agency shall conduct an institutional control program to physically control access to the disposal site following transfer of control of the disposal site from the disposal site operator.

The institutional control program shall also include, but not be limited to, conducting an environmental monitoring program at the disposal site, periodic surveillance, minor custodial care, and other requirements as determined by the Department, and administration of funds to cover the costs for these activities. The period of institutional controls will be determined by the Department but institutional controls may not be relied upon for more than 100 years following transfer of control of the disposal site to the owner.

RHA 7.28. Alternative Requirements for Waste Classification and Characteristics.

The Department licensing a low-level disposal facility may, upon request or on its own initiative, authorize other provisions for the classification and characteristics of waste on a specific basis, if, after evaluation of the specific characteristics of the waste, disposal site, and method of disposal, it finds reasonable assurance of compliance with the performance objectives specified in this part.

RHA 7.29. Applicant Qualifications and Assurances.

Each applicant shall show that it either possesses the necessary funds or has reasonable assurance of obtaining the necessary funds, or by a combination of the two, to cover the estimated costs of conducting all licensed activities over the planned operating life of the project, including costs of construction and disposal.

RHA 7.30. Funding for Disposal Site Closure and Stabilization.

7.30.1 The applicant shall provide assurances prior to the commencement of operations that sufficient funds will be available to carry out disposal site closure and stabilization, including: (1) decontamination or dismantlement of land disposal facility structures; and (2) closure and stabilization of the disposal site so that following transfer of the disposal site to the site owner, the need for ongoing active maintenance is eliminated to the extent practicable and only minor custodial care, surveillance and monitoring are required. These assurances shall be based on Department approved cost estimates reflecting the Department plan for disposal site closure and stabilization. The applicant's cost estimates must take into account total costs that would be incurred if an independent contractor were hired to perform the closure and stabilization work.

7.30.2 In order to avoid unnecessary duplication and expense, the Department will accept financial sureties that have been consolidated with earmarked financial or surety arrangements established to meet requirements of federal or other state agencies (and/or local government bodies) for such decontamination, closure, and stabilization. The Department will accept these arrangements only if they are considered adequate to satisfy the requirements of 7.30 and that the portion of the surety which covers the closure of the disposal site is clearly identified and committed for use in accomplishing these activities.

7.30.3 The licensee's financial or surety arrangement shall be submitted annually for review by the Department to assure that sufficient funds will be available for completion of the closure plan.

7.30.4 The amount of the licensee's financial or surety arrangement shall change in accordance with changes in the predicted costs of closure and stabilization. Factors affecting closure and stabilization cost estimates include inflation, increases in the amount of disturbed land, changes in engineering plans, closure and stabilization that has already been accomplished, and any other conditions affecting costs. The financial or surety arrangement shall be sufficient at all times to cover the costs of closure and stabilization of the disposal units that are expected to be used before the next license renewal.

7.30.5 The financial or surety arrangement shall be written for a specified period of time and shall be automatically renewed unless the person who issues the surety notifies the Department, the beneficiary (the site owner), and the principal (the licensee) not less than 90 days prior to the renewal date of its intention not to renew. In such a situation, the licensee must submit a replacement surety within 30 days after notification of cancellation. If the licensee fails to provide a replacement surety acceptable to the Department, the beneficiary may collect on the original surety.

7.30.6 Proof of forfeiture shall not be necessary to collect the surety so that, in the event that the licensee could not provide an acceptable replacement surety within the required time, the surety shall be automatically collected prior to its expiration. The conditions described above shall be clearly stated on any surety instrument.

7.30.7 Financial or surety arrangements generally acceptable to the Department include surety bonds, cash deposits, certificates of deposit, deposits of government securities, escrow accounts, irrevocable letters or lines of credit, trust funds, and combinations of the above or such other types of arrangements as may be approved by the Department. Self-insurance, or any arrangement which essentially constitutes self-insurance, will not satisfy the surety requirement for private sector applicants.

7.30.8 The licensee's financial or surety arrangement shall remain in effect until the closure and stabilization program has been completed and approved by the Department, and the license has been transferred to the site owner.

RHA 7.31. Financial Assurances for Institutional Controls.

7.31.1 Prior to the issuance of the license, the applicant shall provide for Department approval, a binding arrangement, between the applicant and the disposal site owner that ensures that sufficient funds will be available to cover the costs of monitoring and any required maintenance during the institutional control period. The binding arrangement shall be reviewed annually by the Department to ensure that changes in inflation, technology, and disposal facility operations are reflected in the arrangements.

7.31.2 Subsequent changes to the binding arrangement specified in 7.31.1 relevant to institutional control shall be submitted to the Department for prior approval.

RHA 7.32. Maintenance of Records, Reports, and Transfers.

7.32.1 Each licensee shall maintain any records and make any reports in connection with the licensed activities as may be required by the conditions of the license or by the rules, regulations, and orders of the Department.

7.32.2 Records which are required by these regulations or by license conditions shall be maintained for a period specified by the appropriate regulations or by license condition. If a retention period is not otherwise specified, these records must be maintained and transferred to the officials specified in 7.32.4 as a condition of license termination unless the Department authorizes their disposition.

7.32.3 Records which shall be maintained pursuant to this part may be the original or a reproduced copy or microfilm if this reproduced copy or microfilm is capable of producing copy that is clear and legible at the end of the required retention period.

7.32.4 Notwithstanding 7.32.1 through 7.32.3, copies of records of the location and the quantity of wastes contained in the disposal site must be transferred upon license termination to the chief executive of the nearest municipality, the chief executive of the county in which the facility is located, the county zoning board or land development and planning agency, the state governor, and other state, local and federal governmental agencies as designated by the Department at the time of license termination.

7.32.5 Following receipt and acceptance of a shipment of radioactive waste, the licensee shall record the date that the shipment is received at the disposal facility, the date of disposal of the waste, a traceable shipment manifest number, a description of any engineered barrier or structural overpack provided for disposal of the waste, the location of disposal at the disposal site, the containment integrity of the waste disposal containers as received, any discrepancies between materials listed on the manifest and those received, the volume of any pallets, bracing, or other shipping or onsite generated materials that are contaminated, and are disposed of as contaminated or suspect materials, and any evidence of leaking or damaged disposal containers or radiation or contamination levels in excess of limits specified in U.S. Department of Transportation and Department regulations. The licensee shall briefly describe any repackaging operations of any of the disposal containers included in the shipment, plus any other information required by the Department as a license condition. The licensee shall retain these records until the Department transfers or terminates the license that authorizes the activities described in this section.

7.32.6 Each licensee authorized to dispose of waste received from other persons shall file a copy of its financial report or a certified financial statement annually with the Department in order to update the information base for determining financial qualifications.

7.32.7 Each licensee authorized to dispose of waste received from other persons, pursuant to this part, shall submit annual reports to the Department. Reports shall be submitted by the end of the first calendar quarter of each year for the preceding year.

7.32.7.1 The reports shall include:

7.32.7.1.1 specification of the quantity of each of the principal contaminants released to unrestricted areas in liquid and in airborne effluents during the preceding year,

7.32.7.1.2 the results of the environmental monitoring program,

7.32.7.1.3 a summary of licensee disposal unit servey and maintenance activities,

7.32.7.1.4 a summary, by waste class, of activities and quantities of radionuclides disposed of,

7.32.7.1.5 any instances in which observed site characteristics were significantly different from those described in the application for a license, and

7.32.7.1.6 any other information the Department may require.

7.32.7.2 If the quantities of waste released during the reporting period, monitoring results, or maintenance performed are significantly different from those predicted, the report must cover this specifically.

7.32.8 In addition to the other requirements of this section, the licensee shall store, or have stored, manifest and other information pertaining to receipt and disposal of radioactive waste in an electronic recordkeeping system.

7.32.8.1 The manifest information that must be electronically stored is:

7.32.8.1.1 That required in Part III, Appendix D, RHA 3.55 with the exception of shipper and carrier telephone numbers and shipper and consignee certifications; and

7.32.8.1.2 That information required in RHA 7.32.5.

7.32.8.2 As specified in facility license conditions, the licensee shall report the stored information, or subsets of this information, on a computer-readable medium, or other medium as required by the Department.

HISTORY: Amended by SCSR 42–2 Doc. No. 4791, eff February 23, 2018.

RHA 7.33. Tests on Land Disposal Facilities.

Each licensee shall perform, or permit the Department to perform, any tests the Department deems appropriate or necessary for the administration of the regulations in this part, including, but not limited to, tests of:

7.33.1 Wastes;

7.33.2 Facilities used for the receipt, storage, treatment, handling or disposal of wastes;

7.33.3 Radiation detection and monitoring instruments; or

7.33.4 Other equipment and devices used in connection with the receipt, possession, handling, treatment, storage, or disposal of waste.

RHA 7.34. Department Inspections of Land Disposal Facilities.

7.34.1 Each licensee shall afford to the Department at all reasonable times opportunity to inspect waste not yet disposed of, and the premises, equipment, operations, and facilities in which wastes are received, possessed, handled, treated, stored, or disposed.

7.34.2 Each licensee shall make available to the Department for inspection, upon reasonable notice, records kept by it pursuant to these regulations. Authorized representatives of the Department may copy and take away copies of, for the Department's use, any record required to be kept pursuant to these regulations.

PART VIII
Special Requirements for Well Logging Operations

RHA 8.1. Purpose.

The regulations of this Part establish licensing and radiation safety requirements for persons utilizing sealed sources, radioactive tracers, radioactive marker, and uranium sinker bars for well logging in a single well. The provisions and requirements of this Part are in addition to, and not in substitution for, other requirements of these regulations.

RHA 8.2. Scope.

The regulations established in this Part apply to all licensees using radioactive material for well logging; provided, however, that nothing in this Part applies to the use of radioactive material in tracer studies involving multiple wells, such as field flooding studies, or to the use of sealed sources auxiliary to well logging but not lowered into wells.

RHA 8.3. Definitions.

As used in this Part:

8.3.1 "Energy compensation source" (ECS) means a small sealed source, with an activity not exceeding 100 microcuries (3.7 MBq), used within a logging tool, or other tool components, to provide a reference standard to maintain the tool's calibration when in use.

8.3.2 "Field station" means a facility where radioactive material may be stored or used and from which equipment is dispatched to temporary jobsites.

8.3.3 "Fresh water aquifer", for the purpose of this Part, means a geologic formation that is capable of yielding fresh water to a well or spring.

8.3.4 "Injection tool" means a device used for controlled subsurface injection of radioactive tracer material.

8.3.5 "Irretrievable well logging source" means any sealed source containing radioactive material that is pulled off or not connected to the wireline that suspends the source in the well and for which all reasonable effort at recovery has been expended.

8.3.6 "Logging assistant" means any individual who, under the personal supervision of a logging supervisor, handles sealed sources or tracers that are not in logging tools or shipping containers or who performs surveys required by RHA 8.22.

8.3.7 "Logging supervisor" means an individual who uses radioactive material or provides personal supervision in the use of radioactive material at a temporary jobsite and who is responsible to the licensee for assuring compliance with the requirements of the Department's regulations and the conditions of the license.

8.3.8 "Logging tool" means a device used subsurface to perform well logging.

8.3.9 "Personal supervision" means guidance and instruction by a logging supervisor, who is physically present at a temporary jobsite, who is in personal contact with logging assistants, and who can give immediate assistance.

8.3.10 "Radioactive marker" means radioactive material used for depth determination or direction orientation. For purposes of this Part, this term includes radioactive collar markers and radioactive iron nails.

8.3.11 "Safety review" means a periodic review provided by the licensee for its employees on radiation safety aspects of well logging. The review may include, as appropriate, the results of internal inspections, new procedures or equipment, accidents or errors that have been observed, and opportunities for employees to ask safety questions.

8.3.12 "Sealed source" means any radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.

8.3.13 "Source holder" means a housing or assembly into which a sealed source is placed to facilitate the handling and use of the source in well logging.

8.3.14 "Subsurface tracer study" means the release of unsealed radioactive material or a substance labeled with radioactive material in a single well for the purpose of tracing the movement or position of the material or substance in the well or adjacent formation.

8.3.15 "Surface casing for protecting fresh water aquifers" means a pipe or tube used as a lining in a well to isolate fresh water aquifers from the well.

8.3.16 "Temporary jobsite" means a place where radioactive materials are present for the purpose of performing well logging or subsurface tracer studies.

8.3.17 "Tritium neutron generator target source" means a tritium source used within a neutron generator tube to produce neutrons for use in well logging applications.

8.3.18 "Uranium sinker bar" means a weight containing depleted uranium used to pull a logging tool toward the bottom of a well.

8.3.19 "Well" means a drilled hole in which well logging may be performed. As used in this Part, "well" includes drilled holes for the purpose of oil, gas, mineral, groundwater, or geological exploration.

8.3.20 "Well logging" means, unless otherwise specified, all operations involving the lowering and raising of measuring devices or tools which contain radioactive material or are used to detect radioactive material in wells for the purpose of obtaining information about the well or adjacent formations which may be used in oil, gas, mineral, groundwater, or geological exploration.

RHA 8.4. Specific Licenses for Well Logging.

The Department will approve an application for a specific license for the use of radioactive material in well logging if the applicant meets the following requirements:

8.4.1 The applicant shall satisfy the general requirements specified in RHA 2.6 of these regulations, as appropriate, and any special requirements contained in this Part.

8.4.2 The applicant shall develop a program for training logging supervisors and logging assistants and submit to the Department a description of this program which specifies:

8.4.2.1 Initial training;

8.4.2.2 On-the-job training;

8.4.2.3 Annual safety reviews provided by the licensee;

8.4.2.4 Means the applicant will use to demonstrate the logging supervisor's knowledge and understanding of and ability to comply with the Department's regulations and licensing requirements and the applicant's operating and emergency procedures; and

8.4.2.5 Means the applicant will use to demonstrate the logging assistant's knowledge and understanding of and ability to comply with the applicant's operating and emergency procedures.

8.4.3 The applicant shall submit to the Department written operating and emergency procedures as described in RHA 8.20 or an outline or summary of the procedures that includes the important radiation safety aspects of the procedures.

8.4.4 The applicant shall establish and submit to the Department its program for annual inspections of the job performance of each logging supervisor to ensure that the Department's regulations, license requirements, and the applicant's operating and emergency procedures are followed. Inspection records must be retained for 3 years after each annual internal inspection.

8.4.5 The applicant shall submit a description of its overall organizational structure as it applies to the radiation safety responsibilities in well logging, including specified delegations of authority and responsibility.

8.4.6 If an applicant wants to perform leak testing of sealed sources, the applicant shall identify the manufacturer and the model numbers of the leak test kits to be used. If the applicant wants to analyze its own wipe samples, the applicant shall establish procedures to be followed and submit a description of these procedures to the Department. The description must include:

8.4.6.1 Instruments to be used;

8.4.6.2 Methods of performing the analysis; and

8.4.6.3 Pertinent experience of the person who will analyze the wipe samples.

HISTORY: Amended by State Register Volume 38, Issue No. 10, Doc. No. 4462, eff October 24, 2014.

RHA 8.5. Agreement with Well Owner or Operator.

8.5.1 The licensee may perform well logging with a sealed source only after the licensee has a written agreement with the employing well owner or operator. This written agreement must identify who will meet the following requirements:

8.5.1.1 If a sealed source becomes lodged in the well, a reasonable effort will be made to recover it;

8.5.1.2 A person may not attempt to recover a sealed source in a manner which, in the licensee's opinion, could result in its rupture;

8.5.1.3 The radiation monitoring required in RHA 8.23.1 will be performed;

8.5.1.4 If the environment, any equipment, or personnel are contaminated with radioactive material, they must be decontaminated before release from the site or release for unrestricted use; and

8.5.1.5 If the sealed source is classified as irretrievable after reasonable efforts at recovery have been expended, the following requirements must be implemented within 30 days:

8.5.1.5.1 Each irretrievable well logging source must be immobilized and sealed in place with a cement plug;

8.5.1.5.2 A means to prevent inadvertent intrusion on the source, unless the source is not accessible to any subsequent drilling operations; and

8.5.1.5.3 A permanent identification plaque, constructed of long lasting material such as stainless steel, brass, bronze, or Monel, must be mounted at the surface of the well, unless the mounting of the plaque is not practical. The size of the plaque must be at least 7 inches (17 cm) square and ⅛ inch (3 mm) thick. The plaque must contain:

8.5.1.5.3.1 The word "CAUTION";

8.5.1.5.3.2 The radiation symbol (the color requirement in RHA 3.8.1 of these regulations need not be met);

8.5.1.5.3.3 The date the source was abandoned;

8.5.1.5.3.4 The name of the well owner or operator, as appropriate;

8.5.1.5.3.5 The well name and well identification number(s) or other designation;

8.5.1.5.3.6 An identification of the sealed source(s) by radionuclide and quantity;

8.5.1.5.3.7 The depth of the source and depth of the top of the plug; and

8.5.1.5.3.8 An appropriate warning, such as "DO NOT RE-ENTER THIS WELL".

8.5.2 The licensee shall retain a copy of the written agreement for 3 years after the completion of the well logging operation.

8.5.3 The licensee may apply, pursuant to RHA 1.10 of these regulations for Department approval, on a case-by-case basis, of proposed procedures to abandon an irretrievable well logging source in a manner not otherwise authorized in RHA 8.5.1.5.

8.5.4 A written agreement between the licensee and the well owner or operator is not required if the licensee and the well owner or operator are part of the same corporate structure or otherwise similarly affiliated. However, the licensee shall still otherwise meet the requirements in RHA 8.5.1.1 through 8.5.1.5.

RHA 8.6. Labeling of Well Logging Devices.

8.6.1 The licensee may not use a source, source holder, or logging tool that contains radioactive material unless the smallest component that is transported as a separate piece of equipment with the radioactive material inside bears a durable, legible, and clearly visible marking or label. The marking or label must contain the radiation symbol specified in RHA 3.8.1 of these regulations, without the conventional color requirements, and the wording "DANGER (or CAUTION) RADIOACTIVE MATERIAL."

8.6.2 The licensee may not use a container to store radioactive material unless the container has securely attached to it a durable, legible, and clearly visible label. The label must contain the radiation symbol specified in RHA 3.8.1 of these regulations and the wording "CAUTION (or DANGER), RADIOACTIVE MATERIAL, NOTIFY CIVIL AUTHORITIES (or NAME OF COMPANY)."

RHA 8.7. Storage of Well Logging Devices.

The licensee shall store each source containing radioactive material in a storage container or transportation package. The container or package must be locked and physically secured to prevent tampering or removal of radioactive material from storage by unauthorized personnel. The licensee shall store radioactive material in a manner which will minimize danger from explosion or fire.

RHA 8.8. Transportation of Well Logging Devices.

8.8.1 The licensee may not transport radioactive material unless the material is packaged, labeled, marked, and accompanied with appropriate shipping papers in accordance with regulations set out in the Code of Federal Regulations, Title 10, Part 71.

8.8.2 The licensee shall lock and physically secure the transportation package containing radioactive material in the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal of the radioactive material from the vehicle.

RHA 8.9. Radiation Survey Instruments.

8.9.1 The licensee shall keep a calibrated and operable radiation survey instrument capable of detecting beta and gamma radiation at each field station and temporary jobsite to make the radiation

surveys required by this Part and by Part III of these regulations. To satisfy this requirement, the radiation survey instrument must be capable of measuring 0.001 mSv (0.1 mrem) per hour through at least 0.5 mSv (50 mrem) per hour.

8.9.2 The licensee shall have available additional calibrated and operable radiation detection instruments sensitive enough to detect the low radiation and contamination levels that could be encountered if a sealed source ruptured. The licensee may own the instruments or may have a procedure to obtain them quickly from a second party.

8.9.3 The licensee shall have each radiation survey instrument required under RHA 8.9.1 calibrated as follows:

8.9.3.1 At intervals not to exceed 6 months and after instrument servicing;

8.9.3.2 For linear scale instruments, at two points located approximately ⅓ and ⅔ of full-scale on each scale; for logarithmic scale instruments, at midrange of each decade, and at two points of at least one decade; and for digital instruments, at appropriate points; and

8.9.3.3 So that an accuracy within plus or minus 20 percent of the calibration standard can be demonstrated on each scale.

8.9.4 The licensee shall retain calibration records for a period of 3 years after the date of calibration for inspection by the Department.

History: Amended by SCSR 44–11, eff November 27, 2020 (errata).

RHA 8.10. Leak Testing of Sealed Sources.

8.10.1 Each licensee who uses a sealed source shall have the source tested for leakage periodically. The licensee shall keep records of leak test results in units of microcuries and retain the records for inspection by the Department for 3 years after the leak test is performed.

8.10.2 Method of testing. The wipe of a sealed source must be performed using a leak test kit or method approved by the Department, the U.S. Nuclear Regulatory Commission, or any Agreement State. The wipe sample must be taken from the nearest accessible point to the sealed source where contamination might accumulate. The wipe sample must be analyzed for radioactive contamination. The analysis must be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample and must be performed by a person approved by the Department, the U.S. Nuclear Regulatory Commission, or an Agreement State to perform the analysis.

8.10.3 Test frequency. Each sealed source (except an energy compensation source (ECS)) shall be tested for leakage at intervals not to exceed six (6) months. In the absence of a certificate from a transferor that a leak test has been made within the 6 month period prior to the transfer, the sealed source shall not be put into use until leak tested. Each ECS that is not exempt from testing in accordance with RHA 8.10.5 of this section must be tested at intervals not to exceed 3 years. In the absence of a certificate from a transferor that a test has been made within the 3 years before the transfer, the ECS may not be used until tested.

8.10.4 Removal of leaking source from service. Any test conducted pursuant to RHA 8.10.1, 8.10.2 and 8.10.3 which reveals the presence of 0.005 microcurie or more of removable radioactive material shall be considered evidence that the sealed source is leaking. The licensee shall immediately remove the sealed source involved from use and shall cause it to be decontaminated and repaired or to be disposed of by a licensee authorized by the Department, the NRC or an Agreement State to perform these functions. The licensee shall check the equipment associated with the leaking source for radioactive contamination and, if contaminated, have it decontaminated or disposed of by a licensee authorized by the Department, the NRC or an Agreement State to perform these functions. Within five (5) days after obtaining results of the leak test, the licensee shall file a report with the Department describing the equipment involved, the test results and the corrective action taken.

8.10.5 The following sealed sources are exempt from the periodic leak test requirements set out in RHA 8.10.1 through 8.10.4:

8.10.5.1 Hydrogen–3 (tritium) sources;

8.10.5.2 Sources containing radioactive material with a half-life of 30 days or less;

8.10.5.3 Sealed sources containing radioactive material in gaseous form;

8.10.5.4 Sources of beta or gamma emitting radioactive material with an activity of 100 microcuries or less; and

8.10.5.5 Sources of alpha or neutron emitting radioactive material with an activity of 10 microcuries or less.

RHA 8.11. Physical Inventory.

Each licensee shall conduct a semi-annual physical inventory to account for all radioactive material received and possessed under the license. The licensee shall retain records of the inventory for 3 years from the date of the inventory for inspection by the Department. The inventory must indicate the quantity and kind of radioactive material, the location of the radioactive material, the date of the inventory, and the name of the individual conducting the inventory. Physical inventory records may be combined with leak test records.

RHA 8.12. Utilization Logs.

8.12.1 Each licensee shall maintain records for each use of radioactive material showing:

8.12.1.1 The make, model number, and a serial number or a description of each sealed source used;

8.12.1.2 In the case of unsealed radioactive material used for subsurface tracer studies, the radionuclide and quantity of activity used in a particular well and the disposition of any unused tracer materials;

8.12.1.3 The identity of the logging supervisor who is responsible for the radioactive material and the identity of logging assistants present; and

8.12.1.4 The location and date of use of the radioactive material.

8.12.2 The licensee shall make the records required by RHA 8.12.1 available for inspection by the Department. The licensee shall retain the records for 3 years from the date of the recorded event.

RHA 8.13. Criteria for Sealed Source Design and Integrity.

8.13.1 A licensee may use a sealed source in well logging applications if:

8.13.1.1 The sealed source is doubly encapsulated;

8.13.1.2 The sealed source contains radioactive material whose chemical and physical forms are as insoluble and nondispersible as practical; and

8.13.1.3 The sealed source meets the requirements of RHA 8.13.2, 8.13.3 or 8.13.4.

8.13.2 For a sealed source manufactured on or before July 14, 1989, a licensee may use the sealed source, for use in well logging applications if it meets the requirements of USASI N5.10–1968, "Classification of Sealed Radioactive Sources," or the requirements in RHA 8.13.3 or 8.13.4 of this section.

8.13.3 For a sealed source manufactured after July 14, 1989, a licensee may use the sealed source, for use in well logging applications if it meets the oil-well logging requirements of ANSI/HPS N43.6–1997, "Sealed Radioactive Sources—Classification."

8.13.4 For a sealed source manufactured after July 14, 1989, a licensee may use the sealed source, for use in well logging applications, if—

8.13.4.1 The sealed source's prototype has been tested and found to maintain its integrity after each of the following tests:

8.13.4.1.1 Temperature. The test source must be held at – 40° C for 20 minutes, 600° C for 1 hour, and then be subject to a thermal shock test with a temperature drop from 600° C to 20° C within 15 seconds.

8.13.4.1.2 Impact Test. A 5kg steel hammer, 2.5cm in diameter, must be dropped from a height of 1m onto the test source.

8.13.4.1.3 Vibration Test. The test source must be subject to a vibration from 25Hz to 500Hz at 5g amplitude for 30 minutes.

8.13.4.1.4 Puncture Test. A 1 gram hammer and pin, 0.3cm pin diameter, must be dropped from a height of 1m onto the test source.

8.13.4.1.5 Pressure Test. The test source must be subjected to an external pressure of 24,600 pounds per square inch absolute (1.695×10^7 pascals).

8.13.5 The requirements in RHA 8.13.1, 8.13.2, 8.13.3 and 8.13.4 do not apply to sealed sources that contain radioactive material in gaseous form.

8.13.6 The requirements in RHA 8.13.1, 8.13.2, 8.13.3 and 8.13.4 of this section do not apply to energy compensation sources (ECS). ECSs must be registered with the Department under RHA 2.29 or with the NRC under Sec. 32.210.

8.13.7 Energy compensation source. The licensee may use an energy compensation source (ECS) which is contained within a logging tool, or other tool components, only if the ECS contains quantities of licensed material not exceeding 100 microcuries (3.7 MBq).

(a) For well logging applications with a surface casing for protecting fresh water aquifers, use of the ECS is only subject to the requirements of RHA 8.10, 8.11, and 8.12.

(b) For well logging applications without a surface casing for protecting fresh water aquifers, use of the ECS is only subject to the requirements of RHA 8.5, 8.10, 8.11, 8.12, 8.18, and 8.27.

8.13.8 Tritium neutron generator target source.

(a) Use of a tritium neutron generator target source, containing quantities not exceeding 30 curies (1,110 MBq) and in a well with a surface casing to protect fresh water aquifers, is subject to the requirements of this part except RHA 8.5, 8.13, and 8.27.

(b) Use of a tritium neutron generator target source, containing quantities exceeding 30 curies (1,110 MBq) or in a well without a surface casing to protect fresh water aquifers, is subject to the requirements of this part except RHA 8.13.

RHA 8.14. Inspection, Maintenance, and Opening of a Source or Source Holder.

8.14.1 Each licensee shall visually check source holders, logging tools, and source handling tools, for defects before each use to ensure that the equipment is in good working condition and that required labeling is present. If defects are found, the equipment must be removed from service until repaired and a record must be made listing the date of check, name of inspector, equipment involved, defects found, and repairs made. These records must be retained for 3 years after the defect is found.

8.14.2 Each licensee shall have a program for semiannual visual inspection and routine maintenance of source holders, logging tools, injection tools, source handling tools, storage containers, transport containers, and uranium sinker bars to ensure that the required labeling is legible and that no physical damage is visible. If defects are found, the equipment must be removed from service until repaired, and a record must be made listing date, equipment involved, inspection and maintenance operations performed, any defects found, and any actions taken to correct the defects. These records must be retained for 3 years after the defect is found.

8.14.3 Removal of a sealed source from a source holder or logging tool, and maintenance on sealed sources or holders in which sealed sources are contained may not be performed by the licensee unless a written procedure developed pursuant to RHA 8.20 has been approved either by the Department pursuant to RHA 8.4.3, the U.S. Nuclear Regulatory Commission, any Agreement State, or a Licensing State.

8.14.4 If a sealed source is stuck in the source holder, the licensee may not perform any operation such as drilling, cutting, or chiseling on the source holder unless the licensee is specifically approved by the Department, the U.S. Nuclear Regulatory Commission, any Agreement State or a Licensing State to perform this operation.

8.14.5 The opening, repair, or modification of any sealed source must be performed by persons specifically approved to do so by the Department, the U.S. Nuclear Regulatory Commission, any Agreement State, or a Licensing State.

RHA 8.15. Subsurface Tracer Studies.

8.15.1 The licensee shall require all personnel handling radioactive tracer material to use protective gloves and, if required by the license, other protective clothing and equipment. The licensee shall take precautions to avoid ingestion or inhalation of radioactive tracer material and to avoid contamination of field stations and temporary jobsites.

8.15.2 A licensee may not knowingly inject radioactive material into fresh water aquifers unless specifically authorized to do so by the Department.

RHA 8.16. Radioactive Markers.

The licensee may use radioactive markers in wells only if the individual markers contain quantities of radioactive material not exceeding the quantities specified in RHA 2.24 of these regulations. The use of markers is subject only to the requirements of RHA 8.11.

RHA 8.17. Uranium Sinker Bars.

The licensee may use a uranium sinker bar in well logging applications, only if it is legibly impressed with the words "CAUTION—RADIOACTIVE DEPLETED URANIUM" and "NOTIFY CIVIL AUTHORITIES (or COMPANY NAME) IF FOUND."

RHA 8.18. Use Of Sealed Sources in a Well Without Surface Casings

The licensee may use a sealed source in a well without a surface casing for protecting fresh water aquifers only if the licensee follows a procedure for reducing the probability of the source becoming lodged in the well. The procedure must be approved by the Department pursuant to RHA 8.4.3, the U.S. Nuclear Regulatory Commission, any Agreement State or a Licensing State.

RHA 8.19. Training Requirements for Well Logging Personnel.

8.19.1 The licensee may not permit an individual to act as a logging supervisor until that person:

8.19.1.1 Has completed training in the subjects outlined in RHA 8.19.5;

8.19.1.2 Has received copies of, and instruction in:

8.19.1.2.1 The requirements contained in the applicable sections of Parts III, VI and VIII of these regulations;

8.19.1.2.2 The license under which the logging supervisor will perform well logging; and

8.19.1.2.3 The licensee's operating and emergency procedures required by RHA 8.20;

8.19.1.3 Has completed on-the-job training and demonstrated competence in the use of radioactive material, remote handling tools, and radiation survey instruments by a field evaluation; and

8.19.1.4 Has demonstrated understanding of the requirements in RHA 8.19.1.1 and 8.19.1.2 by successfully completing a written test.

8.19.2 The licensee may not permit an individual to act as a logging assistant until that person:

8.19.2.1 Has received instructions in applicable sections of Parts III and VI of these regulations;

8.19.2.2 Has received copies of and instruction in, the licensee's operating and emergency procedures required by RHA 8.20;

8.19.2.3 Has demonstrated understanding of the materials listed in RHA 8.19.2.1 and 8.19.2.2 by successfully completing a written or oral test; and

8.19.2.4 Has received instruction in the use of radioactive material, remote handling tools, and radiation survey instruments, as appropriate for the logging assistant's intended job responsibilities.

8.19.3 The licensee shall provide safety reviews for logging supervisors and logging assistants at least once during each calendar year.

8.19.4 The licensee shall maintain a record for each logging supervisor's and logging assistant's training and annual safety review. The training records must include copies of written tests and dates of oral tests given after July 14, 1987. The training records must be retained until 3 years following the termination of employment. Records of annual safety reviews must list the topics discussed and be retained for 3 years.

8.19.5 The licensee shall include the following subjects in the training required in RHA 8.19.1.1:

8.19.5.1 Fundamentals of radiation safety including:

8.19.5.1.1 Characteristics of radiation;

8.19.5.1.2 Units of radiation dose and quantity of radioactivity;

8.19.5.1.3 Hazards of exposure to radiation;

8.19.5.1.4 Levels of radiation from radioactive material;

8.19.5.1.5 Methods of controlling radiation dose (time, distance, and shielding); and

8.19.5.1.6 Radiation safety practices, including prevention of contamination, and methods of decontamination;

8.19.5.2 Radiation detection instruments including:

8.19.5.2.1 Use, operation, calibration, and limitations of radiation survey instruments;

8.19.5.2.2 Survey techniques; and

8.19.5.2.3 Use of personnel monitoring equipment;

8.19.5.3 Equipment to be used including:

8.19.5.3.1 Operation of equipment including source handling equipment and remote handling tools;

8.19.5.3.2 Storage, control, and disposal of radioactive material; and

8.19.5.3.3 Maintenance of equipment;

8.19.5.4 The requirements of pertinent federal and state regulations; and

8.19.5.5 Case histories of accidents in well logging.

RHA 8.20. Operating and Emergency Procedures.

Each licensee shall develop and follow written operating and emergency procedures that cover the following items:

8.20.1 The handling and use of radioactive materials including the use of sealed sources in wells without surface casings for protecting fresh water aquifers, if appropriate;

8.20.2 The use of remote handling tools for handling sealed sources and radioactive tracer material except low-activity calibration sources;

8.20.3 Methods and occasions for conducting radiation surveys including surveys for detecting contamination, as required by RHA 8.22.3 through 8.22.5;

8.20.4 Minimizing personnel exposure including exposures from inhalation and ingestion of radioactive tracer materials;

8.20.5 Methods and occasions for locking and securing stored radioactive materials;

8.20.6 Personnel monitoring and the use of personnel monitoring equipment;

8.20.7 Transportation of radioactive materials to field stations or temporary jobsites, packaging of radioactive materials for transport in vehicles, placarding of vehicles when needed, and physically securing radioactive material in transport vehicles during transportation to prevent accidental loss, tampering, or unauthorized removal;

8.20.8 Receiving and opening packages containing radioactive materials in accordance with the Code of Federal Regulations, Title 10, Part 20.205 and RHA 3.14 of these regulations;

8.20.9 For the use of tracers, decontamination of the environment, equipment, and personnel;

8.20.10 Maintenance of records generated by logging personnel at temporary jobsites;

8.20.11 The inspection and maintenance of sealed sources, source holders, logging tools, injection tools, source handling tools, storage containers, transport containers, and uranium sinker bars as required by RHA 8.14.

8.20.12 Identifying and reporting defects and noncompliance to the Department;

8.20.13 Actions to be taken if a sealed source is lodged in a well;

8.20.14 Notifying proper persons in the event of an accident; and

8.20.15 Actions to be taken if a sealed source is ruptured including actions to prevent the spread of contamination and minimize inhalation and ingestion of radioactive material and actions to obtain suitable radiation survey instruments as required by RHA 8.9.2.

RHA 8.21. Personnel Monitoring.

8.21.1 The licensee may not permit an individual to act as a logging supervisor or logging assistant unless that person wears a personnel dosimeter at all times during the handling of radioactive

materials. Each personnel dosimeter must be assigned to and worn by only one individual. Film badges must be replaced at least monthly and other personnel dosimeters that require replacement must be replaced at least quarterly. All personnel dosimeters must be evaluated at least quarterly or promptly after replacement, whichever is more frequent.

8.21.2 The licensee shall provide bioassay services to individuals using radioactive material in subsurface tracer studies if required by the license.

8.21.3 The licensee shall retain records of personnel dosimeters and bioassay results for inspection until the Department authorizes disposition of the records.

HISTORY: Amended by SCSR 45–5 Doc. No. 5036, eff May 28, 2021.

RHA 8.22. Radiation Surveys.

8.22.1 The licensee shall make radiation surveys, including but not limited to the surveys required under RHA 8.22.2 through 8.22.5, of each area where radioactive materials are used and stored.

8.22.2 Before transporting radioactive material, the licensee shall make a radiation survey of the position occupied by each individual in the vehicle and of the exterior of each vehicle used to transport the radioactive materials.

8.22.3 If the sealed source assembly is removed from the logging tool before departure from the temporary jobsite, the licensee shall confirm that the logging tool is free of contamination by energizing the logging tool detector or by using a survey meter.

8.22.4 If the licensee has reason to believe that as a result of any operation involving a sealed source, the encapsulation of the sealed source could be damaged by the operation, the licensee shall conduct a radiation survey, including a contamination survey, during and after the operation.

8.22.5 The licensee shall make a radiation survey at the temporary jobsite before and after each subsurface tracer study to confirm the absence of contamination.

8.22.6 The results of surveys required under RHA 8.22.1 through 8.22.5 must be recorded and must include the date of the survey, the name of the individual making the survey, the identification of the survey, instrument used, and the location of the survey. The licensee shall retain records of surveys for inspection by the Department for 3 years after they are made.

RHA 8.23. Contamination Control.

8.23.1 If the licensee detects evidence that a sealed source has ruptured or radioactive material has caused contamination, the licensee shall initiate immediately the emergency procedures required by RHA 8.20.

8.23.2 If contamination results from the use of radioactive materials in well logging, the licensee shall decontaminate all work areas, equipment and unrestricted areas.

8.23.3 During efforts to recover a sealed source lodged in the well, the licensee shall continuously monitor, with an appropriate radiation detection instrument or a logging tool with a radiation detector, the circulating fluids from the well, if any, to check for contamination resulting from damage to the sealed source.

RHA 8.24. Surveillance of Operations.

8.24.1 A logging supervisor must be physically present at a temporary jobsite whenever radioactive materials are being handled or are not stored and locked in a vehicle or storage place. The logging supervisor may leave the jobsite in order to obtain assistance if a source becomes lodged in a well.

8.24.2 During well logging, except when radiation sources are below ground or in shipping or storage containers, the logging supervisor or other individual designated by the logging supervisor shall maintain direct surveillance of the operation to prevent unauthorized entry into a restricted area, as defined in RHA 1.2 of these regulations.

RHA 8.25. Documents and Records Required at Field Stations.

8.25.1 Each licensee shall maintain the following documents and records at the field station:

8.25.1.1 A copy of Parts III, VI and VIII of these regulations;

8.25.1.2 The license authorizing the use of radioactive materials;

8.25.1.3 Operating and emergency procedures;

8.25.1.4 The record of the radiation survey instrument calibration required by RHA 8.9;

8.25.1.5 The record of the leak test results required by RHA 8.10;

8.25.1.6 Physical inventory records required by RHA 8.11;

8.25.1.7 Utilization records required by RHA 8.12;

8.25.1.8 Records of inspection and maintenance required by RHA 8.14;

8.25.1.9 Training records required by RHA 8.19.4; and

8.25.1.10 Survey records required by RHA 8.22.

8.25.2 Records required by RHA 8.25.1.1 through 8.25.1.3 must be kept until the licensee terminates its well logging operations at the field station. Records required by RHA 8.25.1.4 through 8.25.1.10 must be kept for 3 years.

RHA 8.26. Documents and Records Required at Temporary Jobsites.

Each licensee conducting operations at a temporary jobsite shall maintain the following documents and records at the temporary jobsite until the well logging operation is completed:

8.26.1 Operating and emergency procedures as outlined in RHA 8.20;

8.26.2 Evidence of latest calibration of the radiation survey instruments in use at the site required by RHA 8.9;

8.26.3 Latest survey records required by RHA 8.22.2, 8.22.3 and 8.22.5;

8.26.4 The shipping papers for the transportation of radioactive materials required by the Code of Federal Regulations, Title 10, Part 71.5;

8.26.5 A copy of the U.S. Nuclear Regulatory Commission, an Agreement State, or Licensing State license authorizing the use of radioactive materials when operating under reciprocity pursuant to RHA 2.20 of these regulations.

RHA 8.27. Notification of Incidents and Lost Sources; Abandonment Procedures for Irretrievable Sources.

8.27.1 The licensee shall immediately notify the Department by telephone and subsequently within 30 days by confirmatory letter if it knows or has reason to believe that a sealed source has been ruptured. This notice must designate the well or other location and describe the magnitude and extent of the escape of radioactive material, assess the consequences of the rupture, and explain efforts planned or being taken to mitigate these consequences.

8.27.2 The licensee shall notify the Department of the theft or loss of radioactive materials, radiation overexposures, excessive levels and concentrations of radiation, and certain other accidents as required by RHA 3.17, 3.18 and 3.19 of these regulations.

8.27.3 If a sealed source becomes lodged in a well, and when it becomes apparent that efforts to recover the sealed source will not be successful, the licensee shall:

8.27.3.1 Notify the Department by telephone of the circumstances that resulted in the inability to retrieve the source and request approval to implement abandonment procedures; or that the licensee implemented abandonment before receiving Departmental approval because the licensee believed there was an immediate threat to public health and safety; and

8.27.3.2 Advise the well owner or operator, as appropriate, of the abandonment procedures under RHA 8.5.1 or 8.5.3.

8.27.3.3 Either ensure that abandonment procedures are implemented within 30 days after the sealed source has been classified as irretrievable or request an extension of time if unable to complete the abandonment procedures.

8.27.4 The licensee shall, within 30 days after the sealed source has been classified as irretrievable, make a report in writing to the Department. The licensee shall send a copy of the report to each appropriate state or federal agency that issued permits or otherwise approved of the drilling operation. The report must contain the following information:

8.27.4.1 Date of occurrence;

8.27.4.2 A description of the irretrievable well logging source involved, including radionuclide, quantity, chemical, and physical form;

8.27.4.3 Surface location and identification of the well;

8.27.4.4 Results of efforts to immobilize and seal the source in place;

8.27.4.5 A brief description of the attempted recovery effort;

8.27.4.6 Depth of the source;

8.27.4.7 Depth of the top of the cement plug;

8.27.4.8 Depth of the well;

8.27.4.9 The immediate threat to public health and safety justification for implementing abandonment if prior Departmental approval was not obtained in accordance with RHA 8.27.3.1 of this section.

8.27.4.10 Any other information (e.g. warning statement) contained on the permanent identification plaque; and

8.27.4.11 State and Federal agencies receiving copy of this report.

PART IX
LICENSING OF NATURALLY OCCURRING RADIOACTIVE MATERIAL (NORM)

RHA 9.1. Purpose and Scope.

This part establishes radiation protection standards for the possession, use, transfer, transport, and/or storage of naturally occurring radioactive material (NORM) or the recycling of NORM contaminated materials not subject to regulation under the Atomic Energy Act of 1954, as amended. The requirements of this part are in addition to and not in substitution for other applicable requirements of Parts I, II, III, VI, and VII of these regulations. Except as otherwise specifically provided, these regulations apply to all persons who engage in the extraction, mining, beneficiating, processing, use, transfer, transport, and/or storage of NORM or the recycling of NORM contaminated materials in a manner that alters the chemical properties or physical state of natural sources of radiation or the potential exposure pathways to humans or environment.

RHA 9.2. Definitions.

As used in these regulations:

9.2.1 "Beneficiating" means the processing of materials for the purpose of altering chemical or physical properties to improve the quality, purity, or assay grade.

9.2.2 "Naturally occurring radioactive material (NORM)" means any nuclide that is radioactive in its natural physical state (i.e., not man made), but does not include source, byproduct, or special nuclear material. Examples include, but are not limited to, pipe scale containing radium; pipes and other equipment plated with radon daughters; phosphate overburden or waste; phosphogypsum; phosphate slag; waste, overburden, and residue associated with the extraction of metals or rare earths; water treatment filters containing radium; and zircon sands.

9.2.3 "Product" means something produced, made, manufactured, refined, or beneficiated.

9.2.4 "Recycling" means a process by which materials that have served their intended purpose are collected, separated, or processed and returned to use in the form of raw materials in the production of new products. Recycling shall not include the use of a material that constitutes disposal.

9.2.5 "Technologically enhanced natural radiation" (TENR) means radiation from naturally occurring isotopes to which exposure would not occur by (or would be increased by) some technological activity not expressly designed to produce radiation.

RHA 9.3. Exemptions.

9.3.1 Persons who receive, possess, use, process, transfer, transport, store, and/or commercially distribute NORM are exempt from the requirements of the provisions of this part if the materials contain, or are contaminated at, concentrations of:

9.3.1.1 Thirty (30) picocuries per gram or less of TENR due to radium 226 or radium 228 in soil, averaged over any 100 square meters and averaged over the first 15 centimeters of soil below the surface, provided the radon emanation rate is less than 20 picocuries per square meter per second.

9.3.1.2 Thirty (30) picocuries per gram or less of TENR due to radium 226 or radium 228 in media other than soil, provided the radon emanation rate is less than 20 picocuries per square meter per second; or

9.3.1.3 Five (5) picocuries per gram or less of TENR due to radium 226 or radium 228 in soil, averaged over any 100 square meters and averaged over the first 15 centimeters of soil below the surface, in which the radon emanation rate is equal to or greater than 20 picocuries per square meter per second,

9.3.1.4 Five (5) picocuries per gram or less of TENR due to radium 226 or radium 228 in media other than soil, in which the radon emanation rate is equal to or greater than 20 picocuries per square meter per second; or

9.3.1.5 One hundred fifty (150) picocuries or less per gram of any other NORM radionuclide in soil, averaged over any 100 square meters and averaged over the first 15 centimeters of soil below the surface,

9.3.1.6 One hundred fifty (150) picocuries or less per gram of any other NORM radionuclide in media other than soil;

9.3.1.7 Materials in the recycling process contaminated with scale or residue not otherwise exempted, and other equipment containing NORM are exempt from the requirements of these rules if the maximum radiation exposure level does not exceed 50 microroentgens per hour including the background radiation level at any accessible point; or

9.3.2 Persons who possess facilities, equipment or land contaminated with NORM in quantities less than the following levels are exempt from the requirements of the provisions of this part:

9.3.2.1 Surface contamination which averages 5000 disintegrations per minute per 100 centimeters squared over the entire measured surface;

9.3.2.2 Not to exceed a maximum reading of 15000 disintegrations per minute per 100 centimeters squared to an area of not more than 100 centimeters squared, notwithstanding the maximum aforementioned limit. The maximum radiation exposure level shall not exceed the limit specified in RHA 9.3.1.7; or

9.3.2.3 Removable contamination not to exceed 1000 disintegrations per minute per 100 centimeters squared.

RHA 9.4. Radiation Survey Instruments.

9.4.1 Radiation survey instruments used to determine exemptions pursuant to RHA 9.3 and radiation survey instruments used to make surveys for purposes of compliance with sections RHA 9.5 and 9.7 of these regulations, shall be able to measure from 10 microroentgen per hour through at least 500 microroentgens per hour.

9.4.2 Radiation survey instruments used to make surveys required by this part shall be appropriate, operable and calibrated according to the provisions specified by RHA 3.16 of these regulations.

RHA 9.5. General License.

9.5.1 A general license is hereby issued to mine, receive, possess, own, use, process, transport, store, and transfer for disposal NORM or to recycle NORM contaminated materials not exempted in RHA 9.3 without regard to quantity. This general license does not authorize the manufacture or commercial distribution of products containing NORM in concentrations greater than those specified in RHA 9.3 or of NORM in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being. The melting of scrap metal is authorized by the general license if the dilution of the NORM in the end products or melt byproducts is sufficient to reduce any expected average concentration of NORM to levels not to exceed the concentration specified in RHA 9.3.

9.5.2 Facilities contaminated with NORM in excess of the levels specified in RHA 9.3 and equipment not otherwise exempted under the provisions of 9.3.1.7 shall not be released for unrestricted use. The decontamination of equipment, facilities, and land shall be performed only by persons specifically licensed by the Department or another Licensing Agency to conduct such work.

9.5.3 The transfer of NORM not exempt from these rules from one general licensee to another licensee is authorized by the Department if:

9.5.3.1 The equipment and facilities contaminated with NORM are to be used by the recipient for the same purpose or at the same site;

9.5.3.2 The materials being transferred are unrefined ores or unprocessed materials for processing or refinement; or

9.5.3.3 The materials being transferred are in the recycling process.

9.5.4 NORM materials shall be stored so that the external radiation dose in any one year, excluding radon, to the maximally exposed individual will not exceed the doses specified in Column II, Appendix A, and the average radon concentration in air does not exceed 0.4 picocuries per liter.

RHA 9.6. Transfer of Waste for Disposal.

9.6.1 Each person subject to the general license in RHA 9.5 shall manage and dispose of wastes containing NORM:

9.6.1.1 By transfer of the wastes for disposal to a facility specifically licensed to receive waste containing NORM;

9.6.1.2 By transfer of wastes for disposal to a land disposal facility licensed by the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State; or

9.6.1.3 In accordance with RHA 3.27 of these regulations or alternate methods authorized by the appropriate regulatory agency.

9.6.2 Records of disposal, including waste manifests, shall be maintained according to the provisions of RHA 3.41 of these regulations.

9.6.3 Transfers of waste containing NORM for disposal shall be made only to a person specifically authorized to receive such waste.

RHA 9.7. Specific License.

9.7.1 Unless otherwise exempted under the provisions of RHA 9.3 or licensed under the provisions RHA 9.5 of these regulations, the manufacture and commercial distribution of any material or product containing NORM shall be specifically licensed pursuant to the applicable requirements of Part II of these regulations or pursuant to equivalent rules of another Licensing State.

9.7.2 Persons conducting operations for the purpose of removing NORM contamination from the following shall be specifically licensed pursuant to the requirements of this part:

9.7.2.1 Facilities owned, possessed, or controlled by other persons and contaminated with NORM in excess of the levels set forth in RHA 9.3; and/or

9.7.2.2 Equipment or land owned, possessed, or controlled by other persons and not otherwise exempted under the provisions of RHA 9.3.

9.7.3 Issuance of Specific Licenses.

9.7.3.1 When an application meets the requirements of these regulations, the Department will issue a specific license authorizing the proposed activity in such form and containing appropriate conditions and limitations.

9.7.3.2 The Department may incorporate in a license at the time of issuance, or thereafter by amendment, any additional requirements and conditions with respect to the licensee's receipt, possession, use, and transfer of NORM subject to this part as it considers appropriate or necessary in order to:

9.7.3.2.1 Minimize danger to public health and safety, property, or the environment;

9.7.3.2.2 Require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be appropriate or necessary; and

9.7.3.2.3 Prevent loss or theft of material subject to this part.

9.7.3.3 An application for a specific license to process ground water for the purpose of bottling or for water systems serving more than fifty (50) taps under these provisions will be approved if:

9.7.3.3.1 The applicant will perform environmental monitoring of the closest public receptor to ensure that exposures do not exceed 0.2 Working Level Month (WLM) per year.

9.7.3.3.2 If Gross alpha of raw water exceeds 5 picocuries per liter, a one gallon sample will be provided to the Department for Ra-226 analysis.

9.7.3.4 An applicant for a specific license shall demonstrate by direct measurement or by calculation that the material or product containing NORM is handled in a manner so that:

9.7.3.4.1 During routine use and disposal, it is unlikely that the external radiation dose in any one year, or the dose equivalent resulting from the intake of radioactive material, excluding radon and its daughters, in any one year, to a suitable sample of the group of individuals expected to be the most highly exposed to radiation or radioactive material from the material or product, will exceed the doses specified in Column I of Appendix A.

9.7.3.4.2 During routine handling and storage of the quantities of the material or product likely to accumulate in one location during marketing, commercial distribution, installation, and servicing of the material or product, it is unlikely that the external radiation dose in any one year, or the dose equivalent resulting from the intake of radioactive material, excluding radon, in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from the material or product, will exceed the doses specified in Column II of Appendix A.

9.7.3.4.3 During routine use, disposal, handling, and storage, it is unlikely that the radon released from the material or product will result in an increase in the average radon concentration in air of more than 0.4 picocurie per liter.

9.7.3.4.4 It is unlikely that there will be a significant reduction in the effectiveness of the containment, shielding, or other safety features of the material or product from wear and abuse likely to occur in normal handling and use of the material or product during its useful life.

9.7.4 General Terms and Conditions.

9.7.4.1 Each license issued pursuant to this part shall be subject to all the applicable provisions of Regulation 61-63, Title A, now or hereafter in effect, and to all rules and orders of the Department.

9.7.4.2 No license issued or granted under this part and no right to possess or utilize NORM granted by any license issued pursuant to this part shall be transferred to any person unless the Department, after securing full information, finds that the transfer is in accordance with the provisions of these regulations, and gives its consent in writing.

9.7.4.3 Each person specifically licensed by the Department pursuant to this part is subject to the provisions of RHA 1.15 regarding financial assurances and record keeping for decommissioning.

9.7.4.4 Each person licensed by the Department pursuant to this part is subject to the provisions of RHA 9.4 and RHA 9.6.

9.7.5 Expiration and Termination of Specific Licenses. Except as determined by the Department, each licensee shall be subject to the provisions of RHA 2.11 of these regulations regarding expiration and termination of specific licenses.

Appendix A

Table of Allowable Organ Doses
Total Effective Dose Equivalents (TEDE)

Part of Body	Column I * TEDE (REM)	Column II * TEDE (REM)
Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye	0.005	0.5
Hands and Forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter	0.075	7.5
Other organs	0.015	1.5

* Dose limit is the dose above background from the material or product.

PART X
LICENSING REQUIREMENTS FOR INTERIM STORAGE OF RADIOACTIVE WASTE

RHA 10.1. Purpose and Scope.

10.1.1 The regulations in this part establishes the procedures, criteria, standards, terms, and conditions upon which the Department will require a license or an amendment to an existing license for the establishment and operation of facilities for the interim storage of low-level radioactive waste generated within the state which were or will be routinely transferred for permanent emplacement in a licensed low-level radioactive waste disposal facility. A license will not be issued for storage of waste under this part unless all efforts have been exhausted in determining all other waste management options. The requirements of this part are in addition to, and not in substitution for, other applicable requirements of these regulations or other regulations.

10.1.2 This part establishes technical requirements, procedural requirements, institutional requirements and performance objectives applicable to interim storage of radioactive waste.

10.1.3 Radioactive Material held for decay in storage under 4.8.15 of this regulation is exempted from the requirements in this part.

10.1.4 The regulations in this part do not apply to licensees of the Department or the U.S. Nuclear Regulatory Commission who will store less than seventy-five (75) cubic feet of low-level radioactive waste with a total activity of ten (10) curies or less and where radiation levels on any single package do not exceed five (5) millirem (.05 mSv) per hour at thirty (30) centimeters. Unless exempted under 10.1.3, any facility which stores waste which will readily decompose and produce gases or free liquids or will degrade the integrity of the storage container is subject to the requirements in this part. The Department may on a case-by-case basis grant exemptions or exceptions from the requirements of this part as it determines are authorized by law and will not result in undue hazard to public health and safety or the environment. These licensees will be subject to existing regulations for the possession and control of these radioactive materials under the terms and conditions of their specific license. Any facility constructed specifically for the storage of low-level radioactive waste must comply with the requirements in this part unless exempted by the Department.

10.1.5 Facilities licensed by the U.S. Nuclear Regulatory Commission under the authority in 10 CFR 150.15 are exempt from this part unless otherwise authorized by the U.S. Nuclear Regulatory Commission or by state or federal statute.

RHA 10.2. Definitions.

As used in this part:

10.2.1 "Decontamination and Decommission Plan" means a detailed plan which describes the actions to remove all radioactive material from a facility, survey the facility to confirm the absence of radioactive material, and release the facility for unrestricted use.

10.2.2 "Disposal facility" means a facility licensed by the U.S. Nuclear Regulatory Commission or an agreement state for disposal of low-level radioactive waste.

10.2.3 "Interim storage" means storage of waste temporarily when other waste management options are not available.

10.2.4 "Mixed waste" means waste that contains a hazardous waste component regulated under subtitle C of the Resource Conservation and Recovery Act (RCRA) and a radioactive waste component consisting of source, special nuclear or byproduct material regulated by the Atomic Energy Act (AEA).

10.2.5 "Repackaging" means placement of an existing package and its contents into a new package for the purpose of meeting disposal requirements or to prevent the release of radioactive material from the package during storage. Repackaging does not include the removal of waste from a package.

10.2.6 "Storage facility" means any building or structure or part of a building or structure which meets the requirements of this part and is used for storage of low level radioactive waste.

RHA 10.3. License Required.

10.3.1 No person may receive, possess, and store waste at a waste storage facility unless authorized by a license issued by the Department pursuant to this part, and Part II of these regulations. A certification from the generators must be submitted indicating that a program has been implemented to reduce the volume and activity of their waste using the best available technology to the degree determined to be economically practicable.

10.3.2 Each person shall file an application with the Department pursuant to 2.5 of these regulations and obtain a license as provided in this part before placing waste in a storage facility, unless otherwise authorized by the Department. Failure to comply with the requirements in this part may be grounds for denial of a license.

RHA 10.4. Content of Application.

In addition to the requirements set forth in 2.6 of these regulations, an application to receive, possess, and store wastes shall consist of general information, specific technical information, and financial information as set forth in 10.5 through 10.9.

RHA 10.5. General Information.

The general information shall include each of the following:

10.5.1 Identity of the applicant including:

10.5.1.1 The full name, address, telephone number, and description of the business or occupation of the applicant;

10.5.1.2 If the applicant is a partnership, the name and address of each partner and the principal location where the partnership does business;

10.5.1.3 If the applicant is a corporation or an unincorporated association, (1) state where it is incorporated or organized and the principal location where it does business and (2) the names and addresses of its directors and principal officers; and

10.5.1.4 If the applicant is acting as an agent or representative of another person in filing the application, all information required under 10.5.1 must be supplied with respect to the other person.

10.5.2 Qualifications of the applicant:

10.5.2.1 The organizational structure of the applicant, both off site and on site, including a description of lines of authority and assignments of responsibilities, whether in the form of administrative directives, contract provisions, or otherwise;

10.5.2.2 The technical qualifications, including training and experience, of the applicant and members of the applicant's staff to engage in the proposed activities. Minimum training and experience requirements for personnel filling key positions described in 10.5.2.1 must be provided;

10.5.2.3 A description of the applicant's personnel training program; and

10.5.2.4 The plan to maintain an adequate complement of trained personnel to carry out waste receipt, handling, and storage operations in a safe manner.

10.5.3 A description of:

10.5.3.1 The location of the proposed storage facility;

10.5.3.2 The general character of the proposed activities;

10.5.3.3 The types, physical forms, non-radiological properties, if any (hazardous, pathogenic, corrosive, flammable, explosive) of the waste, quantities of waste to be received, possessed, and stored, and waste container description;

10.5.3.4 The waste repackaging capability in consideration of possible degradation of waste containers during storage and changing disposal requirements;

10.5.3.5 Specification of any increases in possession limits; and

10.5.3.6 The proposed facilities and equipment.

10.5.4 Proposed schedules for construction, receipt of waste, and first placement of waste at the proposed storage facility.

10.5.5 Assurance that the waste packages will be transportable at the end of the storage period.

10.5.6 Proposed plans for ultimate disposal of the stored waste; schedule to dispose of the inventory; estimated date to begin shipment of stored waste for disposal; and provisions for transportation and disposal at a licensed disposal facility.

RHA 10.6. Specific Technical Information.

The specific technical information shall include the following information needed for demonstration that the performance objectives and the applicable technical requirements of this part will be met:

10.6.1 A description of the characteristics of the selected site in relation to the construction of a waste storage facility. The description shall include technical bases and supporting calculations to justify the selection of property boundary and to determine that the operation of the facility will have a minimum impact of the surrounding areas and estimates of radiation doses which could occur at the property boundary in the event of accident conditions.

10.6.2 A description of the design features of the storage facility in relation to containing and maintaining the waste; measures to control access and security; applicability of the wastes containers for storage and disposal; waste container repackaging capability; occupational exposures; and storage site monitoring.

10.6.3 A description of the principal design criteria and their relationship to the performance objectives.

10.6.4 A description of the design basis natural events or phenomena and their relationship to the principal design criteria.

10.6.5 A description of codes and standards which the applicant has applied to the design and which will apply to construction of the storage facility.

10.6.6 A description of the building construction which shall include the pad, roof, weather protection, insulation and humidity control.

10.6.7 A description of the operation of the storage facility which shall include as a minimum the methods of waste storage; program and procedures for waste container segregation; consideration of the effect of radiation field from neighboring packages to container degradation; hazards posed to container integrity; design features of the ventilation systems, fire protection and suppression systems; accessibility for routine and periodic inspection and physical inventory; emergency equipment access; the ability to monitor and detect container failure; collection system capability in case of leakage from damaged containers; and program and equipment including remote handling equipment for handling, repairing or repackaging leaking or damaged containers. The description shall also include a description of the methods to be employed in the handling and storage of wastes containing non radiological substances that might affect meeting the performance objectives of this part.

10.6.8 A description of the decontamination and decommissioning (D & D) plan of the storage facility.

10.6.9 A description of the kind, amount, classification and specification of the radioactive waste proposed to be received, possessed, and stored at the storage facility. The waste classification and packaging must meet the requirements set forth in Part III of these regulations.

10.6.10 A description of the quality control program for the determination of storage site characteristics and for quality control during the design, construction, operation, and D & D of the storage facility and the receipt, handling, and storage of waste. Audits and managerial controls must be included.

10.6.11 A description of the radiation safety program for control and monitoring of radioactive effluents to ensure compliance with the performance objective in 10.14 and occupational radiation exposure to ensure compliance with the requirements of Part III of these regulations and to control contamination of personnel, vehicles, equipment, and the storage facility. A description of the projected exposure rates, needs and types of shielding, and changes in personnel monitoring which will be required as a result of waste storage. Both routine operations and accidents shall be

addressed. The program description must include procedures, instrumentation, facilities, and equipment.

10.6.12 A description of an emergency plan for handling unplanned events must be available to institute protective actions.

10.6.12.1 The plan must incorporate waste management provisions that are sufficient to comply with the requirements of this regulation.

10.6.12.2 The plan must describe arrangements agreed to by local police department, fire department, hospitals, contractors and State and local emergency response teams to coordinate emergency services.

10.6.12.3 The plan must include a list of all emergency equipment at the facility. The list must be up to date and include the location and physical description of each item on the list.

10.6.13 A description of the environmental monitoring program to provide data to evaluate potential health and environmental impacts and the plan for taking corrective measures.

10.6.14 A description of the administrative procedures that the applicant will apply to control activities at and any wastes generated from the operation of the storage facility.

RHA 10.7. Technical Analysis.

The specific technical information shall include the following analyses needed to demonstrate that the performance objective of this part will be met:

10.7.1 An analysis demonstrating that releases of radioactivity to an unrestricted area will not exceed the limits specified in Part III of these regulations.

10.7.2 Analyses of the protection of individuals during operations shall include assessments of expected exposures due to routine operations and likely accidents during handling, and storage of waste. The analyses shall provide reasonable assurance that exposure will be controlled to meet the requirements of Part III of these regulations.

RHA 10.8. Financial Information.

The financial information shall be sufficient to demonstrate that the financial qualifications of the applicant are adequate to carry out the activities for which the license is sought and to meet other financial assurance requirements of this part.

RHA 10.9. Requirements for Issuance of a License.

A license for the receipt, possession, and storage of waste containing or contaminated with radioactive material will be issued by the Department upon finding that:

10.9.1 The issuance of the license will not constitute an unreasonable risk to the health and safety of the public;

10.9.2 The applicant is qualified by reason of training and experience to carry out operations at a storage facility requested in a manner that protects health and minimizes danger to life or property;

10.9.3 The applicant's proposed location and design of the storage facility, facility operations, including equipment, facilities, and procedures, and D & D plans are adequate to protect the public health and safety in that they provide reasonable assurance that the general population will be protected from releases of radioactivity as specified in the performance objective in 10.14;

10.9.4 The applicant's proposed storage facility operations, including equipment, facilities, and procedures, are adequate to protect the public health and safety in that they will provide reasonable assurance that the standards for radiation protection set out in Part III of these regulations will be met;

10.9.5 The applicant's demonstration provides reasonable assurance that the applicable technical requirements of this part will be met;

10.9.6 The financial or surety arrangements meet the requirements in 10.15.

RHA 10.10. Conditions of Licenses.

10.10.1 A license issued under this part, or any right thereunder, may not be transferred, assigned, or in any manner disposed of either voluntarily or involuntarily, directly or indirectly, through transfer of control of the license to any person, unless the Department finds, after securing full information, that the transfer is in accordance with the provisions of the Act and gives its consent in writing in the form of a license amendment.

10.10.2 The licensee shall submit written statements under oath upon request of the Department, at any time before termination of the license, to enable the Department to determine whether the license should be modified, suspended, or revoked.

10.10.3 The license will be terminated only on disposition of stored waste and the full implementation of the D & D plan as approved and determined by the Department.

10.10.4 The licensee shall be subject to the provisions of the Act now or hereafter in effect, and to all rules, regulations, and orders of the Department. The terms and conditions of the license are subject to amendment, revision, or modification, by reason of amendments to, or by reason of rules, regulations, and orders issued in accordance with the terms of the Act.

10.10.5 Each person licensed by the Department pursuant to the regulations in this part shall confine possession to the locations and purposes authorized in the license.

10.10.6 The licensee shall not store waste until the Department has inspected the storage facility and has found it to be in conformance with the description, design, and construction described in the application for a license.

10.10.7 The Department may incorporate in any license at the time of issuance, or thereafter, by appropriate rule, regulation or order, additional requirements and conditions with respect to the licensee's receipt, possession, and storage of waste as it deems appropriate or necessary in order to:

10.10.7.1 Protect health or to minimize danger to life or property;

10.10.7.2 Require reports and the keeping of records, and to provide for inspections of activities under the license that may be necessary or appropriate to effectuate the purposes of the Act and regulations thereunder.

RHA 10.11. Application for Renewal or Termination.

10.11.1 An application for renewal or an application for termination under 10.12 must be filed at least 90 days prior to license expiration.

10.11.2 Applications for renewal of a license must be filed in accordance with 10.4 through 10.8. Applications for termination must be filed in accordance with 10.12. Information contained in previous applications, statements, or reports filed with the Department under the license may be incorporated by reference if the references are clear and specific.

10.11.3 In any case in which a licensee has filed an application in proper form for renewal of a license, the license does not expire until the Department has taken final action on the application for renewal.

10.11.4 In determining whether a license will be renewed, the Department will apply the criteria set forth in 10.9.

RHA 10.12. Contents of Application for Termination of the License.

10.12.1 Prior to termination of the license, or as otherwise directed by the Department, the applicant shall submit an application for termination. This application shall include evidence that all stored waste has been transferred to a disposal facility or storage facility licensed to accept the waste and specific details of the D & D plan included as part of the license application submitted under 10.6.7 that includes:

10.12.1.1 Decontamination and/or dismantlement of facilities; and

10.12.1.2 Any significant new information regarding the environmental impact of the decommissioning activities.

10.12.2 A license shall be terminated only when the Department finds:

10.12.2.1 The requirements in 10.12.1 have been met; and

10.12.2.2 That any additional requirements resulting from new information developed during the D & D of the facility have been met.

10.12.3 Release of the facility for unrestricted use after D & D activities shall be determined by the Department on a case to case basis.

RHA 10.13. Protection of Individuals during Operations.

Operations at the waste storage facility shall be conducted in compliance with the standards for radiation protection set out in Part III of these regulations. Every reasonable effort should be made to maintain radiation exposures as low as is reasonably achievable.

RHA 10.14. Environmental Monitoring.

10.14.1 At the time a license application is submitted, the applicant shall have conducted a pre-operational monitoring program to provide basic environmental data on the storage site characteristics.

10.14.2 During the storage facility site construction and operation, the licensee shall maintain an environmental monitoring program. Measurements and observations must be made and recorded to provide data to evaluate the potential health and environmental impacts during both the construction and the operation of the facility. The monitoring system must be capable of providing early warning of releases of radioactive material from the storage site before they leave the site boundary.

10.14.3 The licensee shall have plans for taking corrective measures if the environmental monitoring program detects contamination which exceeds those allowed under Part III of these regulations.

RHA 10.15. Applicant Qualifications and Assurances.

10.15.1 Each applicant shall provide the necessary funds or has reasonable assurance in providing the necessary funds, or by a combination of the two, to:

10.15.1.1 Cover the estimated costs of conducting all licensed activities over the planned operating life of the storage facility, including costs of construction;

10.15.1.2 Cover the cost of contingencies arising from the operation of the storage facility;

10.15.1.3 Cover the cost of handling, transport and ultimate disposal of the stored waste;

10.15.1.4 Cover the cost of handling, transport and disposal of waste stored for other generators in the event of inability of the other generators to dispose of their wastes. Payment of fees for using the storage facility must be made available to a fund to defray the expenses incurred in disposing of their wastes; and

10.15.1.5 Cover the cost of D & D of the storage facility. An arrangement for payment into a D & D trust fund must be established with the Department.

10.15.2 The Department will accept financial sureties that have been consolidated with earmarked financial or surety arrangements established to meet requirements of federal or other state agencies (and/or local government bodies).

10.15.3 The licensees's financial or surety arrangement shall be submitted annually for review by the Department.

10.15.4 The amount of the licensee's financial or surety arrangement shall change in accordance with changes in predicted costs. The financial or surety arrangement shall be sufficient at all times to cover the costs specified in 10.15.1.

10.15.5 Financial or surety arrangements generally acceptable to the Department include surety bonds, cash deposits, certificates of deposit, deposits of government securities, escrow accounts, irrevocable letters or lines of credit, trust funds, and combination of the above or such other types of arrangements as may be approved by the Department. Self insurance, or any arrangement which essentially constitutes self insurance, will not satisfy the surety requirement for private sector applicants.

10.15.6 The licensee's financial or surety arrangement shall remain in effect until the Department finds that compliance of requirements of license termination has been meet.

RHA 10.16. Institutional Requirements.

Land ownership. Storage of waste received from other persons shall be permitted only on land owned in fee by the federal or a state government.

RHA 10.17. Maintenance of Records and Reports.

10.17.1 Each licensee shall maintain any records and make any reports in connection with the licensed activities as may be required by the conditions of the license or by the rules, regulations, and orders of the Department.

10.17.2 Records which are required by these regulations or by license conditions shall be maintained for a period specified by appropriate regulations or by license conditions.

10.17.3 Records which shall be maintained pursuant to this part may be the original or a reproduced copy or microfilm if this reproduced copy or microfilm is capable of producing a copy that is clear and legible at the end of the required retention period. Other record maintenance systems may be used if approved by the Department.

10.17.4 Records of the location and the quantity of wastes contained in the storage facility and of the actual physical inventory must be maintained by the licensee.

10.17.5 Following receipt and acceptance of a shipment of waste, the licensee shall record the date of storage of the waste, the location in the storage facility, the condition of the waste packages as received, any discrepancies between materials listed on the manifest and those received, and any evidence of leaking or damaged packages or radiation or contamination levels in excess of limits specified in U.S. Department of Transportation and Department regulations. Any leaking or damaged packages must be repackaged prior to placement in the storage facility. The licensee shall briefly describe any repackaging operations of any of the waste packages included in the shipment, plus any other information required by the Department as a license condition.

10.17.6 Each licensee authorized to store waste received from other persons shall file a copy of its financial report or a certified financial statement annually with the Department in order to update the information base for determining financial qualifications.

10.17.7 Each licensee authorized to store waste, pursuant to this part, shall submit annual reports to the Department. Reports shall be submitted by the end of the first calendar quarter of each year for the preceding year.

10.17.7.1 The reports shall include:

10.17.7.1.1 Any releases of contaminants to unrestricted areas in liquid and in airborne effluents during the preceding year,

10.17.7.1.2 The results of the environmental monitoring program,

10.17.7.1.3 A summary of licensee's storage unit survey and maintenance activities.

10.17.7.1.4 A summary, by waste class, of activities and quantities of radionuclides stored,

10.17.7.1.5 Any instances in which observed site characteristics were significantly different from those described in the application for a license,

10.17.7.1.6 The results of physical inventories, and

10.17.7.1.7 Any other information the Department may require.

10.17.7.2 If the quantities of waste stored during the reporting period, monitoring results, or maintenance performed are significantly different from those predicted, the report must cover this specifically and must identify actions which will be taken to reduce both the volume and activity of additional waste placed in the facility.

RHA 10.18. Tests on Storage Facilities.

Each licensee shall perform, or permit the Department to perform, any tests the Department deems appropriate or necessary for the administration of the regulations in this part, including, but not limited to, tests of:

10.18.1 Wastes;

10.18.2 Facilities used for the receipt, storage, treatment, or handling of wastes;

10.18.3 Radiation detection and monitoring instruments; or

10.18.4 Other equipment and devices used in connection with the receipt, possession, handling, or storage.

RHA 10.19. Department Inspections of Storage Facilities.

10.19.1 Each licensee shall afford to the Department at all reasonable times opportunity to inspect stored waste, and the premises, equipment, operations, and facilities in which wastes are received, possessed, handled, or stored.

10.19.2 Each licensee shall make available to the Department for inspection, upon reasonable notice, records kept by it pursuant to these regulations. Authorized representatives of the Department may copy and take away copies of, for the Department's use, any record required to be kept pursuant to these regulations.

PART XI
Licensing and Radiation Safety Requirements for Irradiators

RHA 11.1. Purpose and Scope.

This part contains requirements for the issuance of a license authorizing the use of sealed sources containing radioactive materials in irradiators used to irradiate objects or materials using gamma radiation. This part also contains radiation safety requirements for operating irradiators. The requirements of this part are in addition to other requirements of these regulations. In particular, the provisions of Parts I, II, III and VI of these regulations apply to applications and licenses subject to this part. Nothing in this part relieves the licensee from complying with other applicable Federal, State and local regulations governing the siting, zoning, land use, and building code requirements for industrial facilities.

The regulations in this part apply to panoramic irradiators that have either dry or wet storage of the radioactive sealed sources and to underwater irradiators in which both the source and the product being irradiated are under water. Irradiators whose dose rates exceed 500 rads (5 grays) per hour at 1 meter from the radioactive sealed sources in air or in water, as applicable for the irradiator type, are covered by this part.

The regulations in this part do not apply to self-contained dry-source-storage irradiators (those in which both the source and the area subject to irradiation are contained within a device and are not accessible by personnel), medical radiology or teletherapy, radiography (the irradiation of materials for nondestructive testing purposes), gauging, or open-field (agricultural) irradiations.

RHA 11.2. Definitions.

11.2.1 "Annually" means either (1) at intervals not to exceed 1 year or (2) once per year, at about the same time each year (plus or minus 1 month).

11.2.2 "Doubly encapsulated sealed source" means a sealed source in which the radioactive material is sealed within a capsule and that capsule is sealed within another capsule.

11.2.3 "Irradiator" means a facility that uses radioactive sealed sources for the irradiation of objects or materials and in which radiation dose rates exceeding 500 rads (5 grays) per hour exist at 1 meter from the sealed radioactive sources in air or water, as applicable for the irradiator type, but does not include irradiators in which both the sealed source and the area subject to irradiation are contained within a device and are not accessible to personnel.

11.2.4 "Irradiator operator" means an individual who has successfully completed the training and testing described in RHA 11.18 and is authorized by the terms of the license to operate the irradiator without a supervisor present.

11.2.5 "Panoramic dry-source-storage irradiator" means an irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored in shields made of solid materials. The term includes beam-type dry-source-storage irradiators in which only a narrow beam of radiation is produced for performing irradiations.

11.2.6 "Panoramic irradiator" means an irradiator in which the irradiations are done in air in areas potentially accessible to personnel. The term includes beam-type irradiators.

11.2.7 "Panoramic wet-source-storage irradiator" means an irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored under water in a storage pool.

11.2.8 "Pool irradiator" means any irradiator at which the sources are stored or used in a pool of water including panoramic wet-source-storage irradiator and underwater irradiators.

11.2.9 "Product conveyor system" means a system for moving the product to be irradiated to, from and within the area where irradiation takes place.

11.2.10 "Radiation room" means a shielded room in which irradiations take place. Underwater irradiators do not have radiation rooms.

11.2.11 "Radiation safety officer" means an individual with responsibility for the overall radiation safety program at the facility.

11.2.12 "Sealed source" means any byproduct material that is used as a source of radiation and is encased in a capsule designed to prevent leakage or escape of the byproduct material.

11.2.13 "Seismic area" means any area where the probability of a horizontal acceleration in rock of more than 0.3 times the acceleration of gravity in 250 years is greater than 10 percent, as designated by the U.S. Geological Survey.

11.2.14 "Underwater irradiator" means an irradiator in which the sources always remain shielded under water and humans do not have access to the sealed sources or the space subject to irradiation without entering the pool.

RHA 11.3. Specific Licenses for Irradiators.

11.3.1 The Department will approve an application for a specific license for the use of licensed material in an irradiator if the applicant meets the requirements contained in this section.

11.3.2 The applicant shall satisfy the general requirements specified in RHA 2.6 and the requirements contained in this Part.

11.3.3 The application must describe the training provided to irradiator operators including:

11.3.3.1 Classroom training;

11.3.3.2 On-the-job or simulator training;

11.3.3.3 Safety reviews;

11.3.3.4 Means employed by the applicant to test each operator's understanding of the Department's regulations and licensing requirements and the irradiator operating and emergency procedures; and

11.3.3.5 Minimum training and experience of personnel who may provide training.

11.3.4 The application must include an outline of the written operating and emergency procedures listed in RHA 11.19 that describes the radiation safety aspects of the procedures.

11.3.5 The application must describe the organizational structure for managing the irradiator, specifically the radiation safety responsibilities and authorities of the radiation safety officer and those management personnel who have important radiation safety responsibilities or authorities. In particular, the application must specify who, within the management structure, has the authority to stop unsafe operations. The application must also describe the training and experience required for the position of radiation safety officer.

11.3.6 The application must include a description of the access control systems required by RHA 11.8, the radiation monitors required by RHA 11.11, the method of detecting leaking sources required by RHA 11.22 including the sensitivity of the method, and a diagram of the facility that shows the locations of all required interlocks and radiation monitors.

11.3.7 If the applicant intends to perform leak testing of dry-source-storage sealed sources, the applicant shall establish procedures for leak testing and submit a description of these procedures to the Department. The description must include the—

11.3.7.1 Instruments to be used;

11.3.7.2 Methods of performing the analysis; and

11.3.7.3 Pertinent experience of the individual who analyzes the samples.

11.3.8 If licensee personnel are to load or unload sources, the applicant shall describe the qualifications and training of the personnel and the procedures to be used. If the applicant intends to contract for source loading or unloading at its facility, the loading or unloading must be done by an organization specifically authorized by the Nuclear Regulatory Commission or an Agreement State to load or unload irradiator sources.

11.3.9 The applicant shall describe the inspection and maintenance checks, including the frequency of the checks required by RHA 11.23.

HISTORY: Amended by State Register Volume 38, Issue No. 10, Doc. No. 4462, eff October 24, 2014.

RHA 11.5. Applications for Exemptions.

11.5.1 The Department may, upon application of any interested person or upon its own initiative, grant any exemptions from the requirements in this part that it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

11.5.2 Any application for a license or for amendment of a license authorizing use of a teletherapy-type unit for irradiation of materials or objects may include proposed alternatives for the requirements of this part. The Department will approve the proposed alternatives if the applicant provides adequate rationale for the proposed alternatives and demonstrates that they are likely to provide an adequate level of safety for workers and the public.

RHA 11.6. Request for Written Statements.

11.6.1 After the filing of the original application, the Department may request further information necessary to enable the Department to determine whether the application should be granted or denied.

11.6.2 Each license is issued with the condition that the licensee will, at any time before expiration of the license, upon the Department's request, submit written statements to enable the Department to determine whether the license should be modified, suspended, or revoked.

RHA 11.7. Performance Criteria for Sealed Sources.

11.7.1 Requirements. Sealed sources installed after July 1, 1996:

11.7.1.1 Must have a certificate of registration issued under 10 CFR 32.210 or RHA 2.29;

11.7.1.2 Must be doubly encapsulated;

11.7.1.3 Must use radioactive material that is as nondispersible as practical and that is as insoluble as practical if the source is used in a wet-source-storage or wet-source-change irradiator;

11.7.1.4 Must be encapsulated in a material resistant to general corrosion and to localized corrosion, such as 316L stainless steel or other material with equivalent resistance if the sources are for use in irradiator pools; and

11.7.1.5 In prototype testing of the sealed source, must have been leak tested and found leak-free after each of the tests described in paragraphs 11.7.2 through 11.7.7 of this section.

11.7.2 Temperature. The test source must be held at -40°C for 20 minutes, 600°C for 1 hour, and then be subjected to a thermal shock test with a temperature drop from 600°C to 20°C within 15 seconds.

11.7.3 Pressure. The test source must be twice subjected for at least 5 minutes to an external pressure (absolute) of 2 million Newtons per square meter.

11.7.4 Impact. A 2-kilogram steel weight, 2.5 centimeters in diameter, must be dropped from a height of 1 meter onto the test source.

11.7.5 Vibration. The test source must be subjected 3 times for 10 minutes each to vibrations sweeping from 25 hertz to 500 hertz with a peak amplitude of 5 times the acceleration of gravity. In addition, each test source must be vibrated for 30 minutes at each resonant frequency found.

11.7.6 Puncture. A 50-gram weight and pin, 0.3-centimeter pin diameter, must be dropped from a height of 1 meter onto the test source.

11.7.7 Bend. If the length of the source is more than 15 times larger than the minimum cross-sectional dimension, the test source must be subjected to a force of 2000 Newtons at its center equidistant from two support cylinders, the distance between which is 10 times the minimum cross-sectional dimension of the source.

History: Amended by SCSR 44–11, eff November 27, 2020 (errata).

RHA 11.8. Access Control.

11.8.1 Each entrance to a radiation room at a panoramic irradiator must have a door or other physical barrier to prevent inadvertent entry of personnel if the sources are not in the shielded position. Product conveyor systems may serve as barriers as long as they reliably and consistently function as a barrier. It must not be possible to move the sources out of their shielded position if the door or barrier is open. Opening the door or barrier while the sources are exposed must cause the sources to return promptly to their shielded position. The personnel entrance door or barrier must have a lock that is operated by the same key used to move the sources. The doors and barriers must not prevent any individual in the radiation room from leaving.

11.8.2 In addition, each entrance to a radiation room at a panoramic irradiator must have an independent backup access control to detect personnel entry while the sources are exposed. Detection of entry while the sources are exposed must cause the sources to return to their fully shielded position and must also activate a visible and audible alarm to make the individual entering the room aware of the hazard. The alarm must also alert at least one other individual who is onsite of the entry. That individual shall be trained on how to respond to the alarm and prepared to promptly render or summon assistance.

11.8.3 A radiation monitor must be provided to detect the presence of high radiation levels in the radiation room of a panoramic irradiator before personnel entry. The monitor must be integrated with personnel access door locks to prevent room access when radiation levels are high. Attempted personnel entry while the monitor measures high radiation levels must activate the alarm described in paragraph 11.8.2. The monitor may be located in the entrance (normally referred to as the maze) but not in the direct radiation beam.

11.8.4 Before the sources move from their shielded position in a panoramic irradiator, the source control must automatically activate conspicuous visible and audible alarms to alert people in the radiation room that the sources will be moved from their shielded position. The alarms must give individuals enough time to leave the room before the sources leave the shielded position.

11.8.5 Each radiation room at a panoramic irradiator must have a clearly visible and readily accessible control that would allow an individual in the room to make the sources return to their fully shielded position.

11.8.6 Each radiation room of a panoramic irradiator must contain a control that prevents the sources from moving from the shielded position unless the control has been activated and the door or barrier to the radiation room has been closed within a preset time after activation of the control.

11.8.7 Each entrance to the radiation room of a panoramic irradiator and each entrance to the area within the personnel access barrier of an underwater irradiator must be posted as required by RHA 3.22. Radiation postings for panoramic irradiators must comply with the posting requirements of RHA 3.22, except that signs may be removed, covered, or otherwise made inoperative when the sources are fully shielded.

11.8.8 If the radiation room of a panoramic irradiator has roof plugs or other movable shielding, it must not be possible to operate the irradiator unless the shielding is in its proper location. This requirement may be met by interlocks that prevent operation if shielding is not placed properly or by an operating procedure requiring inspection of shielding before operating.

11.8.9 Underwater irradiators must have a personnel access barrier around the pool which must be locked to prevent access when the irradiator is not attended. Only operators and facility management may have access to keys to the personnel access barrier. There must be an intrusion alarm to detect unauthorized entry when the personnel access barrier is locked. Activation of the intrusion alarm must alert an individual (not necessarily onsite) who is prepared to respond or summon assistance.

RHA 11.9. Shielding.

11.9.1 The radiation dose rate in areas that are normally occupied during operation of a panoramic irradiator may not exceed 2 millirems (0.00002 sievert) per hour at any location 30 centimeters or more from the wall of the room when the sources are exposed. The dose rate must be averaged over an area not to exceed 100 square centimeters having no linear dimension greater than 20 cm. Areas where the radiation dose rate exceeds 2 millirems (0.00002 sievert) per hour must be locked, roped off, or posted.

11.9.2 The radiation dose at 30 centimeters over the edge of the pool of a pool irradiator may not exceed 2 millirems (0.00002 sievert) per hour when the sources are in the fully shielded position.

11.9.3 The radiation dose rate at 1 meter from the shield of a dry-source-storage panoramic irradiator when the source is shielded may not exceed 2 millirems (0.00002) per hour and at 5 centimeters from the shield must not exceed 20 millirems (0.0002 sievert) per hour.

RHA 11.10. Fire Protection.

11.10.1 The radiation room at a panoramic irradiator must have heat and smoke detectors. The detectors must activate an audible alarm. The alarm must be capable of alerting a person who is prepared to summon assistance promptly. The sources must automatically become fully shielded if a fire is detected.

11.10.2 The radiation room at a panoramic irradiator must be equipped with a fire extinguishing system capable of extinguishing a fire without the entry of personnel into the room. The system for the radiation room must have a shut-off valve to control flooding into unrestricted areas.

RHA 11.11. Radiation Monitors.

11.11.1 Irradiators with automatic product conveyor systems must have a radiation monitor with an audible alarm located to detect loose radioactive sources that are carried toward the product exit. If the monitor detects a source, an alarm must sound and product conveyors must stop automatically. The alarm must be capable of alerting an individual in the facility who is prepared to summon assistance. Underwater irradiators in which the product moves within an enclosed stationary tube are exempt from the requirements of this paragraph.

11.11.2 Underwater irradiators that are not in a shielded radiation room must have a radiation monitor over the pool to detect abnormal radiation levels. The monitor must have an audible alarm and a visible indicator at entrances to the personnel access barrier around the pool. The audible alarm may have a manual shut-off. The alarm must be capable of alerting an individual who is prepared to respond promptly.

RHA 11.12. Control of Source Movement.

11.12.1 The mechanism that moves the sources of a panoramic irradiator must require a key to actuate. Actuation of the mechanism must cause an audible signal to indicate that the sources are leaving the shielded position. Only one key may be in use at any time, and only operators or facility management may possess it. The key must be attached to a portable radiation survey meter by a chain or cable. The lock for source control must be designed so that the key may not be removed if the sources are in an unshielded position. The door to the radiation room must require the same key.

11.12.2 The console of a panoramic irradiator must have a source position indicator that indicates when the sources are in the fully shielded position, when they are in transit, and when the sources are exposed.

11.12.3 The control console of a panoramic irradiator must have a control that promptly returns the sources to the shielded position.

11.12.4 Each control for a panoramic irradiator must be clearly marked as to its function.

RHA 11.13. Irradiator Pools.

11.13.1 For licenses initially issued after July 1, 1996, irradiator pools must either:

11.13.1.1 Have a water-tight stainless steel liner or a liner metallurgically compatible with other components in the pool; or

11.13.1.2 Be constructed so that there is a low likelihood of substantial leakage and have a surface designed to facilitate decontamination. In either case, the licensee shall have a method to safely store the sources during repairs of the pool.

11.13.2 For licenses initially issued after July 1, 1996, irradiator pools must have no outlets more than 0.5 meter below the normal low water level that could allow water to drain out of the pool. Pipes that have intakes more than 0.5 meter below the normal low water level and that could act as siphons must have siphon breakers to prevent the siphoning of pool water.

11.13.3 A means must be provided to replenish water losses from the pool.

11.13.4 A visible indicator must be provided in a clearly visible location to indicate if the pool water level is below the normal low water level or above the normal high water level.

11.13.5 Irradiator pools must be equipped with a purification system designed to be capable of maintaining the water during normal operation at a conductivity of 20 microsiemens per centimeter or less and with a clarity so that the sources can be seen clearly.

11.13.6 A physical barrier, such as a railing or cover, must be used around or over irradiator pools during normal operation to prevent personnel from accidentally falling into the pool. The barrier may be removed during maintenance, inspection, and service operations.

11.13.7 If long-handled tools or poles are used in irradiator pools, the radiation dose rate on the handling areas of the tools may not exceed 2 millirems (0.00002 sievert) per hour.

RHA 11.14. Source Rack Protection.

If the product to be irradiated moves on a product conveyor system, the source rack and the mechanism that moves the rack must be protected by a barrier or guides to prevent products and product carriers from hitting or touching the rack or mechanism.

RHA 11.15. Power Failures.

11.15.1 If electrical power at a panoramic irradiator is lost for longer than 10 seconds, the sources must automatically return to the shielded position.

11.15.2 The lock on the door of the radiation room of a panoramic irradiator may not be deactivated by a power failure.

11.15.3 During a power failure, the area of any irradiator where sources are located may be entered only when using an operable and calibrated radiation survey meter.

RHA 11.16. Design Requirements.

Irradiators whose construction begins after July 1, 1996, must meet the design requirements of this section.

11.16.1 Shielding. For panoramic irradiators, the licensee shall design shielding walls to meet generally accepted building code requirements for reinforced concrete and design the walls, wall penetrations, and entryways to meet the radiation shielding requirements of RHA 11.9. If the irradiator will use more than 5 million curies (2×10^{17} becquerels) of activity, the licensee shall evaluate the effects of heating of the shielding walls by the irradiator sources.

11.16.2 Foundations. For panoramic irradiators, the licensee shall design the foundation, with consideration given to soil characteristics, to ensure it is adequate to support the weight of the facility shield walls.

11.16.3 Pool integrity. For pool irradiators, the licensee shall design the pool to assure that it is leak resistant, that it is strong enough to bear the weight of the pool water and shipping casks, that a dropped cask would not fall on sealed sources, that all outlets or pipes meet the requirements of paragraph 11.13.2 and that metal components are metallurgically compatible with other components in the pool.

11.16.4 Water handling system. For pool irradiators, the licensee shall verify that the design of the water purification system is adequate to meet the requirements of paragraph 11.13.5. The system must be designed so that water leaking from the system does not drain to unrestricted areas without being monitored.

11.16.5 Radiation monitors. For all irradiators, the licensee shall evaluate the location and sensitivity of the monitor to detect sources carried by the product conveyor system as required by paragraph 11.11.1. The licensee shall verify that the product conveyor is designed to stop before a source on the product conveyor would cause a radiation overexposure to any person. For pool irradiators, if the licensee uses radiation monitors to detect contamination under paragraph 11.22.2, the licensee shall verify that the design of radiation monitoring systems to detect pool contamination includes sensitive detectors located close to where contamination is likely to concentrate.

11.16.6 Source rack. For pool irradiators, the licensee shall verify that there are no crevices on the source or between the source and source holder that would promote corrosion on a critical area of the source. For panoramic irradiators, the licensee shall determine that source rack drops due to loss of power will not damage the source rack and that source rack drops due to failure of cables (or alternate means of support) will not cause loss of integrity of sealed sources. For panoramic irradiators, the licensee shall review the design of the mechanism that moves the sources to assure that the likelihood of a stuck source is low and that, if the rack sticks, a means exists to free it with minimal risk to personnel.

11.16.7 Access control. For panoramic irradiators, the licensee shall verify from the design and logic diagram that the access control system will meet the requirements of RHA 11.8.

11.16.8 Fire protection. For panoramic irradiators, the licensee shall verify that the number, location, and spacing of the smoke and heat detectors are appropriate to detect fires and that the detectors are protected from mechanical and radiation damage. The licensee shall verify that the design of the fire extinguishing system provides the necessary discharge patterns, densities, and flow characteristics for complete coverage of the radiation room and that the system is protected from mechanical and radiation damage.

11.16.9 Source return. For panoramic irradiators, the licensee shall verify that the source rack will automatically return to the fully shielded position if offsite power is lost for more than 10 seconds.

11.16.10 Seismic. For panoramic irradiators to be built in seismic areas, the licensee shall design the reinforced concrete radiation shields to retain their integrity in the event of an earthquake by designing to the seismic requirements of an appropriate source such as American Concrete Institute Standard ACI 318-89, "Building Code Requirements for Reinforced Concrete," Chapter 21, "Special Provisions for Seismic Design," or local building codes, if current.

11.16.11 Wiring. For panoramic irradiators, the licensee shall verify that electrical wiring and electrical equipment in the radiation room are selected to minimize failures due to prolonged exposure to radiation.

History: Amended by SCSR 44–11, eff November 27, 2020 (errata).

RHA 11.17. Construction Monitoring and Acceptance Testing.

The requirements of this section must be met for irradiators whose construction begins after July 1, 1996. The requirements must be met prior to loading sources.

11.17.1 Shielding. For panoramic irradiators, the licensee shall monitor the construction of the shielding to verify that its construction meets design specifications and generally accepted building code requirements for reinforced concrete.

11.17.2 Foundations. For panoramic irradiators, the licensee shall monitor the construction of the foundations to verify that their construction meets design specifications.

11.17.3 Pool integrity. For pool irradiators, the licensee shall verify that the pool meets design specifications and shall test the integrity of the pool. The licensee shall verify that outlets and pipes meet the requirements of paragraph 11.13.2.

11.17.4 Water handling system. For pool irradiators, the licensee shall verify that the water purification system, the conductivity meter, and the water level indicators operate properly.

11.17.5 Radiation monitors. For all irradiators, the licensee shall verify the proper operation of the monitor to detect sources carried on the product conveyor system and the related alarms and interlocks required by paragraph 11.11.1. For pool irradiators, the licensee shall verify the proper operation of the radiation monitors and the related alarm if used to meet paragraph 11.22.2. For

underwater irradiators, the licensee shall verify the proper operation of the over-the-pool monitor, alarms, and interlocks required by paragraph 11.11.2.

11.17.6 Source rack. For panoramic irradiators, the licensee shall test the movement of the source racks for proper operation prior to source loading; testing must include source rack lowering due to simulated loss of power. For all irradiators with product conveyor systems, the licensee shall observe and test the operation of the conveyor system to assure that the requirements in RHA 11.14 are met for protection of the source rack and the mechanism that moves the rack; testing must include tests of any limit switches and interlocks used to protect the source rack and mechanism that moves the rack from moving product carriers.

11.17.7 Access control. For panoramic irradiators, the licensee shall test the completed access control system to assure that it functions as designed and that all alarms, controls, and interlocks work properly.

11.17.8 Fire protection. For panoramic irradiators, the licensee shall test the ability of the heat and smoke detectors to detect a fire, to activate alarms, and to cause the source rack to automatically become fully shielded. The licensee shall test the operability of the fire extinguishing system.

11.17.9 Source return. For panoramic irradiators, the licensee shall demonstrate that the source racks can be returned to their fully shielded positions without offsite power.

11.17.10 Computer systems. For panoramic irradiators that use a computer system to control the access control system, the licensee shall verify that the access control system will operate properly if offsite power is lost and shall verify that the computer has security features that prevent an irradiator operator from commanding the computer to override the access control system when it is required to be operable.

11.17.11 Wiring. For panoramic irradiators, the licensee shall verify that the electrical wiring and electrical equipment that were installed meet the design specifications.

RHA 11.18. Training.

11.18.1 Before an individual is permitted to operate an irradiator without a supervisor present, the individual must be instructed in:

11.18.1.1 The fundamentals of radiation protection applied to irradiators (including the differences between external radiation and radioactive contamination, units of radiation dose, Department dose limits, why large radiation doses must be avoided, how shielding and access controls prevent large doses, how an irradiator is designed to prevent contamination, the proper use of survey meters and personnel dosimeters, other radiation safety features of an irradiator, and the basic function of the irradiator);

11.18.1.2 The requirements of Parts 6 and 11 of Department regulations that are relevant to the irradiator;

11.18.1.3 The operation of the irradiator;

11.18.1.4 Those operating and emergency procedures listed in RHA 11.19 that the individual is responsible for performing; and

11.18.1.5 Case histories of accidents or problems involving irradiators.

11.18.2 Before an individual is permitted to operate an irradiator without a supervisor present, the individual shall pass a written test on the instruction received consisting primarily of questions based on the licensee's operating and emergency procedures that the individual is responsible for performing and other operations necessary to safely operate the irradiator without supervision.

11.18.3 Before an individual is permitted to operate an irradiator without a supervisor present, the individual must have received on-the-job training or simulator training in the use of the irradiator as described in the license application. The individual shall also demonstrate the ability to perform those portions of the operating and emergency procedures that he or she is to perform.

11.18.4 The licensee shall conduct safety reviews for irradiator operators at least annually. The licensee shall give each operator a brief written test on the information. Each safety review must include, to the extent appropriate, each of the following—

11.18.4.1 Changes in operating and emergency procedures since the last review, if any;

11.18.4.2 Changes in regulations and license conditions since the last review, if any;

11.18.4.3 Reports on recent accidents, mistakes, or problems that have occurred at irradiators, if any;

11.18.4.4 Relevant results of inspections of operator safety performance;

11.18.4.5 Relevant results of the facility's inspection and maintenance checks; and

11.18.4.6 A drill to practice an emergency or abnormal event procedure.

11.18.5 The licensee shall evaluate the safety performance of each irradiator operator at least annually to ensure that regulations, license conditions, and operating and emergency procedures are followed. The licensee shall discuss the results of the evaluation with the operator and shall instruct the operator on how to correct any mistakes or deficiencies observed.

11.18.6 Individuals who will be permitted unescorted access to the radiation room of the irradiator or the area around the pool of an underwater irradiator, but who have not received the training required for operators and the radiation safety officer, shall be instructed and tested in any precautions they should take to avoid radiation exposure, any procedures or parts of procedures listed in RHA 11.19 that they are expected to perform or comply with, and their proper response to alarms required in this Part. Tests may be oral.

11.18.7 Individuals who must be prepared to respond to alarms required by paragraphs 11.8.2, 11.8.9, 11.10.1, 11.11.1, 11.11.2, and 11.22.2 shall be trained and tested on how to respond. Each individual shall be retested at least once a year. Tests may be oral.

RHA 11.19. Operating and Emergency Procedures.

11.19.1 The licensee shall have and follow written operating procedures for—

11.19.1.1 Operation of the irradiator, including entering and leaving the radiation room;

11.19.1.2 Use of personnel dosimeters;

11.19.1.3 Surveying the shielding of panoramic irradiators;

11.19.1.4 Monitoring pool water for contamination while the water is in the pool and before release of pool water to unrestricted areas;

11.19.1.5 Leak testing of sources;

11.19.1.6 Inspection and maintenance checks required by RHA 11.23;

11.19.1.7 Loading, unloading, and repositioning sources, if the operations will be performed by the licensee; and

11.19.1.8 Inspection of movable shielding required by paragraph 11.8.8, if applicable.

11.19.2 The licensee shall have and follow emergency or abnormal event procedures, appropriate for the irradiator type, for—

11.19.2.1 Sources stuck in the unshielded position;

11.19.2.2 Personnel overexposures;

11.19.2.3 A radiation alarm from the product exit portal monitor or pool monitor;

11.19.2.4 Detection of leaking sources, pool contamination, or alarm caused by contamination of pool water;

11.19.2.5 A low or high water level indicator, an abnormal water loss, or leakage from the source storage pool;

11.19.2.6 A prolonged loss of electrical power;

11.19.2.7 A fire alarm or explosion in the radiation room;

11.19.2.8 An alarm indicating unauthorized entry into the radiation room, area ground pool, or another alarmed area;

11.19.2.9 Natural phenomena, including an earthquake, a tornado, flooding, or other phenomena as appropriate for the geographical location of the facility; and

11.19.2.10 The jamming of automatic conveyor systems.

11.19.3 The licensee may revise operating and emergency procedures without Department approval only if all of the following conditions are met:

11.19.3.1 The revisions do not reduce the safety of the facility,

11.19.3.2 The revisions are consistent with the outline or summary of procedures submitted with the license application,

11.19.3.3 The revisions have been reviewed and approved by the radiation safety officer, and

11.19.3.4 The users or operators are instructed and tested on the revised procedures before they are put into use.

RHA 11.20. Personnel Monitoring.

11.20.1 Irradiator operators shall wear a personnel dosimeter while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator. The personnel dosimeter processor must be capable of detecting high energy photons in the normal and accident dose ranges. Each personnel dosimeter must be assigned to and worn by only one individual. Film badges must be processed at least monthly, and other personnel dosimeters must be processed at least quarterly. All personnel dosimeters must be evaluated at least quarterly or promptly after replacement, whichever is more frequent.

11.20.2 Other individuals who enter the radiation room of a panoramic irradiator shall wear a dosimeter, which may be a pocket dosimeter. For groups of visitors, only two people who enter the radiation room are required to wear dosimeters. If pocket dosimeters are used to meet the requirements of this paragraph, a check of their response to radiation must be done at least annually. Acceptable dosimeters must read within plus or minus 30 percent of the true radiation dose.

HISTORY: Amended by SCSR 45–5 Doc. No. 5036, eff May 28, 2021.

RHA 11.21. Radiation Surveys.

11.21.1 A radiation survey of the area outside the shielding of the radiation room of a panoramic irradiator must be conducted with the sources in the exposed position before the facility starts to operate. A radiation survey of the area above the pool of pool irradiators must be conducted after the sources are loaded but before the facility starts to operate. Additional radiation surveys of the shielding must be performed at intervals not to exceed 3 years and before resuming operation after addition of new sources or any modification to the radiation room shielding or structure that might increase dose rate.

11.21.2 If the radiation levels specified in RHA 11.9 are exceeded, the facility must be modified to comply with the requirements in RHA 11.9.

11.21.3 Portable radiation survey meters must be calibrated at least annually to an accuracy of +20 percent for the gamma energy of the sources in use. The calibration must be done at two points on each scale or, for digital instruments, at one point per decade over the range that will be used. Portable radiation survey meters must be of a type that does not saturate and read zero at high radiation dose rates.

11.21.4 Water from the irradiator pool, other potentially contaminated liquids, and sediments from pool vacuuming must be monitored for radioactive contamination before release to unrestricted areas. Radioactive concentrations must not exceed those specified in Part III, RHA 3.53, Table 2, Column 2 or Table 3 of Appendix B, "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage."

11.21.5 Before releasing resins for unrestricted use, they must be monitored before release in an area with a background level less than 0.05 millirem (0.0005 millisievert) per hour. The resins may be released only if the survey does not detect radiation levels above background radiation levels. The survey meter used must be capable of detecting radiation levels of 0.05 millirem (0.0005 millisievert) per hour.

RHA 11.22. Detection of Leaking Sources.

11.22.1 Each dry-source-storage sealed source must be tested for leakage at intervals not to exceed 6 months using a leak test kit or method approved by the Department. In the absence of a certificate from a transferor that a test has been made within the 6 months before the transfer, the sealed source may not be used until tested. The test must be capable of detecting the presence of 0.005 microcurie

(200 becquerels) of radioactive material and must be performed by a person approved by the Nuclear Regulatory Commission or an Agreement State to perform the test.

11.22.2 For pool irradiators, sources may not be put into the pool unless the licensee tests the sources for leaks or has a certificate from a transferor that a leak test has been done within the 6 months before the transfer. Water from the pool must be checked for contamination each day the irradiator operates. The check may be done either by using a radiation monitor on a pool water circulating system or by analysis of a sample of pool water. If a check for contamination is done by analysis of a sample of pool water, the results of the analysis must be available within 24 hours. If the licensee uses a radiation monitor on a pool water circulating system, the detection of above normal radiation levels must activate an alarm. The alarm set-point must be set as low as practical, but high enough to avoid false alarms. The licensee may reset the alarm set-point to a higher level if necessary to operate the pool water purification system to clean up contamination in the pool if specifically provided for in written emergency procedures.

11.22.3 If a leaking source is detected, the licensee shall arrange to remove the leaking source from service and have it decontaminated, repaired, or disposed of by an NRC or Agreement State licensee that is authorized to perform these functions. The licensee shall promptly check its personnel, equipment, facilities, and irradiated product for radioactive contamination. No product may be shipped until the product has been checked and found free of contamination. If a product has been shipped that may have been inadvertently contaminated, the licensee shall arrange to locate and survey that product for contamination. If any personnel are found to be contaminated, decontamination must be performed promptly. If contaminated equipment, facilities, or products are found, the licensee shall arrange to have them decontaminated or disposed of by an NRC or Agreement State licensee that is authorized to perform these functions. If a pool is contaminated, the licensee shall arrange to clean the pool until the contamination levels do not exceed the appropriate concentration in Table 2, Column 2, of Part III, RHA 3.53, Appendix B. (See RHA 2.32 for reporting requirements.)

RHA 11.23. Inspection and Maintenance.

11.23.1 The licensee shall perform inspection and maintenance checks that include, as a minimum, each of the following at the frequency specified in the license or license application:

11.23.1.1 Operability of each aspect of the access control system required by RHA 11.8.

11.23.1.2 Functioning of the source position indicator required by paragraph 11.12.2.

11.23.1.3 Operability of the radiation monitor for radioactive contamination in pool water required by paragraph 11.22.2 using a radiation check source, if applicable.

11.23.1.4 Operability of the over-pool radiation monitor at underwater irradiators as required by paragraph 11.11.2.

11.23.1.5 Operability of the product exit monitor required by paragraph 11.11.1.

11.23.1.6 Operability of the emergency source return control required by paragraph 11.12.3.

11.23.1.7 Leak-tightness of systems through which pool water circulates (visual inspection).

11.23.1.8 Operability of the heat and smoke detectors and extinguisher system required by RHA 11.10 (but without turning extinguishers on).

11.23.1.9 Operability of the means of pool water replenishment required by paragraph 11.13.3.

11.23.1.10 Operability of the indicators of high and low pool water levels required by paragraph 11.13.4.

11.23.1.11 Operability of the intrusion alarm required by paragraph 11.8.9, if applicable.

11.23.1.12 Functioning and wear of the system, mechanisms, and cables used to raise and lower sources.

11.23.1.13 Condition of the barrier to prevent products from hitting the sources or source mechanism as required by RHA 11.14.

11.23.1.14 Amount of water added to the pool to determine if the pool is leaking.

11.23.1.15 Electrical wiring on required safety systems for radiation damage.

11.23.1.16 Pool water conductivity measurements and analysis as required by paragraph 11.24.2.

11.23.2 Malfunctions and defects found during inspection and maintenance checks must be repaired without undue delay.

RHA 11.24. Pool Water Purity.

11.24.1 Pool water purification system must be run sufficiently to maintain the conductivity of the pool water below 20 microsiemens per centimeter under normal circumstances. If pool water conductivity rises above 20 microsiemens per centimeter, the licensee shall take prompt actions to lower the pool water conductivity and shall take corrective actions to prevent future recurrences.

11.24.2 The licensee shall measure the pool water conductivity frequently enough, but no less than weekly, to assure that the conductivity remains below 20 microsiemens per centimeter. Conductivity meters must be calibrated at least annually.

RHA 11.25. Attendance during Operation.

11.25.1 Both an irradiator operator and at least one other individual, who is trained on how to respond and prepared to promptly render or summon assistance if the access control alarm sounds, shall be present onsite:

11.25.1.1 Whenever the irradiator is operated using an automatic product conveyor system; and

11.25.1.2 Whenever the product is moved into or out of the radiation room when the irradiator is operated in a batch mode.

11.25.2 At a panoramic irradiator at which static irradiations (no movement of the product) are occurring, a person who has received the training on how to respond to alarms described in paragraph 11.18.7 must be onsite.

11.25.3 At an underwater irradiator, an irradiator operator must be present at the facility whenever the product is moved into or out of the pool. Individuals who move the product into or out of the pool of an underwater irradiator need not be qualified as irradiator operators; however, they must have received the training described in paragraphs 11.18.6 and 11.18.7. Static irradiations may be performed without a person present at the facility.

RHA 11.26. Entering and Leaving the Radiation Room.

11.26.1 Upon first entering the radiation room of a panoramic irradiator after an irradiation, the irradiator operator shall use a survey meter to determine that the source has returned to its fully shielded position. The operator shall check the functioning of the survey meter with a radiation check source prior to entry.

11.26.2 Before exiting from and locking the door to the radiation room of a panoramic irradiator prior to a planned irradiation, the irradiator operator shall:

11.26.2.1 Visually inspect the entire radiation room to verify that no one else is in it; and

11.26.2.2 Activate a control in the radiation room that permits the sources to be moved from the shielded position only if the door to the radiation room is locked within a preset time after setting the control.

11.26.3 During a power failure, the area around the pool of an underwater irradiator may not be entered without using an operable and calibrated radiation survey meter unless the over-the-pool monitor required by paragraph 11.11.2 is operating with backup power.

RHA 11.27. Irradiation of Explosives or Flammable Materials.

11.27.1 Irradiation of explosive material is prohibited unless the licensee has received prior written authorization from the Department. Authorization will not be granted unless the licensee can demonstrate that detonation of the explosive would not rupture the sealed sources, injure personnel, damage safety systems, or cause radiation overexposures of personnel.

11.27.2 Irradiation of more than small quantities of flammable material (flash point below 140°F) is prohibited in panoramic irradiators unless the licensee has received prior written authorization from the Department. Authorization will not be granted unless the licensee can demonstrate that a fire in

the radiation room could be controlled without damage to sealed sources or safety systems and without radiation overexposures of personnel.

History: Amended by SCSR 44–11, eff November 27, 2020 (errata).

RHA 11.28. Records and Retention Records.

The licensee shall maintain the following records at the irradiator for the periods specified.

11.28.1 A copy of the license, license conditions, documents incorporated into a license by reference, and amendments thereto until superseded by new documents or until the Department terminates the license for documents not superseded.

11.28.2 Records of each individual's training, tests, and safety reviews provided to meet the requirements of paragraphs 11.18.1, 11.18.2, 11.18.3, 11.18.4, 11.18.6, and 11.18.7 until 3 years after the individual terminates work.

11.28.3 Records of the annual evaluations of the safety performance of irradiator operators required by paragraph 11.18.5 for 3 years after the evaluation.

11.28.4 A copy of the current operating and emergency procedures required by RHA 11.19 superseded or the Department terminates the license. Records of the radiation safety officer's review and approval of changes in procedures as required by paragraph 11.19.3.3 retained for 3 years from the date of the change.

11.28.5 Evaluations of personnel dosimeters required by RHA 11.20 until the Department terminates the license.

11.28.6 Records of radiation surveys required by RHA 11.21 for 3 years from the date of the survey.

11.28.7 Records of radiation survey meter calibrations required by RHA 11.21 and pool water conductivity meter calibrations required by paragraph 11.24.2 until 3 years from the date of calibration.

11.28.8 Records of the results of leak tests required by paragraph 11.22.1 and the results of contamination checks required by paragraph 11.22.2 for 3 years from the date of each test.

11.28.9 Records of inspection and maintenance checks required by RHA 11.23 for 3 years.

11.28.10 Records of major malfunctions, significant defects, operating difficulties or irregularities, and major operating problems that involve required radiation safety equipment for 3 years after repairs are completed.

11.28.11 Records of the receipt, transfer and disposal, of all licensed sealed sources as required by RHA 1.5 and RHA 2.18.

11.28.12 Records on the design checks required by RHA 11.16 and the construction control checks as required by RHA 11.17 until the license is terminated. The records must be signed and dated. The title or qualification of the person signing must be included.

11.28.13 Records related to decommissioning of the irradiator as required by RHA 1.15.11.

RHA 11.29. Reports.

11.29.1 In addition to the reporting requirements in other parts of these regulations, the licensee shall report the following events if not reported under other parts of the Department regulations:

11.29.1.1 Source stuck in an unshielded position.

11.29.1.2 Any fire or explosion in a radiation room.

11.29.1.3 Damage to the source racks.

11.29.1.4 Failure of the cable or drive mechanism used to move the source racks.

11.29.1.5 Inoperability of the access control system.

11.29.1.6 Detection of radiation source by the product exit monitor.

11.29.1.7 Detection of radioactive contamination attributable to licensed radioactive material.

11.29.1.8 Structural damage to the pool liner or walls.

11.29.1.1 [2] Abnormal water loss or leakage from the source storage pool.

11.29.1.9 Pool water conductivity exceeding 100 microsiemens per centimeter.

11.29.2 The report must include a telephone report within 24 hours as described in RHA 2.32.3.1, and a written report within 30 days as described in RHA 2.32.3.2.

PART XII
PHYSICAL PROTECTION OF CATEGORY 1 AND CATEGORY 2 QUANTITIES OF RADIOACTIVE MATERIAL

Subpart A—General Provisions
12.1 Purpose
12.2 Definitions
12.3 Specific exemptions

Subpart B—Background Investigations and Access Control Program
12.4 Personnel access authorization requirements for Category 1 or Category 2 quantities of radioactive material
12.5 Access authorization program requirements
12.6 Background investigations
12.7 Requirements for criminal history records checks of individuals granted unescorted access to Category 1 or Category 2 quantities of radioactive material
12.8 Relief from fingerprinting, identification, and criminal history records checks and other elements of background investigations for designated categories of individuals permitted unescorted access to certain radioactive materials
12.9 Protection of information
12.10 Access authorization program review

Subpart C—Physical Protection Requirements During Use
12.11 Security program
12.12 General security program requirements
12.13 LLEA coordination
12.14 Security zones
12.15 Monitoring, detection, and assessment
12.16 Maintenance and testing
12.17 Requirements for mobile devices
12.18 Security program review
12.19 Reporting of events

Subpart D—Physical Protection in Transit
12.20 Additional requirements for transfer of Category 1 and Category 2 quantities of radioactive material
12.21 Applicability of physical protection of Category 1 and Category 2 quantities of radioactive material during transit
12.22 Preplanning and coordination of shipment of Category 1 or Category 2 quantities of radioactive material
12.23 Advance notification of shipment of Category 1 quantities of radioactive material
12.24 Requirements for physical protection of Category 1 and Category 2 quantities of radioactive material during shipment
12.25 Reporting of events

Subpart E—Records
12.26 Form of records
12.27 Record retention

Appendix A—Category 1 and Category 2 Radioactive Materials

SUBPART A
General Provisions

[2] So in original

RHA 12.1. Purpose.

This part has been established to provide the requirements for the physical protection program for any licensee that possesses an aggregated Category 1 or Category 2 quantity of radioactive material listed in Appendix A to this part. These requirements provide reasonable assurance of the security of Category 1 or Category 2 quantities of radioactive material by protecting these materials from theft or diversion. Specific requirements for access to material, use of material, transfer of material, and transport of material are included. No provision of this part authorizes possession of licensed material.

HISTORY: Added by State Register Volume 38, Issue No. 10, Doc. No. 4462, eff October 24, 2014.

RHA 12.2. Definitions.

As used in this part:

12.2.1 "**Access control**" means a system for allowing only approved individuals to have unescorted access to the security zone and for ensuring that all other individuals are subject to escorted access.

12.2.2 "**Aggregated**" means accessible by the breach of a single physical barrier that would allow access to radioactive material in any form, including any devices that contain the radioactive material, when the total activity equals or exceeds a Category 2 quantity of radioactive material.

12.2.3 "**Approved individual**" means an individual whom the licensee has determined to be trustworthy and reliable for unescorted access in accordance with Subpart B and who has completed the training required by RHA 12.12.3.

12.2.4 "**Background investigation**" means the investigation conducted by a licensee or applicant to support the determination of trustworthiness and reliability.

12.2.5 "**Carrier**" means a person engaged in the transportation of passengers or property by land or water as a common, contract, or private carrier, or by civil aircraft.

12.2.6 "**Category 1 quantity of radioactive material**" means a quantity of radioactive material meeting or exceeding the Category 1 threshold in Table 1 of Appendix A to this part. This is determined by calculating the ratio of the total activity of each radionuclide to the Category 1 threshold for that radionuclide and adding the ratios together. If the sum is equal to or exceeds 1, the quantity would be considered a Category 1 quantity. Category 1 quantities of radioactive material do not include the radioactive material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet.

12.2.7 "**Category 2 quantity of radioactive material**" means a quantity of radioactive material meeting or exceeding the Category 2 threshold but less than the Category 1 threshold in Table 1 of Appendix A to this part. This is determined by calculating the ratio of the total activity of each radionuclide to the Category 2 threshold for that radionuclide and adding the ratios together. If the sum is equal to or exceeds 1, the quantity would be considered a Category 2 quantity. Category 2 quantities of radioactive material do not include the radioactive material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet.

12.2.8 "**Curie**" means that amount of radioactive material which disintegrates at the rate of 37 billion atoms per second.

12.2.9 "**Department**" means the SC Department of Health & Environmental Control or its duly authorized representatives.

12.2.10 "**Diversion**" means the unauthorized movement of radioactive material subject to this part to a location different from the material's authorized destination inside or outside of the site at which the material is used or stored.

12.2.11 "**Escorted access**" means accompaniment while in a security zone by an approved individual who maintains continuous direct visual surveillance at all times over an individual who is not approved for unescorted access.

12.2.12 "**Fingerprint orders**" means the orders issued by the U.S. Nuclear Regulatory Commission or the legally binding requirements issued by Agreement States that require fingerprints and criminal history records checks for individuals with unescorted access to Category 1 and Category 2 quantities of radioactive material or safeguards information-modified handling.

12.2.13 "**Local law enforcement agency (LLEA)**" means a public or private organization that has been approved by a federal, state, or local government to carry firearms and make arrests, and is authorized and has the capability to provide an armed response in the jurisdiction where the licensed Category 1 or Category 2 quantity of radioactive material is used, stored, or transported.

12.2.14 "**Mobile device**" means a piece of equipment containing licensed radioactive material that is either mounted on wheels or casters, or otherwise equipped for moving without a need for disassembly or dismounting; or designed to be hand carried. Mobile devices do not include stationary equipment installed in a fixed location.

12.2.15 "**Movement control center**" means an operations center that is remote from transport activity and that maintains position information on the movement of radioactive material, receives reports of attempted attacks or thefts, provides a means for reporting these and other problems to appropriate agencies and can request and coordinate appropriate aid.

12.2.16 "**No-later-than arrival time**" means the date and time that the shipping licensee and receiving licensee have established as the time at which an investigation will be initiated if the shipment has not arrived at the receiving facility. The no-later-than-arrival time may not be more than 6 hours after the estimated arrival time for shipments of Category 2 quantities of radioactive material.

12.2.17 "**Reviewing official**" means the individual who shall make the trustworthiness and reliability determination of an individual to determine whether the individual may have, or continue to have, unescorted access to the Category 1 or Category 2 quantities of radioactive materials that are possessed by the licensee.

12.2.18 "**Sabotage**" means deliberate damage, with malevolent intent, to a Category 1 or Category 2 quantity of radioactive material, a device that contains a Category 1 or Category 2 quantity of radioactive material, or the components of the security system.

12.2.19 "**Safe haven**" means a readily recognizable and readily accessible site at which security is present or from which, in the event of an emergency, the transport crew can notify and wait for the local law enforcement authorities.

12.2.20 "**Security zone**" means any temporary or permanent area determined and established by the licensee for the physical protection of Category 1 or Category 2 quantities of radioactive material.

12.2.21 "**Telemetric position monitoring system**" means a data transfer system that captures information by instrumentation and/or measuring devices about the location and status of a transport vehicle or package between the departure and destination locations.

12.2.22 "**Trustworthiness and reliability**" are characteristics of an individual considered dependable in judgment, character, and performance, such that unescorted access to Category 1 or Category 2 quantities of radioactive material by that individual does not constitute an unreasonable risk to the public health and safety or security. A determination of trustworthiness and reliability for this purpose is based upon the results from a background investigation.

12.2.23 "**Unescorted access**" means solitary access to an aggregated Category 1 or Category 2 quantity of radioactive material or the devices that contain the material.

HISTORY: Added by State Register Volume 38, Issue No. 10, Doc. No. 4462, eff October 24, 2014.

RHA 12.3. Specific exemptions.

A licensee that possesses radioactive waste that contains Category 1 or Category 2 quantities of radioactive material is exempt from the requirements of Subparts B, C, and D. Except that any radioactive waste that contains discrete sources, ion-exchange resins, or activated material that weighs less than 2,000 kg (4,409 lbs) is not exempt from the requirements of this part. The licensee shall implement the following requirements to secure the radioactive waste:

12.3.1 Use continuous physical barriers that allow access to the radioactive waste only through established access control points;

12.3.2 Use a locked door or gate with monitored alarm at the access control point;

12.3.3 Assess and respond to each actual or attempted unauthorized access to determine whether an actual or attempted theft, sabotage, or diversion occurred; and

12.3.4 Immediately notify the LLEA and request an armed response from the LLEA upon determination that there was an actual or attempted theft, sabotage, or diversion of the radioactive waste that contains Category 1 or Category 2 quantities of radioactive material.

HISTORY: Added by State Register Volume 38, Issue No. 10, Doc. No. 4462, eff October 24, 2014.

SUBPART B
Background Investigations and Access Control Program

RHA 12.4. Personnel access authorization requirements for Category 1 or Category 2 quantities of radioactive material.

12.4.1 General.

12.4.1.1 Each licensee that possesses an aggregated quantity of radioactive material at or above the Category 2 threshold shall establish, implement, and maintain its access authorization program in accordance with the requirements of Subpart B.

12.4.1.2 An applicant for a new license and each licensee that would become newly subject to the requirements of Subpart B upon application for modification of its license shall implement the requirements of Subpart B, as appropriate, before taking possession of an aggregated Category 1 or Category 2 quantity of radioactive material.

12.4.1.3 Any licensee that has not previously implemented the Security Orders or been subject to the provisions of Subpart B shall implement the provisions of Subpart B before aggregating radioactive material to a quantity that equals or exceeds the Category 2 threshold.

12.4.2 General performance objective. The licensee's access authorization program must ensure that the individuals specified in paragraph RHA 12.4.3.1 of this section are trustworthy and reliable.

12.4.3 Applicability.

12.4.3.1 Licensees shall subject the following individuals to an access authorization program:

12.4.3.1.1 Any individual whose assigned duties require unescorted access to Category 1 or Category 2 quantities of radioactive material or to any device that contains the radioactive material; and

12.4.3.1.2 Reviewing officials.

12.4.3.2 Licensees need not subject the categories of individuals listed in RHA12.8.1.1 through 12.8.1.13 to the investigation elements of the access authorization program.

12.4.3.3 Licensees shall approve for unescorted access to Category 1 or Category 2 quantities of radioactive material only those individuals with job duties that require unescorted access to Category 1 or Category 2 quantities of radioactive material.

12.4.3.4 Licensees may include individuals needing access to safeguards information-modified handling under 10 CFR Part 73 in the access authorization program under Subpart B.

HISTORY: Added by State Register Volume 38, Issue No. 10, Doc. No. 4462, eff October 24, 2014.

RHA 12.5. Access authorization program requirements.

12.5.1 Granting unescorted access authorization.

12.5.1.1 Licensees shall implement the requirements of Subpart B for granting initial or reinstated unescorted access authorization.

12.5.1.2 Individuals who have been determined to be trustworthy and reliable shall also complete the security training required by RHA 12.12.3 before being allowed unescorted access to Category 1 or Category 2 quantities of radioactive material.

12.5.2 Reviewing officials.

12.5.2.1 Reviewing officials are the only individuals who may make trustworthiness and reliability determinations that allow individuals to have unescorted access to Category 1 or Category 2 quantities of radioactive materials possessed by the licensee.

12.5.2.2 Each licensee shall name one or more individuals to be reviewing officials. After completing the background investigation on the reviewing official, the licensee shall provide under oath or affirmation, a certification that the reviewing official is deemed trustworthy and reliable by

the licensee. Licensees shall provide oath or affirmation certificates to the Department. The fingerprints of the named reviewing official must be taken by a law enforcement agency, Federal or State agencies that provide fingerprinting services to the public, or commercial fingerprinting services authorized by a State to take fingerprints. The licensee shall recertify that the reviewing official is deemed trustworthy and reliable every ten (10) years in accordance with RHA 12.6.3.

12.5.2.3 Reviewing officials must be permitted to have unescorted access to Category 1 or Category 2 quantities of radioactive materials or access to safeguards information or safeguards information-modified handling, if the licensee possesses safeguards information or safeguards information modified handling.

12.5.2.4 Reviewing officials cannot approve other individuals to act as reviewing officials.

12.5.2.5 A reviewing official does not need to undergo a new background investigation before being named by the licensee as the reviewing official if:

12.5.2.5.1 The individual has undergone a background investigation that included fingerprinting and an FBI criminal history records check and has been determined to be trustworthy an reliable by the licensee; or

12.5.2.5.2 The individual is subject to a Category listed in RHA 12.8.1.

12.5.3 Informed consent.

12.5.3.1 Licensees may not initiate a background investigation without the informed and signed consent of the subject individual. This consent must include authorization to share personal information with other individuals or organizations as necessary to complete the background investigation. Before a final adverse determination, the licensee shall provide the individual with an opportunity to correct any inaccurate or incomplete information that is developed during the background investigation. Licensees do not need to obtain signed consent from those individuals that meet the requirements of RHA 12.6.2. A signed consent must be obtained prior to any reinvestigation.

12.5.3.2 The subject individual may withdraw his or her consent at any time. Licensees shall inform the individual that:

12.5.3.2.1 If an individual withdraws his or her consent, the licensee may not initiate any elements of the background investigation that were not in progress at the time the individual withdrew his or her consent; and

12.5.3.2.2 The withdrawal of consent for the background investigation is sufficient cause for denial or termination of unescorted access authorization.

12.5.4 Personal history disclosure.

Any individual who is applying for unescorted access authorization shall disclose the personal history information that is required by the licensee's access authorization program for the reviewing official to make a determination of the individual's trustworthiness and reliability. Refusal to provide, or the falsification of, any personal history information required by Subpart B is sufficient cause for denial or termination of unescorted access.

12.5.5 Determination basis.

12.5.5.1 The reviewing official shall determine whether to permit, deny, unfavorably terminate, maintain, or administratively withdraw an individual's unescorted access authorization based on an evaluation of all of the information collected to meet the requirements of Subpart B.

12.5.5.2 The reviewing official may not permit any individual to have unescorted access until the reviewing official has evaluated all of the information collected to meet the requirements of Subpart B and determined that the individual is trustworthy and reliable. The reviewing official may deny unescorted access to any individual based on information obtained at any time during the background investigation.

12.5.5.3 The licensee shall document the basis for concluding whether or not there is reasonable assurance that an individual is trustworthy and reliable.

12.5.5.4 The reviewing official may terminate or administratively withdraw an individual's unescorted access authorization based on information obtained after the background investigation has been completed and the individual granted unescorted access authorization.

12.5.5.5 Licensees shall maintain a list of persons currently approved for unescorted access authorization. When a licensee determines that a person no longer requires unescorted access or meets the access authorization requirement, the licensee shall remove the person from the approved list as soon as possible, but no later than 7 working days, and take prompt measures to ensure that the individual is unable to have unescorted access to the material.

12.5.6 Procedures. Licensees shall develop, implement, and maintain written procedures for implementing the access authorization program. The procedures must include provisions for the notification of individuals who are denied unescorted access. The procedures must include provisions for the review, at the request of the affected individual, of a denial or termination of unescorted access authorization. The procedures must contain a provision to ensure that the individual is informed of the grounds for the denial or termination of unescorted access authorization and allow the individual an opportunity to provide additional relevant information.

12.5.7 Right to correct and complete information.

12.5.7.1 Prior to any final adverse determination, licensees shall provide each individual subject to Subpart B with the right to complete, correct, and explain information obtained as a result of the licensee's background investigation. Confirmation of receipt by the individual of this notification must be maintained by the licensee for a period of 1 year from the date of the notification.

12.5.7.2 If, after reviewing his or her criminal history record, an individual believes that it is incorrect or incomplete in any respect and wishes to change, correct, update, or explain anything in the record, the individual may initiate challenge procedures. These procedures include direct application by the individual challenging the record to the law enforcement agency that contributed the questioned information or a direct challenge as to the accuracy or completeness of any entry on the criminal history record to the Federal Bureau of Investigation, Criminal Justice Information Services (CJIS) Division, ATTN: SCU, Mod. D-2, 1000 Custer Hollow Road, Clarksburg, WV 26306 as set forth in 28 CFR 16.30 through 16.34. In the latter case, the Federal Bureau of Investigation (FBI) will forward the challenge to the agency that submitted the data, and will request that the agency verify or correct the challenged entry. Upon receipt of an official communication directly from the agency that contributed the original information, the FBI Identification Division makes any changes necessary in accordance with the information supplied by that agency. Licensees must provide at least 10 days for an individual to initiate action to challenge the results of an FBI criminal history records check after the record being made available for his or her review. The licensee may make a final adverse determination based upon the criminal history records only after receipt of the FBI's confirmation or correction of the record.

12.5.8 Records.

12.5.8.1 The licensee shall retain documentation regarding the trustworthiness and reliability of individual employees for 3 years from the date the individual no longer requires unescorted access to Category 1 or Category 2 quantities of radioactive material.

12.5.8.2 The licensee shall retain a copy of the current access authorization program procedures as a record for 3 years after the procedure is no longer needed. If any portion of the procedure is superseded, the licensee shall retain the superseded material for 3 years after the record is superseded.

12.5.8.3 The licensee shall retain the list of persons approved for unescorted access authorization for 3 years after the list is superseded or replaced.

HISTORY: Added by State Register Volume 38, Issue No. 10, Doc. No. 4462, eff October 24, 2014. Amended by SCSR 42–2 Doc. No. 4791, eff February 23, 2018; SCSR 44–11, eff November 27, 2020 (errata); SCSR 45–5 Doc. No. 5036, eff May 28, 2021.

RHA 12.6. Background investigations.

12.6.1 Initial investigation. Before allowing an individual unescorted access to Category 1 or Category 2 quantities of radioactive material or to the devices that contain the material, licensees shall complete a background investigation of the individual seeking unescorted access authorization. The scope of the investigation must encompass at least the 7 years preceding the date of the background investigation or since the individual's eighteenth birthday, whichever is shorter. The background investigation must include at a minimum:

12.6.1.1 Fingerprinting and an FBI identification and criminal history records check in accordance with RHA 12.7;

12.6.1.2 Verification of true identity. Licensees shall verify the true identity of the individual who is applying for unescorted access authorization to ensure that the applicant is who he or she claims to be. A licensee shall review official identification documents (*e.g.*, driver's license; passport; government identification; certificate of birth issued by the state, province, or country of birth) and compare the documents to personal information data provided by the individual to identify any discrepancy in the information. Licensees shall document the type, expiration, and identification number of the identification document, or maintain a photocopy of identifying documents on file in accordance with RHA 12.9. Licensees shall certify in writing that the identification was properly reviewed, and shall maintain the certification and all related documents for review upon inspection;

12.6.1.3 Employment history verification. Licensees shall complete an employment history verification, including military history. Licensees shall verify the individual's employment with each previous employer for the most recent 7 years before the date of application;

12.6.1.4 Verification of education. Licensees shall verify that the individual participated in the education process during the claimed period;

12.6.1.5 Character and reputation determination. Licensees shall complete reference checks to determine the character and reputation of the individual who has applied for unescorted access authorization. Unless other references are not available, reference checks may not be conducted with any person who is known to be a close member of the individual's family, including but not limited to the individual's spouse, parents, siblings, or children, or any individual who resides in the individual's permanent household. Reference checks under Subpart B must be limited to whether the individual has been and continues to be trustworthy and reliable;

12.6.1.6 The licensee shall also, to the extent possible, obtain independent information to corroborate that provided by the individual (*e.g.*, seek references not supplied by the individual); and

12.6.1.7 If a previous employer, educational institution, or any other entity with which the individual claims to have been engaged fails to provide information or indicates an inability or unwillingness to provide information within a time frame deemed appropriate by the licensee but at least after 10 business days of the request or if the licensee is unable to reach the entity, the licensee shall document the refusal, unwillingness, or inability in the record of investigation; and attempt to obtain the information from an alternate source.

12.6.2 Grandfathering.

12.6.2.1 Individuals who have been determined to be trustworthy and reliable for unescorted access to Category 1 or Category 2 quantities of radioactive material under the Fingerprint Orders may continue to have unescorted access to Category 1 and Category 2 quantities of radioactive material without further investigation. These individuals shall be subject to the reinvestigation requirement.

12.6.2.2 Individuals who have been determined to be trustworthy and reliable under the provisions of 10 CFR Part 73 or the security orders for access to safeguards information, safeguards information-modified handling, or risk-significant material may have unescorted access to Category 1 and Category 2 quantities of radioactive material without further investigation. The licensee shall document that the individual was determined to be trustworthy and reliable under the provisions of 10 CFR Part 73 or a security order. Security order, in this context, refers to any order that was issued by the NRC that required fingerprints and an FBI criminal history records check for access to safeguards information, safeguards information-modified handling, or risk significant material such as special nuclear material or large quantities of uranium hexafluoride. These individuals shall be subject to the reinvestigation requirement.

12.6.3 Reinvestigations. Licensees shall conduct a reinvestigation every 10 years for any individual with unescorted access to Category 1 or Category 2 quantities of radioactive material. The reinvestigation shall consist of fingerprinting and an FBI identification and criminal history records check in accordance with RHA 12.7. The reinvestigations must be completed within 10 years of the date on which these elements were last completed.

HISTORY: Added by State Register Volume 38, Issue No. 10, Doc. No. 4462, eff October 24, 2014.

RHA 12.7. Requirements for criminal history records checks of individuals granted unescorted access to Category 1 or Category 2 quantities of radioactive material.

12.7.1 General performance objective and requirements.

12.7.1.1 Except for those individuals listed in RHA 12.8 and those individuals grandfathered under RHA 12.6.2, each licensee subject to the provisions of Subpart B shall fingerprint each individual who is to be permitted unescorted access to Category 1 or Category 2 quantities of radioactive material. Licensees shall transmit all collected fingerprints to the U.S. Nuclear Regulatory Commission for transmission to the FBI. The licensee shall use the information received from the FBI as part of the required background investigation to determine whether to grant or deny further unescorted access to Category 1 or Category 2 quantities of radioactive materials for that individual.

12.7.1.2 The licensee shall notify each affected individual that his or her fingerprints will be used to secure a review of his or her criminal history record, and shall inform him or her of the procedures for revising the record or adding explanations to the record.

12.7.1.3 Fingerprinting is not required if a licensee is reinstating an individual's unescorted access authorization to Category 1 or Category 2 quantities of radioactive materials if:

12.7.1.3.1 The individual returns to the same facility that granted unescorted access authorization within 365 days of the termination of his or her unescorted access authorization; and

12.7.1.3.2 The previous access was terminated under favorable conditions.

12.7.1.4 Fingerprints do not need to be taken if an individual who is an manufacturer, or supplier has been granted unescorted access to Category 1 or Category 2 quantities of radioactive material, access to safeguards information, or safeguards information modified handling by another licensee, based upon a background investigation conducted under Subpart B, the Fingerprint Orders, or 10 CFR Part 73. An existing criminal history records check file may be transferred to the licensee asked to grant unescorted access in accordance with the provisions of RHA 12.9.3.

12.7.1.5 Licensees shall use the information obtained as part of a criminal history records check solely for the purpose of determining an individual's suitability for unescorted access authorization to Category 1 or Category 2 quantities of radioactive materials, access to safeguards information, or safeguards information modified handling.

12.7.2 Prohibitions.

12.7.2.1 Licensees may not base a final determination to deny an individual unescorted access authorization to Category 1 or Category 2 quantities of radioactive material solely on the basis of information received from the FBI involving:

12.7.2.1.1 An arrest more than 1 year old for which there is no information of the disposition of the case; or

12.7.2.1.2 An arrest that resulted in dismissal of the charge or an acquittal.

12.7.2.2 Licensees may not use information received from a criminal history records check obtained under Subpart B in a manner that would infringe upon the rights of any individual under the First Amendment to the Constitution of the United States, nor shall licensees use the information in any way that would discriminate among individuals on the basis of race, religion, national origin, gender, or age.

12.7.3 Procedures for processing of fingerprint checks.

12.7.3.1 For the purpose of complying with this subpart, Department licensees shall use an appropriate method listed in 10 CFR 37.7 to submit to the U.S. Nuclear Regulatory Commission, Director Division of Physical and Cyber Security Policy, 11545 Rockville Pike, ATTN: Criminal History Program, Mail Stop T-8B20, Rockville, MD 20852, one completed, legible standard fingerprint card (Form FD-258, ORIMDNRCOOOZ), electronic fingerprint scan or, where practicable, other fingerprint record for each individual requiring unescorted access to Category 1 or Category 2 quantities of radioactive material. Copies of these forms may be obtained by e-mailing *MAILSVS.Resource@nrc.gov*. Guidance on submitting electronic fingerprints can be found at https://www.nrc.gov/security/chp.html.

12.7.3.2 Fees for the processing of fingerprint checks are due upon application. Licensees shall submit payment with the application for the processing of fingerprints through corporate check, certified check, cashier's check, money order, or electronic payment, made payable to "U.S. NRC." (For guidance on making electronic payments, contact the Division of Physical and Cyber Security Policy by e-mailing Crimhist.Resource@nrc.gov.) Combined payment for multiple applications is acceptable. The Commission publishes the amount of the fingerprint check application fee on the NRC's public Web site. (To find the current fee amount, go to the Licensee Criminal History Records Check & Firearms Background Check information page at https://www.nrc.gov/security/chp.html and see the link for How do I determine how much to pay for the request?).

12.7.3.3 The U.S. Nuclear Regulatory Commission will forward to the submitting Department licensee all data received from the FBI as a result of the licensee's application(s) for criminal history records checks.

HISTORY: Added by State Register Volume 38, Issue No. 10, Doc. No. 4462, eff October 24, 2014. Amended by SCSR 42–2 Doc. No. 4791, eff February 23, 2018; SCSR 45–5 Doc. No. 5036, eff May 28, 2021.

RHA 12.8. Relief from fingerprinting, identification, and criminal history records checks and other elements of background investigations for designated categories of individuals permitted unescorted access to certain radioactive materials.

12.8.1 Fingerprinting, and the identification and criminal history records checks required by section 149 of the Atomic Energy Act of 1954, as amended, and other elements of the background investigation are not required for the following individuals prior to granting unescorted access to Category 1 or Category 2 quantities of radioactive materials:

12.8.1.1 An employee of the Department who has undergone fingerprinting for a prior U.S. Government criminal history records check;

12.8.1.2 A Member of Congress;

12.8.1.3 An employee of a member of Congress or Congressional committee who has undergone fingerprinting for a prior U.S. Government criminal history records check;

12.8.1.4 The Governor of a State or his or her designated State employee representative;

12.8.1.5 Federal, State, or local law enforcement personnel;

12.8.1.6 State Radiation Control Program Directors and State Homeland Security Advisors or their designated State employee representatives;

12.8.1.7 Agreement State employees conducting security inspections on behalf of the NRC under an agreement executed under section 274.i. of the Atomic Energy Act; (8) Representatives of the International Atomic Energy Agency (IAEA) engaged in activities associated with the U.S./IAEA Safeguards Agreement who have been certified by the NRC;

12.8.1.9 Emergency response personnel who are responding to an emergency;

12.8.1.10 Commercial vehicle drivers for road shipments of Category 1 and Category 2 quantities of radioactive material;

12.8.1.11 Package handlers at transportation facilities such as freight terminals and railroad yards;

12.8.1.12 Any individual who has an active Federal security clearance, provided that he or she makes available the appropriate documentation. Written confirmation from the agency/employer that granted the Federal security clearance or reviewed the criminal history records check must be provided to the licensee. The licensee shall retain this documentation for a period of 3 years from the date the individual no longer requires unescorted access to Category 1 or Category 2 quantities of radioactive material; and

12.8.1.13 Any individual employed by a service provider licensee for which the service provider licensee has conducted the background investigation for the individual and approved the individual for unescorted access to Category 1 or Category 2 quantities of radioactive material. Written verification from the service provider must be provided to the licensee. The licensee shall retain the documentation for a period of 3 years from the date the individual no longer requires unescorted access to Category 1 or Category 2 quantities of radioactive material.

12.8.2 Fingerprinting, and the identification and criminal history records checks required by section 149 of the Atomic Energy Act of 1954, as amended, are not required for an individual who has had a favorably adjudicated U.S. Government criminal history records check within the last 5 years, under a comparable U.S. Government program involving fingerprinting and an FBI identification and criminal history records check provided that he or she makes available the appropriate documentation. Written confirmation from the agency/employer that reviewed the criminal history records check must be provided to the licensee. The licensee shall retain this documentation for a period of 3 years from the date the individual no longer requires unescorted access to Category 1 or Category 2 quantities of radioactive material. These programs include, but are not limited to:

12.8.2.1 National Agency Check;

12.8.2.2 Transportation Worker Identification Credentials (TWIC) under 49 CFR part 1572;

12.8.2.3 Bureau of Alcohol, Tobacco, Firearms, and Explosives background check and clearances under 27 CFR part 555;

12.8.2.4 Health and Human Services security risk assessments for possession and use of select agents and toxins under 42 CFR part 73;

12.8.2.5 Hazardous Material security threat assessment for hazardous material endorsement to commercial driver's license under 49 CFR part 1572; and

12.8.2.6 Customs and Border Protection's Free and Secure Trade (FAST) Program.

HISTORY: Added by State Register Volume 38, Issue No. 10, Doc. No. 4462, eff October 24, 2014. Amended by SCSR 42–2 Doc. No. 4791, eff February 23, 2018; SCSR 44–11, eff November 27, 2020 (errata).

RHA 12.9. Protection of information.

12.9.1 Each licensee who obtains background information on an individual under Subpart B shall establish and maintain a system of files and written procedures for protection of the record and the personal information from unauthorized disclosure.

12.9.2 The licensee may not disclose the record or personal information collected and maintained to persons other than the subject individual, his or her representative, or to those who have a need to have access to the information in performing assigned duties in the process of granting or denying unescorted access to Category 1 or Category 2 quantities of radioactive material, safeguards information, or safeguards information-modified handling. No individual authorized to have access to the information may disseminate the information to any other individual who does not have a need to know.

12.9.3 The personal information obtained on an individual from a background investigation may be provided to another licensee:

12.9.3.1 Upon the individual's written request to the licensee holding the data to disseminate the information contained in his or her file; and

12.9.3.2 The recipient licensee verifies information such as name, date of birth, social security number, gender, and other applicable physical characteristics.

12.9.4 The licensee shall make background investigation records obtained under Subpart B available for examination by an authorized representative of the Department to determine compliance with the regulations and laws.

12.9.5 The licensee shall retain all fingerprint and criminal history records (including data indicating no record) received from the FBI, or a copy of these records if the individual's file has been transferred, on an individual for 3 years from the date the individual no longer requires unescorted access to Category 1 or Category 2 quantities of radioactive material.

HISTORY: Added by State Register Volume 38, Issue No. 10, Doc. No. 4462, eff October 24, 2014.

RHA 12.10. Access authorization program review.

12.10.1 Each licensee shall be responsible for the continuing effectiveness of the access authorization program. Each licensee shall ensure that access authorization programs are reviewed to confirm compliance with the requirements of Subpart B and that comprehensive actions are taken to correct any noncompliance that is identified. The review program shall evaluate all program performance

objectives and requirements. Each licensee shall periodically (at least annually) review the access program content and implementation.

12.10.2 The results of the reviews, along with any recommendations, must be documented. Each review report must identify conditions that are adverse to the proper performance of the access authorization program, the cause of the condition(s), and, when appropriate, recommend corrective actions, and corrective actions taken. The licensee shall review the findings and take any additional corrective actions necessary to preclude repetition of the condition, including reassessment of the deficient areas where indicated.

12.10.3 Review records must be maintained for 3 years.

HISTORY: Added by State Register Volume 38, Issue No. 10, Doc. No. 4462, eff October 24, 2014.

SUBPART C
Physical Protection Requirements During Use

RHA 12.11. Security program.

12.11.1 Applicability

12.11.1.1 Each licensee that possesses an aggregated Category 1 or Category 2 quantity of radioactive material shall establish, implement, and maintain a security program in accordance with the requirements of Subpart C.

12.11.1.2 An applicant for a new license and each licensee that would become newly subject to the requirements of Subpart C upon application for modification of its license shall implement the requirements of Subpart C, as appropriate, before taking possession of an aggregated Category 1 or Category 2 quantity of radioactive material.

12.11.1.3 Any licensee that has not previously implemented the Security Orders or been subject to the provisions of Subpart C shall provide written notification to the Department at least 90 days before aggregating radioactive material to a quantity that equals or exceeds the Category 2 threshold.

12.11.2 General performance objective. Each licensee shall establish, implement, and maintain a security program that is designed to monitor and, without delay, detect, assess, and respond to an actual or attempted unauthorized access to Category 1 or Category 2 quantities of radioactive material.

12.11.3 Program features. Each licensee's security program must include the program features, as appropriate, described in RHA 12.12, 12.13, 12.14, 12.15, 12.16, 12.17, and 12.18.

HISTORY: Added by State Register Volume 38, Issue No. 10, Doc. No. 4462, eff October 24, 2014.

RHA 12.12. General security program requirements.

12.12.1 Security plan.

12.12.1.1 Each licensee identified in RHA 12.11.1 shall develop a written security plan specific to its facilities and operations. The purpose of the security plan is to establish the licensee's overall security strategy to ensure the integrated and effective functioning of the security program required by Subpart C. The security plan must, at a minimum:

12.12.1.1.1 Describe the measures and strategies used to implement the requirements of Subpart C; and

12.12.1.1.2 Identify the security resources, equipment, and technology used to satisfy the requirements of Subpart C.

12.12.1.2 The security plan must be reviewed and approved by the individual with overall responsibility for the security program.

12.12.1.3 A licensee shall revise its security plan as necessary to ensure the effective implementation of Department requirements. The licensee shall ensure that:

12.12.1.3.1 The revision has been reviewed and approved by the individual with overall responsibility for the security program; and

12.12.1.3.2 The affected individuals are instructed on the revised plan before the changes are implemented.

12.12.1.4 The licensee shall retain a copy of the current security plan as a record for 3 years after the security plan is no longer required. If any portion of the plan is superseded, the licensee shall retain the superseded material for 3 years after the record is superseded.

12.12.2 Implementing procedures.

12.12.2.1 The licensee shall develop and maintain written procedures that document how the requirements of Subpart C and the security plan will be met.

12.12.2.2 The implementing procedures and revisions to these procedures must be approved in writing by the individual with overall responsibility for the security program.

12.12.2.3 The licensee shall retain a copy of the current procedure as a record for 3 years after the procedure is no longer needed. Superseded portions of the procedure must be retained for 3 years after the record is superseded.

12.12.3 Training.

12.12.3.1 Each licensee shall conduct training to ensure that those individuals implementing the security program possess and maintain the knowledge, skills, and abilities to carry out their assigned duties and responsibilities effectively. The training must include instruction in:

12.12.3.1.1 The licensee's security program and procedures to secure Category 1 or Category 2 quantities of radioactive material, and in the purposes and functions of the security measures employed;

12.12.3.1.2 The responsibility to report promptly to the licensee any condition that causes or may cause a violation of Department requirements;

12.12.3.1.3 The responsibility of the licensee to report promptly to the local law enforcement agency and licensee any actual or attempted theft, sabotage, or diversion of Category 1 or Category 2 quantities of radioactive material; and

12.12.3.1.4 The appropriate response to security alarms.

12.12.3.2 In determining those individuals who shall be trained on the security program, the licensee shall consider each individual's assigned activities during authorized use and response to potential situations involving actual or attempted theft, diversion, or sabotage of Category 1 or Category 2 quantities of radioactive material. The extent of the training must be commensurate with the individual's potential involvement in the security of Category 1 or Category 2 quantities of radioactive material.

12.12.3.3 Refresher training must be provided at a frequency not to exceed 12 months and when significant changes have been made to the security program. This training must include:

12.12.3.3.1 Review of the training requirements of RHA 12.12.3 and any changes made to the security program since the last training;

12.12.3.3.2 Reports on any relevant security issues, problems, and lessons learned;

12.12.3.3.3 Relevant results of Department inspections; and

12.12.3.3.4 Relevant results of the licensee's program review and testing and maintenance.

12.12.3.4 The licensee shall maintain records of the initial and refresher training for 3 years from the date of the training. The training records must include dates of the training, topics covered, a list of licensee personnel in attendance, and related information.

12.12.4 Protection of information.

12.12.4.1 Licensees authorized to possess Category 1 or Category 2 quantities of radioactive material shall limit access to and unauthorized disclosure of their security plan, implementing procedures, and the list of individuals that have been approved for unescorted access.

12.12.4.2 Efforts to limit access shall include the development, implementation, and maintenance of written policies and procedures for controlling access to, and for proper handling and protection against unauthorized disclosure of, the security plan, implementing procedures, and the list of individuals that have been approved for unescorted access.

12.12.4.3 Before granting an individual access to the security plan, implementing procedures, or the list of individuals that have been approved for unescorted access, licensees shall:

12.12.4.3.1 Evaluate an individual's need to know the security plan, implementing procedures, or the list of individuals that have been approved for unescorted access; and

12.12.4.3.2 If the individual has not been authorized for unescorted access to Category 1 or Category 2 quantities of radioactive material, safeguards information, or safeguards information modified handling, the licensee must complete a background investigation to determine the individual's trustworthiness and reliability. A trustworthiness and reliability determination shall be conducted by the reviewing official and shall include the background investigation elements contained in RHA 12.6.1.2 through 12.6.1.7.

12.12.4.4 Licensees need not subject the following individuals to the background investigation elements for protection of information:

12.12.4.4.1 The categories of individuals listed in RHA 12.8.1.1 through 12.8.1.13; or

12.12.4.4.2 Security service provider employees, provided written verification that the employee has been determined to be trustworthy and reliable, by the required background investigation in RHA 12.6.1.2 through 12.6.1.7, has been provided by the security service provider.

12.12.4.5 The licensee shall document the basis for concluding that an individual is trustworthy and reliable and should be granted access to the security plan, implementing procedures, or the list of individuals that have been approved for unescorted access.

12.12.4.6 Licensees shall maintain a list of persons currently approved for access to the security plan, implementing procedures, or the list of individuals that have been approved for unescorted access. When a licensee determines that a person no longer needs access to the security plan, implementing procedures, or the list of individuals that have been approved for unescorted access or no longer meets the access authorization requirements for access to the information, the licensee shall remove the person from the approved list as soon as possible, but no later than 7 working days, and take prompt measures to ensure that the individual is unable to obtain the security plan, implementing procedures, or the list of individuals that have been approved for unescorted access.

12.12.4.7 When not in use, the licensee shall store its security plan, implementing procedures, and the list of individuals that have been approved for unescorted access in a manner to prevent unauthorized access. Information stored in nonremovable electronic form must be password protected.

12.12.4.8 The licensee shall retain as a record for 3 years after the document is no longer needed:

12.12.4.8.1 A copy of the information protection procedures; and

12.12.4.8.2 The list of individuals approved for access to the security plan, implementing procedures, or the list of individuals that have been approved for unescorted access.

HISTORY: Added by State Register Volume 38, Issue No. 10, Doc. No. 4462, eff October 24, 2014. Amended by SCSR 42–2 Doc. No. 4791, eff February 23, 2018; SCSR 45–5 Doc. No. 5036, eff May 28, 2021.

RHA 12.13. LLEA coordination.

12.13.1 A licensee subject to Subpart C shall coordinate, to the extent practicable, with an LLEA for responding to threats to the licensee's facility, including any necessary armed response. The information provided to the LLEA must include:

12.13.1.1 A description of the facilities and the Category 1 and Category 2 quantities of radioactive materials along with a description of the licensee's security measures that have been implemented to comply with Subpart C; and

12.13.1.2 A notification that the licensee will request a timely armed response by the LLEA to any actual or attempted theft, sabotage, or diversion of Category 1 or Category 2 quantities of material.

12.13.2 The licensee shall notify the Department within 3 business days if:

12.13.2.1 The LLEA has not responded to the request for coordination within 60 days of the coordination request; or

12.13.2.2 The LLEA notifies the licensee that the LLEA does not plan to participate in coordination activities.

12.13.3 The licensee shall document its efforts to coordinate with the LLEA. The documentation must be kept for 3 years.

12.13.4 The licensee shall coordinate with the LLEA at least every 12 months, or when changes to the facility design or operation adversely affect the potential vulnerability of the licensee's material to theft, sabotage, or diversion.

HISTORY: Added by State Register Volume 38, Issue No. 10, Doc. No. 4462, eff October 24, 2014.

RHA 12.14. Security zones.

12.14.1 Licensees shall ensure that all aggregated Category 1 and Category 2 quantities of radioactive material are used or stored within licensee established security zones. Security zones may be permanent or temporary.

12.14.2 Temporary security zones must be established as necessary to meet the licensee's transitory or intermittent business activities, such as periods of maintenance, source delivery, and source replacement.

12.14.3 Security zones must, at a minimum, allow unescorted access only to approved individuals through:

12.14.3.1 Isolation of Category 1 and Category 2 quantities of radioactive materials by the use of continuous physical barriers that allow access to the security zone only through established access control points. A physical barrier is a natural or man-made structure or formation sufficient for the isolation of the Category 1 or Category 2 quantities of radioactive material within a security zone; or

12.14.3.2 Direct control of the security zone by approved individuals at all times; or

12.14.3.3 A combination of continuous physical barriers and direct control.

12.14.4 For Category 1 quantities of radioactive material during periods of maintenance, source receipt, preparation for shipment, installation, or source removal or exchange, the licensee shall, at a minimum, provide sufficient individuals approved for unescorted access to maintain continuous surveillance of sources in temporary security zones and in any security zone in which physical barriers or intrusion detection systems have been disabled to allow such activities.

12.14.5 Individuals not approved for unescorted access to Category 1 or Category 2 quantities of radioactive material must be escorted by an approved individual when in a security zone.

HISTORY: Added by State Register Volume 38, Issue No. 10, Doc. No. 4462, eff October 24, 2014.

RHA 12.15. Monitoring, detection, and assessment.

12.15.1 Monitoring and detection.

12.15.1.1 Licensees shall establish and maintain the capability to continuously monitor and detect without delay all unauthorized entries into its security zones. Licensees shall provide the means to maintain continuous monitoring and detection capability in the event of a loss of the primary power source, or provide for an alarm and response in the event of a loss of this capability to continuously monitor and detect unauthorized entries.

12.15.1.2 Monitoring and detection must be performed by:

12.15.1.2.1 A monitored intrusion detection system that is linked to an onsite or offsite central monitoring facility; or

12.15.1.2.2 Electronic devices for intrusion detection alarms that will alert nearby facility personnel; or

12.15.1.2.3 A monitored video surveillance system; or

12.15.1.2.4 Direct visual surveillance by approved individuals located within the security zone; or

12.15.1.2.5 Direct visual surveillance by a licensee designated individual located outside the security zone.

12.15.1.3 A licensee subject to Subpart C shall also have a means to detect unauthorized removal of the radioactive material from the security zone. This detection capability must provide:

12.15.1.3.1 For Category 1 quantities of radioactive material, immediate detection of any attempted unauthorized removal of the radioactive material from the security zone. Such immediate detection capability must be provided by:

12.15.1.3.1.1 Electronic sensors linked to an alarm; or

12.15.1.3.1.2 Continuous monitored video surveillance; or

12.15.1.3.1.3 Direct visual surveillance.

12.15.1.3.2 For Category 2 quantities of radioactive material, weekly verification through physical checks, tamper indicating devices, use, or other means to ensure that the radioactive material is present.

12.15.2 Assessment. Licensees shall immediately assess each actual or attempted unauthorized entry into the security zone to determine whether the unauthorized access was an actual or attempted theft, sabotage, or diversion.

12.15.3 Personnel communications and data transmission. For personnel and automated or electronic systems supporting the licensee's monitoring, detection, and assessment systems, licensees shall:

12.15.3.1 Maintain continuous capability for personnel communication and electronic data transmission and processing among site security systems; and

12.15.3.2 Provide an alternative communication capability for personnel, and an alternative data transmission and processing capability, in the event of a loss of the primary means of communication or data transmission and processing. Alternative communications and data transmission systems may not be subject to the same failure modes as the primary systems.

12.15.4 Response. Licensees shall immediately respond to any actual or attempted unauthorized access to the security zones, or actual or attempted theft, sabotage, or diversion of Category 1 or Category 2 quantities of radioactive material at licensee facilities or temporary job sites. For any unauthorized access involving an actual or attempted theft, sabotage, or diversion of Category 1 or Category 2 quantities of radioactive material, the licensee's response shall include requesting, without delay, an armed response from the LLEA.

HISTORY: Added by State Register Volume 38, Issue No. 10, Doc. No. 4462, eff October 24, 2014.

RHA 12.16. Maintenance and testing.

12.16.1 Each licensee subject to Subpart C shall implement a maintenance and testing program to ensure that intrusion alarms, associated communication systems, and other physical components of the systems used to secure or detect unauthorized access to radioactive material are maintained in operable condition and are capable of performing their intended function when needed. The equipment relied on to meet the security requirements of this part must be inspected and tested for operability and performance at the manufacturer's suggested frequency. If there is no suggested manufacturer's suggested frequency, the testing must be performed at least annually, not to exceed 12 months.

12.16.2 The licensee shall maintain records on the maintenance and testing activities for 3 years.

HISTORY: Added by State Register Volume 38, Issue No. 10, Doc. No. 4462, eff October 24, 2014.

RHA 12.17. Requirements for mobile devices.

Each licensee that possesses mobile devices containing Category 1 or Category 2 quantities of radioactive material must:

12.17.1 Have two independent physical controls that form tangible barriers to secure the material from unauthorized removal when the device is not under direct control and constant surveillance by the licensee; and

12.17.2 For devices in or on a vehicle or trailer, unless the health and safety requirements for a site prohibit the disabling of the vehicle, the licensee shall utilize a method to disable the vehicle or trailer when not under direct control and constant surveillance by the licensee. Licensees shall not rely on the removal of an ignition key to meet this requirement.

HISTORY: Added by State Register Volume 38, Issue No. 10, Doc. No. 4462, eff October 24, 2014.

RHA 12.18. Security program review.

12.18.1 Each licensee shall be responsible for the continuing effectiveness of the security program. Each licensee shall ensure that the security program is reviewed to confirm compliance with the requirements of Subpart C and that comprehensive actions are taken to correct any noncompliance that is identified. The review must include the radioactive material security program content and implementation. Each licensee shall periodically (at least annually) review the security program content and implementation.

12.18.2 The results of the review, along with any recommendations, must be documented. Each review report must identify conditions that are adverse to the proper performance of the security program, the cause of the condition(s), and, when appropriate, recommend corrective actions, and corrective actions taken. The licensee shall review the findings and take any additional corrective actions necessary to preclude repetition of the condition, including reassessment of the deficient areas where indicated.

12.18.3 The licensee shall maintain the review documentation for 3 years.

HISTORY: Added by State Register Volume 38, Issue No. 10, Doc. No. 4462, eff October 24, 2014.

RHA 12.19. Reporting of events.

12.19.1 The licensee shall immediately notify the LLEA after determining that an unauthorized entry resulted in an actual or attempted theft, sabotage, or diversion of a Category 1 or Category 2 quantity of radioactive material. As soon as possible after initiating a response, but not at the expense of causing delay or interfering with the LLEA response to the event, the licensee shall notify the Department. In no case shall the notification to the Department be later than 4 hours after the discovery of any attempted or actual theft, sabotage, or diversion.

12.19.2 The licensee shall assess any suspicious activity related to possible theft, sabotage, or diversion of Category 1 or Category 2 quantities of radioactive material and notify the LLEA as appropriate. As soon as possible but not later than 4 hours after notifying the LLEA, the licensee shall notify the Department.

12.19.3 The initial telephonic notification required by RHA 12.19.1 must be followed within a period of 30 days by a written report submitted to the Department. The report must include sufficient information for Department analysis and evaluation, including identification of any necessary corrective actions to prevent future instances.

HISTORY: Added by State Register Volume 38, Issue No. 10, Doc. No. 4462, eff October 24, 2014.

SUBPART D
Physical Protection in Transit

RHA 12.20. Additional requirements for transfer of Category 1 and Category 2 quantities of radioactive material.

A licensee transferring a Category 1 or Category 2 quantity of radioactive material to a licensee of the Department shall meet the license verification provisions listed below instead of those listed in RHA 2.18.4:

12.20.1 Any licensee transferring Category 1 quantities of radioactive material to a licensee of the Department, U.S. Nuclear Regulatory Commission, or an Agreement State, prior to conducting such transfer, shall verify with the NRC's license verification system or the license issuing authority that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred and that the licensee is authorized to receive radioactive material at the location requested for delivery. If the verification is conducted by contacting the license issuing authority, the transferor shall document the verification. For transfers within the same organization, the licensee does not need to verify the transfer.

12.20.2 Any licensee transferring Category 2 quantities of radioactive material to a licensee of the Department, U.S. Nuclear Regulatory Commission, or an Agreement State, prior to conducting such transfer, shall verify with the NRC's license verification system or the license issuing authority that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred. If the verification is conducted by contacting the license issuing authority, the transferor

shall document the verification. For transfers within the same organization, the licensee does not need to verify the transfer.

12.20.3 In an emergency where the licensee cannot reach the license issuing authority and the license verification system is nonfunctional, the licensee may accept a written certification by the transferee that it is authorized by license to receive the type, form, and quantity of radioactive material to be transferred. The certification must include the license number, current revision number, issuing agency, expiration date, and for a Category 1 shipment the authorized address. The licensee shall keep a copy of the certification. The certification must be confirmed by use of the NRC's license verification system or by contacting the license issuing authority by the end of the next business day.

12.20.4 The transferor shall keep a copy of the verification documentation as a record for 3 years.

HISTORY: Added by State Register Volume 38, Issue No. 10, Doc. No. 4462, eff October 24, 2014.

RHA 12.21. Applicability of physical protection of Category 1 and Category 2 quantities of radioactive material during transit.

The shipping licensee shall be responsible for meeting the requirements of Subpart D unless the receiving licensee has agreed in writing to arrange for the in-transit physical protection required under Subpart D.

HISTORY: Added by State Register Volume 38, Issue No. 10, Doc. No. 4462, eff October 24, 2014.

RHA 12.22. Preplanning and coordination of shipment of Category 1 or Category 2 quantities of radioactive material.

12.22.1 Each licensee that plans to transport, or deliver to a carrier for transport, licensed material that is a Category 1 quantity of radioactive material outside the confines of the licensee's facility or other place of use or storage shall:

12.22.1.1 Preplan and coordinate shipment arrival and departure times with the receiving licensee;

12.22.1.2 Preplan and coordinate shipment information with the governor or the governor's designee of any State through which the shipment will pass to:

12.22.1.2.1 Discuss the State's intention to provide law enforcement escorts; and

12.22.1.2.2 Identify safe havens; and

12.22.1.3 Document the preplanning and coordination activities.

12.22.2 Each licensee that plans to transport, or deliver to a carrier for transport, licensed material that is a Category 2 quantity of radioactive material outside the confines of the licensee's facility or other place of use or storage shall coordinate the shipment no-later-than arrival time and the expected shipment arrival with the receiving licensee. The licensee shall document the coordination activities.

12.22.3 Each licensee who receives a shipment of a Category 2 quantity of radioactive material shall confirm receipt of the shipment with the originator. If the shipment has not arrived by the no-later-than arrival time, the receiving licensee shall notify the originator.

12.22.4 Each licensee, who transports or plans to transport a shipment of a Category 2 quantity of radioactive material, and determines that the shipment will arrive after the no-later than arrival time provided pursuant to RHA 12.22.2, shall promptly notify the receiving licensee of the new no-later-than arrival time.

12.22.5 The licensee shall retain a copy of the documentation for preplanning and coordination and any revision thereof, as a record for 3 years.

HISTORY: Added by State Register Volume 38, Issue No. 10, Doc. No. 4462, eff October 24, 2014.

RHA 12.23. Advance notification of shipment of Category 1 quantities of radioactive material.

As specified in RHA 12.23.1 and 12.23.2, each licensee shall provide advance notification to the Department and the governor of a State, or the governor's designee, of the shipment of licensed material in a Category 1 quantity, through or across the boundary of the State, before the transport, or

delivery to a carrier for transport of the licensed material outside the confines of the licensee's facility or other place of use or storage.

12.23.1 Procedures for submitting advance notification.

12.23.1.1 The notification must be made to the Department and to the office of each appropriate governor or governor's designee. The contact information, including telephone numbers and mailing addresses, of governors and governors' designees, is available on the NRC's Web site at https://scp.nrc.gov/special/designee.pdf. A list of the contact information is also available upon request from the Director, Division of Materials Safety, Security, State, and Tribal Programs, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. The notification to the Department may be made by email to RAMQC_shipments@dhec.sc.gov or by fax to 803–898–0391. Notifications to the Department must be to the Director, Division of Land & Waste Management, Bureau of Waste Management, 2600 Bull Street, Columbia, SC 29201.

12.23.1.2 A notification delivered by mail must be postmarked at least 7 days before transport of the shipment commences at the shipping facility.

12.23.1.3 A notification delivered by any means other than mail must reach the Department at least 4 days before the transport of the shipment commences and must reach the office of the governor or the governor's designee at least 4 days before transport of a shipment within or through the State.

12.23.2 Information to be furnished in advance notification of shipment.

Each advance notification of shipment of Category 1 quantities of radioactive material must contain the following information, if available at the time of notification:

12.23.2.1 The name, address, and telephone number of the shipper, carrier, and receiver of the Category 1 radioactive material;

12.23.2.2 The license numbers of the shipper and receiver;

12.23.2.3 A description of the radioactive material contained in the shipment, including the radionuclides and quantity;

12.23.2.4 The point of origin of the shipment and the estimated time and date that shipment will commence;

12.23.2.5 The estimated time and date that the shipment is expected to enter each State along the route;

12.23.2.6 The estimated time and date of arrival of the shipment at the destination; and

12.23.2.7 A point of contact, with a telephone number, for current shipment information.

12.23.3 Revision notice.

12.23.3.1 The licensee shall provide any information not previously available at the time of the initial notification, as soon as the information becomes available but not later than commencement of the shipment, to the governor of the State or the governor's designee, and to the Department.

12.23.3.2 A licensee shall promptly notify the governor of the State or the governor's designee of any changes to the information provided in accordance with RHA 12.23.2 and 12.23.3.1 of this section. The licensee shall also immediately notify the Department of any such changes.

12.23.4 Cancellation notice. Each licensee who cancels a shipment for which advance notification has been sent shall send a cancellation notice to the governor of each State or to the governor's designee previously notified and to the Department. The licensee shall send the cancellation notice before the shipment would have commenced or as soon thereafter as possible. The licensee shall state in the notice that it is a cancellation and identify the advance notification that is being cancelled.

12.23.5 Records. The licensee shall retain a copy of the advance notification and any revision and cancellation notices as a record for 3 years.

12.23.6 Protection of information. State officials, State employees, and other individuals, whether or not licensees of the Commission or an Agreement State, who receive schedule information of the

kind specified in RHA 12.23.2 shall protect that information against unauthorized disclosure as specified in RHA 12.12.4 of this part.

HISTORY: Added by State Register Volume 38, Issue No. 10, Doc. No. 4462, eff October 24, 2014. Amended by SCSR 42–2 Doc. No. 4791, eff February 23, 2018; SCSR 45–5 Doc. No. 5036, eff May 28, 2021.

RHA 12.24. Requirements for physical protection of Category 1 and Category 2 quantities of radioactive material during shipment.

12.24.1 Shipments by road.

12.24.1.1 Each licensee who transports, or delivers to a carrier for transport, in a single shipment, a Category 1 quantity of radioactive material shall:

12.24.1.1.1 Ensure that movement control centers are established that maintain position information from a remote location. These control centers must monitor shipments 24 hours a day, 7 days a week, and have the ability to communicate immediately, in an emergency, with the appropriate law enforcement agencies.

12.24.1.1.2 Ensure that redundant communications are established that allow the transport to contact the escort vehicle (when used) and movement control center at all times. Redundant communications may not be subject to the same interference factors as the primary communication.

12.24.1.1.3 Ensure that shipments are continuously and actively monitored by a telemetric position monitoring system or an alternative tracking system reporting to a movement control center. A movement control center must provide positive confirmation of the location, status, and control over the shipment. The movement control center must be prepared to promptly implement preplanned procedures in response to deviations from the authorized route or a notification of actual, attempted, or suspicious activities related to the theft, loss, or diversion of a shipment. These procedures will include, but not be limited to, the identification of and contact information for the appropriate LLEA along the shipment route.

12.24.1.1.4 Provide an individual to accompany the driver for those highway shipments with a driving time period greater than the maximum number of allowable hours of service in a 24-hour duty day as established by the Department of Transportation Federal Motor Carrier Safety Administration. The accompanying individual may be another driver.

12.24.1.1.5 Develop written normal and contingency procedures to address:

12.24.1.1.5.1 Notifications to the communication center and law enforcement agencies;

12.24.1.1.5.2 Communication protocols. Communication protocols must include a strategy for the use of authentication codes and duress codes and provisions for refueling or other stops, detours, and locations where communication is expected to be temporarily lost;

12.24.1.1.5.3 Loss of communications; and

12.24.1.1.5.4 Responses to an actual or attempted theft or diversion of a shipment.

12.24.1.1.6 Each licensee who makes arrangements for the shipment of Category 1 quantities of radioactive material shall ensure that drivers, accompanying personnel, and movement control center personnel have access to the normal and contingency procedures.

12.24.1.2 Each licensee that transports Category 2 quantities of radioactive material shall maintain constant control and/or surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance.

12.24.1.3 Each licensee who delivers to a carrier for transport, in a single shipment, a Category 2 quantity of radioactive material shall:

12.24.1.3.1 Use carriers that have established package tracking systems. An established package tracking system is a documented, proven, and reliable system routinely used to transport objects of value. In order for a package tracking system to maintain constant control and/or surveillance, the package tracking system must allow the shipper or transporter to identify when anywhere the package was last and when it should arrive at the next point of control.

12.24.1.3.2 Use carriers that maintain constant control and/or surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance; and

12.24.1.3.3 Use carriers that have established tracking systems that require an authorized signature prior to releasing the package for delivery or return.

12.24.2 Shipments by rail.

12.24.2.1 Each licensee who transports, or delivers to a carrier for transport, in a single shipment, a Category 1 quantity of radioactive material shall:

12.24.2.1.1 Ensure that rail shipments are monitored by a telemetric position monitoring system or an alternative tracking system reporting to the licensee, third-party, or railroad communications center. The communications center shall provide positive confirmation of the location of the shipment and its status. The communications center shall implement preplanned procedures in response to deviations from the authorized route or to a notification of actual, attempted, or suspicious activities related to the theft or diversion of a shipment. These procedures will include, but not be limited to, the identification of and contact information for the appropriate LLEA along the shipment route.

12.24.2.1.2 Ensure that periodic reports to the communications center are made at preset intervals.

12.24.2.2 Each licensee who transports, or delivers to a carrier for transport, in a single shipment, a Category 2 quantity of radioactive material shall:

12.24.2.2.1 Use carriers that have established package tracking systems. An established package tracking system is a documented, proven, and reliable system routinely used to transport objects of value. In order for a package tracking system to maintain constant control and/or surveillance, the package tracking system must allow the shipper or transporter to identify when and where the package was last and when it should arrive at the next point of control.

12.24.2.2.2 Use carriers that maintain constant control and/or surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance; and

12.24.2.2.3 Use carriers that have established tracking systems that require an authorized signature prior to releasing the package for delivery or return.

12.24.3 Investigations. Each licensee who makes arrangements for the shipment of Category 1 quantities of radioactive material shall immediately conduct an investigation upon the discovery that a Category 1 shipment is lost or missing. Each licensee who makes arrangements for the shipment of Category 2 quantities of radioactive material shall immediately conduct an investigation, in coordination with the receiving licensee, of any shipment that has not arrived by the designated no-later-than arrival time.

HISTORY: Added by State Register Volume 38, Issue No. 10, Doc. No. 4462, eff October 24, 2014.

RHA 12.25. Reporting of events.

12.25.1 The shipping licensee shall notify the appropriate LLEA and the Department within 1 hour of its determination that a shipment of Category 1 quantities of radioactive material is lost or missing. The appropriate LLEA would be the law enforcement agency in the area of the shipment's last confirmed location. During the investigation required by RHA 12.24.3, the shipping licensee will provide agreed upon updates to the Department on the status of the investigation.

12.25.2 The shipping licensee shall notify the Department within 4 hours of its determination that a shipment of Category 2 quantities of radioactive material is lost or missing. If, after 24 hours of its determination that the shipment is lost or missing, the radioactive material has not been located and secured, the licensee shall immediately notify the Department.

12.25.3 The shipping licensee shall notify the designated LLEA along the shipment route as soon as possible upon discovery of any actual or attempted theft or diversion of a shipment or suspicious activities related to the theft or diversion of a shipment of a Category 1 quantity of radioactive material. As soon as possible after notifying the LLEA, the licensee shall notify the Department upon discovery

of any actual or attempted theft or diversion of a shipment, or any suspicious activity related to the shipment of Category 1 radioactive material.

12.25.4 The shipping licensee shall notify the Department as soon as possible upon discovery of any actual or attempted theft or diversion of a shipment, or any suspicious activity related to the shipment, of a Category 2 quantity of radioactive material.

12.25.5 The shipping licensee shall notify the Department and the LLEA as soon as possible upon recovery of any lost or missing Category 1 quantities of radioactive material.

12.25.6 The shipping licensee shall notify the Department as soon as possible upon recovery of any lost or missing Category 2 quantities of radioactive material.

12.25.7 The initial telephonic notification required by paragraphs RHA 12.25.1 through 12.25.4 must be followed within a period of 30 days by a written report submitted to the Department. A written report is not required for notifications on suspicious activities required by RHA 12.25.3 and 12.25.4. The report must set forth the following information:

12.25.7.1 A description of the licensed material involved, including kind, quantity, and chemical and physical form;

12.25.7.2 A description of the circumstances under which the loss or theft occurred;

12.25.7.3 A statement of disposition, or probable disposition, of the licensed material involved;

12.25.7.4 Actions that have been taken, or will be taken, to recover the material; and

12.25.7.5 Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed material.

12.25.7.6 Subsequent to filing the written report, the licensee shall also report any additional substantive information on the loss or theft within 30 days after the licensee learns of such information.

HISTORY: Added by State Register Volume 38, Issue No. 10, Doc. No. 4462, eff October 24, 2014.

SUBPART E
Records

RHA 12.26. Form of records.

Each record required by this part must be legible throughout the retention period specified by each Department regulation. The record may be the original or a reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

HISTORY: Added by State Register Volume 38, Issue No. 10, Doc. No. 4462, eff October 24, 2014.

RHA 12.27. Record retention.

Licensees shall maintain the records that are required by the regulations in this part for the period specified by the appropriate regulation. If a retention period is not otherwise specified, these records must be retained until the Department terminates the facility's license. All records related to this part may be destroyed upon Department termination of the facility license.

HISTORY: Added by State Register Volume 38, Issue No. 10, Doc. No. 4462, eff October 24, 2014.

Appendix A. Category 1 and Category 2 Radioactive Materials.

Table 1—Category 1 and Category 2 Threshold

Radioactive material	Category 1(TBq)	Category 1 (Ci)	Category 2 (TBq)	Category 2 (Ci)
Americium-241	60	1,620	0.6	16.2
Americium-241/Be	60	1,620	0.6	16.2
Californium-252	20	540	0.2	5.40

Radioactive material	Category 1(TBq)	Category 1 (Ci)	Category 2 (TBq)	Category 2 (Ci)
Cobalt-60	30	810	0.3	8.10
Curium-244	50	1,350	0.5	13.5
Cesium-137	100	2,700	1	27.0
Gadolinium-153	1,000	27,000	10	270
Iridium-192	80	2,160	0.8	21.6
Plutonium-238	60	1,620	0.6	16.2
Plutonium-239/Be	60	1,620	0.6	16.2
Promethium-147	40,000	1,080,000	400	10,800
Radium-226	40	1,080	0.4	10.8
Selenium-75	200	5,400	2	54.0
Strontium-90	1,000	27,000	10	270
Thulium-170	20,000	540,000	200	5,400
Ytterbium-169	300	8,100	3	81.0

**The terabecquerel (TBq) values are the regulatory standard. The curie (Ci) values specified are obtained by converting from the TBq value. The curie values are provided for practical usefulness only.

Note: ***Calculations Concerning Multiple Sources or Multiple Radionuclides***

The "sum of fractions" methodology for evaluating combinations of multiple sources or multiple radionuclides is to be used in determining whether a location meets or exceeds the threshold and is thus subject to the requirements of this part.

I. If multiple sources of the same radionuclide and/or multiple radionuclides are aggregated at a location, the sum of the ratios of the total activity of each of the radionuclides must be determined to verify whether the activity at the location is less than the Category 1 or Category 2 thresholds of Table 1, as appropriate. If the calculated sum of the ratios, using the equation below, is greater than or equal to 1.0, then the applicable requirements of this part apply.

II. First determine the total activity for each radionuclide from Table 1. This is done by adding the activity of each individual source, material in any device, and any loose or bulk material that contains the radionuclide. Then use the equation below to calculate the sum of the ratios by inserting the total activity of the applicable radionuclides from Table 1 in the numerator of the equation and the corresponding threshold activity from Table 1 in the denominator of the equation. Calculations must be performed in metric values (i.e., TBq) and the numerator and denominator values must be in the same units.

R_1 = total activity for radionuclide 1

R_2 = total activity for radionuclide 2

R_n = total activity for radionuclide n

AR_1 = activity threshold for radionuclide 1

AR_2 = activity threshold for radionuclide 2

AR_n = activity threshold for radionuclide n

$$\sum_{1}^{n}\left[\frac{R_1}{AR_1}+\frac{R_2}{AR_2}+\frac{R_n}{AR_n}\right]\geq 1.0$$

HISTORY: Added by State Register Volume 38, Issue No. 10, Doc. No. 4462, eff October 24, 2014.