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**DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL**

CHAPTER 61

Statutory Authority: 1976 Code Section 13‑7‑70

61‑63. Radioactive Materials (Title A).

**Synopsis:**

The federal Atomic Energy Act of 1954 enables the United States Nuclear Regulatory Commission (“Commission”) to enter into agreements with state governors allowing for state regulation of byproduct, source, and special nuclear material. 42 U.S.C. Section 2121. The Commission enters into such agreements if it finds the state regulatory program complies with applicable federal regulations. *Id*. To renew South Carolina’s ongoing agreement with the Commission, the Department of Health and Environmental Control (“Department”) amends R.61‑63 for compliance with the Commission’s federal regulatory updates. The amendments add clarifications or corrections to Part II of the regulation. Additionally, the amendments authorize the Department to review their general licensees’ quality assurance program for the use of Commission‑approved Type B packaging for transportation of radioactive material as required in NRC Regulation Title 10, Code of Federal Regulation (“CFR”) Part 71.

The Administrative Procedures Act, S.C. Code Section 1‑23‑120(H)(1), exempts these amendments from General Assembly review, as the Department promulgates these amendments for compliance with federal law.

The Department had a Notice of Drafting published in the October 25, 2019, *South Carolina State Register*.

**Instructions:**

Amend R.61-63 pursuant to each individual instruction provided with the text of the amendments below.

**Text:**

61‑63. Radioactive Materials (Title A).

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

**Add 2.22.5 and subparagraphs 2.22.5.1 through 2.22.5.5 as shown.**

 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.

**Add 2.22.6 and subparagraphs 2.22.6.1 through 2.22.6.4.2 as shown.**

 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.

**Add 2.22.7 and subparagraphs 2.22.7.1 through 2.22.7.2 as shown.**

 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.

**Add 2.22.8 and subparagraphs 2.22.8.1 through 2.22.8.3 as shown.**

 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.

**Add 2.22.9 and subparagraph 2.22.9.1.**

 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.

**Add 2.22.10 and subparagraphs 2.22.10.1 through 2.22.10.3 as shown.**

 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.

**Add 2.22.11 and subparagraph 2.22.11.1 as shown.**

 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.

**Statement of Need and Reasonableness:**

The following presents an analysis of the factors listed in 1976 Code Sections 1‑23‑115(C)(1)‑(3) and (9)‑(11):

DESCRIPTION OF REGULATION: 61‑63, Radioactive Materials (Title A).

Purpose: The Department amends R.61‑63 for compliance with federal regulatory updates to 10 CFR Part 71. The Department promulgates these amendments in order to renew South Carolina’s ongoing agreement with the Commission.

Legal Authority: 1976 Code Section 13‑7‑70.

Plan for Implementation: Upon taking legal effect, Department personnel will take appropriate steps to inform the regulated community of the amendments and any associated information. The DHEC Regulation Development Update (accessible at http://www.scdhec.gov/Agency/RegulationsAndUpdates/RegulationDevelopmentUpdate/) provides a summary of and link to these amendments. Additionally, printed copies are available for a fee from the Department’s Freedom of Information Office.

DETERMINATION OF NEED AND REASONABLENESS OF THE REGULATION BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFITS:

The Department amends R.61‑63 for compliance with the Commission’s federal regulatory updates. The federal Atomic Energy Act of 1954 enables the Commission to enter into agreements with state governors allowing for state regulation of byproduct, source, and special nuclear material. 42 U.S.C. Section 2121. The Commission enters into such agreements if it finds the state regulatory program complies with applicable federal regulations. The amendments are needed in order to renew South Carolina’s ongoing agreement with the Commission. The amendments are beneficial in that they ensure state oversight of required standards.

DETERMINATION OF COSTS AND BENEFITS:

Neither the state nor its political subdivisions will incur additional cost through implementation of this amendment. Existing staff and resources will be utilized to implement this amendment to the regulation. The amendment will not create any significant additional cost to the regulated community since requirements or changes to the regulations will be substantially consistent with the current guidelines and review guidelines utilized by the Department.

UNCERTAINTIES OF ESTIMATES:

None.

EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH:

These amendments seek to ensure an effective regulatory program for radioactive material users under state jurisdiction and protection of the public and worker from unnecessary exposure to ionizing radiation.

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATION IS NOT IMPLEMENTED:

None. Federal requirements will apply to all affected users. The amendments eliminate possible duplicative or redundant requirements.