SOUTH CAROLINA STATE REGISTER DISCLAIMER

SOUTH CAROLINA STATE REGISTER

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This issue contains notices, proposed regulations, emergency regulations, final form regulations, and other documents filed in the Office of the Legislative Council, pursuant to Article 1, Chapter 23, Title 1, Code of Laws of South Carolina, 1976.

South Carolina State Register

An official state publication, the *South Carolina State Register* is a temporary update to South Carolina's official compilation of agency regulations--the *South Carolina Code of Regulations*. Changes in regulations, whether by adoption, amendment, repeal or emergency action must be published in the *State Register* pursuant to the provisions of the Administrative Procedures Act. The *State Register* also publishes the Governor's Executive Orders, notices or public hearings and meetings, and other documents issued by state agencies considered to be in the public interest. All documents published in the *State Register* are drafted by state agencies and are published as submitted. Publication of any material in the *State Register* is the official notice of such information.

STYLE AND FORMAT

Documents are arranged within each issue of the *State Register* according to the type of document filed:

Notices are documents considered by the agency to have general public interest.
Notices of Drafting Regulations give interested persons the opportunity to comment during the initial drafting period before regulations are submitted as proposed.
Proposed Regulations are those regulations pending permanent adoption by an agency.
Pending Regulations Submitted to the General Assembly are regulations adopted by the agency pending approval by the General Assembly.
Final Regulations have been permanently adopted by the agency and approved by the General Assembly.
Emergency Regulations have been adopted on an emergency basis by the agency.
Executive Orders are actions issued and taken by the Governor.

2005 PUBLICATION SCHEDULE

Documents will be accepted for filing on any normal business day from 8:30 A.M. until 5:00 P.M. All documents must be submitted in the format prescribed in the *Standards Manual for Drafting and Filing Regulations.*

To be included for publication in the next issue of the *State Register*, documents will be accepted no later than 5:00 P.M. on any closing date. The modification or withdrawal of documents filed for publication must be made **by 5:00 P.M.** on the closing date for that issue.

	Jan.	Feb.	Mar.	Apr.	May	June	July	Aug.	Sept.	Oct.	Nov.	Dec.
Submission Deadline	1/14	2/11	3/11	4/8	5/13	6/10	7/8	8/12	9/9	10/14	11/11	12/9
Publishing Date	1/28	2/25	3/25	4/22	5/27	6/24	7/22	8/26	9/23	10/28	11/25	12/23

REPRODUCING OFFICIAL DOCUMENTS

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ADOPTION, AMENDMENT AND REPEAL OF REGULATIONS

To adopt, amend or repeal a regulation, an agency must publish in the *State Register* a Notice of Drafting; a Notice of the Proposed Regulation that contains an estimate of the proposed action's economic impact; and, a notice that gives the public an opportunity to comment on the proposal. If requested by twenty-five persons, a public hearing must be held at least thirty days after the date of publication of the notice in the *State Register*.

After the date of hearing, the regulation must be submitted to the General Assembly for approval. The General Assembly has one hundred twenty days to consider the regulation. If no legislation is introduced to disapprove or enacted to approve before the expiration of the one-hundred-twenty-day review period, the regulation is approved on the one hundred twentieth day and is effective upon publication in the *State Register*.

EMERGENCY REGULATIONS

An emergency regulation may be promulgated by an agency if the agency finds imminent peril to public health, safety or welfare. Emergency regulations are effective upon filing for a ninety-day period. If the original filing began and expired during the legislative interim, the regulation can be renewed once.

REGULATIONS PROMULGATED TO COMPLY WITH FEDERAL LAW

Regulations promulgated to comply with federal law are exempt from General Assembly review. Following the notice of proposed regulation and hearing, regulations are submitted to the *State Register* and are effective upon publication.

EFFECTIVE DATE OF REGULATIONS

Final Regulations take effect on the date of publication in the *State Register* unless otherwise noted within the text of the regulation.
Emergency Regulations take effect upon filing with the Legislative Council and remain effective for ninety days. If the original ninety-day period begins and expires during legislative interim, the regulation may be refiled for one additional ninety-day period.

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2890		SR29-2	Chapter Revisions	1/17/05	LLR: Manufactured Housing Board
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2005-10

WHEREAS, on April 20, 2005, I received a Decision of the South Carolina State Election Commission, in its capacity as the State Board of Canvassers, upholding the Order of the Charleston County Election Commission (Charleston County Board of Elections and Voter Registration) to overturn the January 11, 2005, special election for Charleston County Council District 7 due to voting irregularities that could have changed the outcome of the election; and

WHEREAS, on April 11, 2005, the South Carolina Supreme Court denied a writ of certiorari to hear a challenge to the Decision of the South Carolina State Election Commission thereby upholding its Decision to overturn the January 11, 2005, special election; and

WHEREAS, the Charleston County Board of Elections and Voter Registration ("Board") has requested that a new election be held on Tuesday, July 19, 2005; and

WHEREAS, the Board has stated that, in requesting this date, it has complied with the notice provisions in the South Carolina Code of Laws and the pre-clearance requirements of Section 5 of the Voting Rights Act of 1965; and

WHEREAS, Section 7-13-1170 of the South Carolina Code of Laws (1976), as amended, provides "when any election official of any political subdivision of this State charged with ordering, providing for, or holding an election has neglected, failed, or refused to order, provide for, or hold the election at the time appointed, or if for any reason the election is declared void by competent authority, and these facts are made to appear to the satisfaction of the Governor, he shall, should the law not otherwise provide for this contingency, order an election or a new election to be held at the time and place, and upon the notice being given which to him appears adequate to insure the will of the electorate being fairly expressed. To that end, he may designate the existing election official or other person as he may appoint to perform the necessary official duties pertaining to the election and to declare the result."

NOW, THEREFORE, pursuant to the authority vested in me by the Constitution and Statutes of the State of South Carolina, I hereby (a) order that a new election be held for Charleston County Council District 7 on July 19, 2005, subject to pre-clearance approval by the United States Department of Justice, or at the earliest possible date and time after July 19, 2005, as is permitted by the United States Department of Justice; and (b) designate the Charleston County Board of Elections Voter Registration to perform the necessary official duties pertaining to the election to declare the result.

GIVEN UNDER MY HAND AND THE GREAT SEAL OF THE STATE OF SOUTH CAROLINA, THIS 29th DAY OF APRIL, 2005.

MARK SANFORD
Governor

2005-11

WHEREAS, by Executive Order 1989-10, a Conservation, Education and Communications Advisory Board was created upon the request of the Wildlife and Marine Resources Commission and in furtherance of the objectives of that Commission; and

WHEREAS, conditions now exist which justify the rescission of the order creating such Commission.

NOW, **THEREFORE**, by virtue of the power and authority vested in me as Governor, pursuant to the Constitution and Statutes of the State of South Carolina, I hereby declare that Executive Order 1989-10 is cancelled, rescinded, and from this date declared null and void.

GIVEN UNDER MY HAND AND THE GREAT SEAL OF THE STATE OF SOUTH CAROLINA, THIS 6th DAY OF MAY 2005.

MARK SANFORD
Governor

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

Notice of General Public Interest
Public Notice #05-522-GP-N
May 27, 2005

The South Carolina Department of Health and Environmental Control (DHEC), Bureau of Air Quality, does hereby give notice of authorization being granted to the following source who has requested coverage under General Conditional Major Operating Permit (GCMP-04) "Concrete Batch Plants." This general permit was previously open for a thirty (30) day public comment period on March 28, 2001, with final issuance on November 1, 2001. Pursuant to South Carolina Regulation 61-62.1, Section II G(7)(a)&(b), DHEC may now grant coverage to any qualified sources seeking to operate under the terms and conditions of this general permit. The authorization of each facility's coverage shall be a final permit action for purposes of administrative review.

In accordance with the provisions of the Pollution Control Act, Sections 48-1-50(5) and 48-1-110(a), the 1976 Code of Laws of South Carolina, as amended, and Regulation 61-62.1 "Air Pollution Control Regulations and Standards," this sources is hereby granted permission to discharge air contaminants into the ambient air. The Bureau of Air Quality authorizes the operation of this source in accordance with the plans, specifications, and other information submitted by the facility in the General Conditional Major Permit application. Any facility operating under this permit seeks to limit its potential to emit to below the thresholds which define a major source by complying with the federally enforceable conditions contained in the permit. Permit coverage is subject to and conditioned upon the terms, limitations, standards, and schedules contained in or specified on said permit.

Interested persons may review the final general permit, materials submitted by the applicant, and any written comments received, during normal business hours, at the following location: SC DHEC, Bureau of Air Quality, 2600 Bull Street, Columbia, South Carolina, 29201 at (803) 898-4123.

This notice is given pursuant to the requirements of South Carolina Regulation 61-62.1, Section II G(7)(c). Comments and questions concerning the following facility's coverage under this permit should be directed to: Mr. Carl W. Richardson, P.E., Director, Engineering Services Division, Bureau of Air Quality, SC DHEC, 2600 Bull Street, Columbia, South Carolina, 29201 at (803) 898-4123.

Anderson County

Mark Twain Redi-Mix, Inc.
110 Highview Road
Williamston, South Carolina
(Permit No. GCM04-9900-0453)

DEPARTMENT OF HEALTH AND ENVIRONMENAL CONTROL

NOTICE OF PROPOSED REVISION TO THE SOUTH CAROLINA STATE IMPLEMENTATION PLAN AND NOTICE OF PUBLIC HEARING

Synopsis:

The South Carolina Department of Health and Environmental Control (Department) is proposing to revise the South Carolina State Implementation Plan also referred to as the SIP. The proposed revision is being conducted in accordance with our commitments under the Early Action Compact (EAC) process. The EAC process is an

alternative to traditional nonattainment planning that allows local areas flexibility to control air emissions from their sources and offers a means to achieve cleaner air sooner than the Clean Air Act requires. In December 2002, the Department entered in compacts with the Environmental Protection Agency (EPA) and local governments for the purpose of developing ozone reduction strategies as part of the EAC process. The compacts require EAC areas to attain the 8-hour ozone standard by December 31, 2007, a date that is sooner than would otherwise be required through the traditional nonattainment designation process. The compacts include all necessary elements of a comprehensive air quality plan, but are tailored to local needs. As a result of an area's participation, the EAC process calls for EPA to recognize the area's commitment to early action by provisionally deferring the effective date of the nonattainment designation.

The EAC process sets forth a series of rolling deferrals that are contingent upon the participating area's meeting all terms and milestones of the compact. On April 30, 2004 (69 FR 23857), following the completion of the first set of milestones, EPA promulgated the first deferrals of the effective date of the nonattainment designations for eligible EAC areas. In accordance with the EAC process, the Department submitted a final EAC SIP on December 29, 2004, consisting of local plans, including all adopted control measures, and a demonstration that the areas will attain the 8-hour ozone standard by December 31, 2007. After several discussions with the EPA, the Department has made some modifications to this final EAC SIP to include maintenance plan action triggers. Therefore, the Department is proposing to amend the SIP and allow opportunity to comment on these modifications as noticed below.

Public Hearing:

Staff of the Department will conduct a public hearing to receive public comments on the proposed revision of the SIP on June 30, 2005, at 10:00 a.m. in Room 2380 of the Aycock Building, South Carolina Department of Health and Environmental Control, 2600 Bull Street, Columbia, SC. Interested members of the public are invited to attend and comment on the proposed revisions. Interested persons may also submit comments in writing to Heather Preston at the South Carolina Department of Health and Environmental Control, Bureau of Air Quality, 2600 Bull Street, Columbia, SC 29201. To be considered, comments must be received by June 30 2005, the close of the comment period.

Copies of the proposed SIP revision for public notice and comment will be available at the public hearing. Copies may also be obtained by contacting Heather Preston at the South Carolina Department of Health and Environmental Control, Bureau of Air Quality, 2600 Bull Street, Columbia, SC 29201, or by calling (803) 898-4287.

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

In accordance with Section 44-7-200(C), Code of Laws of South Carolina, the public is hereby notified that a Certificate of Need application has been accepted for filing and publication May 27, 2005, for the following project(s). After the application is deemed complete, affected persons will be notified that the review cycle has begun. For further information, please contact Mr. Albert N. Whiteside, Director, Division of Planning and Certification of Need, 2600 Bull St., Columbia, SC 29201 at (803) 545-4200.

Affecting Charleston County

Addition of one (1) fixed four (4) slice Computed Tomography (CT) scanner.
Charleston Cancer Center, LLC
Charleston, South Carolina
Project Cost: $848,140

Construction of a replacement hospital with the addition of 40 general acute care beds and four Level II Neonatal Intensive Care bassinets to include replacement of a mobile Magnetic Resonance Imaging (MRI) service with a fixed MRI unit and replacement of an existing Computed Tomography (CT) Scanner with a multi-slice CT Scanner.
East Cooper Regional Medical Center
Mt. Pleasant, South Carolina
Project Cost: $159,612,353

Replacement of a linear accelerator and retention of the old existing linear accelerator for the pediatric population and time intensive treatments.
Medical University of South Carolina Medical Center
Charleston, South Carolina
Project Cost: $1,498,721

Affecting Chesterfield County

Construction to replace one (1) single-slice Computed Tomography (CT) scanner with a multi-slice CT scanner.
Chesterfield General Hospital
Cheraw, South Carolina
Project Cost: $744,879

Affecting Clarendon County

Construction of an addition to Clarendon Memorial Hospital to house the replacement of the existing mobile 1.0T Magnetic Resonance Imaging (MRI) unit with a fixed 1.5 MRI unit and replacement of the existing fixed Single Slice Computerized Tomography (CT) scanner with a fixed Sixteen (16) slice CT scanner.
Clarendon Memorial Hospital
Manning, South Carolina
Project Cost: $4,527,197

Affecting Greenville County

Construction for the addition of seven (7) psychiatric beds, to include renovation of the lobby and administrative areas for a total of seventy-six (76) licensed psychiatric beds and 13 substance abuse beds.
UHS of Greenville, Inc.
d/b/a The Carolina Center for Behavioral Health
Greer, South Carolina
Project Cost: $1,924,970

Affecting Horry County

Purchase and installation of a linear accelerator and the development of a freestanding radiation oncology facility in an existing building adjacent to Conway Medical Center in Conway, South Carolina.
South Carolina Radiation Oncology center, LLC
Conway, South Carolina
Project Cost: $2,810,406

Affecting Lexington County

Construction for an addition of fifty-six (56) nursing home beds, that do not participate in the Medicaid (Title XIX) program, for a total of 100 licensed nursing home beds.
Agape Nursing & Rehab, Inc.
West Columbia, South Carolina
Project Cost: $3,500,000

Affecting Richland County

Addition of sixty (60) nursing home beds that do not participate in the Medicaid (Title XIX) Program for a total of one hundred eighty (180) nursing home beds.
NHC HealthCare/Parklane, LLC
Columbia, South Carolina
Project Cost: $5,027,000

Affecting York County

Renovations and replacement of equipment for the interventional angiography suite.
Piedmont Medical Center
Rock Hill, South Carolina
Project Cost: $1,632,601

Renovations and replacement of the existing four (4) Slice Computerized Tomography (CT) scanner with a sixty-four (64) Slice CT scanner.
Piedmont Medical Center
Rock Hill, South Carolina
Project Cost: $1,957,980

In accordance with S.C. DHEC Regulation 61-15, the public and affected persons are hereby notified that the review cycle has begun for the following project(s) and a proposed decision will be made within 60 days beginning May 27, 2005. "Affected persons" have 30 days from the above date to submit comments or requests for a public hearing to Mr. Albert N. Whiteside, Director, Division of Planning and Certification of Need, 2600 Bull Street, Columbia, S.C. 29201. For further information call (803) 545-4200.

Affecting Aiken County

Establish an outpatient narcotic treatment program (Methadone Treatment Center) to be located at 1740 Jefferson Davis Highway, Graniteville, SC 29829.
Aiken Treatment Associates
Graniteville, South Carolina
Project Cost: $275,258

Affecting Charleston County

Replacement of a linear accelerator and retention of the old existing linear accelerator for the pediatric population and time intensive treatments.
Medical University of South Carolina Medical Center
Charleston, South Carolina
Project Cost: $1,498,721

Affecting Clarendon County

Construction of an addition to Clarendon Memorial Hospital to house the replacement of the existing mobile 1.0T Magnetic Resonance Imaging (MRI) unit with a fixed 1.5 MRI and replacement of the existing fixed Single Slice Computerized Tomography (CT) scanner with a fixed Sixteen (16) Slice CT scanner.
Clarendon Memorial Hospital
Manning, South Carolina
Project Cost: $4,527,197

Affecting Greenville County

Construction of a new replacement hospital to include the existing fifty-eight (58) general acute care beds and the conversion of the existing ten (10) hospital based nursing home beds to acute care beds for a total of sixty-eight (68) licensed general acute care beds.
Allen Bennett Memorial Hospital
Greer, South Carolina
Project Cost: $48,500,000

Change in licensure of five (5) long-term adult psychiatric beds to short-term adult psychiatric beds for a total of 20 psychiatric beds and 68 Residential Treatment Facility (RTF) bed for children and adolescents.
SpringBrook Behavioral Health System
Travelers Rest, South Carolina
Project Cost: $-0-

Affecting Greenville County

Construction for the addition of seven (7) psychiatric beds to include renovation of the lobby and administrative areas for a total of seventy-six (76) licensed psychiatric beds and 13 substance abuse beds.
UHS of Greenville, Inc.
d/b/a The Carolina Center for Behavioral Health
Greenville, South Carolina
Project Cost: $1,924,970

Construction of a new nursing home to replace the existing 44 bed nursing home with the addition of 16 nursing home beds, which do not participate in the Medicaid (Title XIX) program, resulting in a total licensed capacity of 60 nursing home beds.
Fountain Inn Nursing Home
Fountain Inn, South Carolina
Project Cost: $3,922,205

Affecting Laurens County

Establish an outpatient narcotic treatment program (Methadone Treatment center) to be located at Lot 5, Professional Park Road, Clinton, South Carolina 29325.
Laurens Treatment Associates
Clinton, South Carolina
Project Cost: $262,000

Construction to establish an Ambulatory Surgical Facility (ASF) with two (2) operating rooms (ORs).
The Surgery & Laser Center at Professional Park, LLC
Clinton, South Carolina
Project Cost: $3,741,258

Affecting Richland County

Construction of an Ambulatory Surgery Facility (ASF) with two (2) licensed endoscopy rooms restricted to gastroenterology procedures only.
Berkeley Endoscopy Center, LLC
Columbia, South Carolina
Project Cost: $5,428,644

Addition of sixty (60) nursing home beds that do not participate in the Medicaid (Title XIX) Program for a total of one hundred eighty (180) nursing home beds.
NHC HealthCare/Parklane, LLC
Columbia, South Carolina
Project Cost: $5,027,000

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

Bureau of Land and Waste Management
Former Pontiac Bombing Range, Richland County

NOTICE OF SETTLEMENT

PLEASE TAKE NOTICE that the South Carolina Department of Health and Environmental Control ("SCDHEC") intends to enter into a Settlement Agreement with The United States Department of Defense, the United States Army (f/k/a The United States War Department), and The United States Army Corps of Engineers (referred to collectively as "the US" or "the United States"). Prior to final execution by SCDHEC, the Settlement Agreement is subject to a 30-day public comment period, consistent with the Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA") Section 122, 42 U.S.C. Section 9622 and the South Carolina Hazardous Waste Management Act ("SCHWMA") S.C. Code Ann. Section 44-56-200 (2002).

The Settlement Agreement relates to the alleged release, and threatened release, of hazardous substances, pollutants, or contaminants at the Former Pontiac Bombing Range Site (the "Site"), located in Richland County, South Carolina, in and around the vicinity of 216 Cherry Stone Drive, 200 cherry Stone Drive and 107 Cherry Stone Drive. The Settlement Agreement provides for recovery of response costs from the US in the amount of $160,000.00 for the SCDHEC's past response actions at the Site. In consideration of the foregoing, the Settlement Agreement provides for a release of the US from further liability related to the matters addressed by the Settlement Agreement and confers contribution protection upon the US pursuant to CERCLA Section 113, 42 U.S.C. Section 9613.

Notice of the proposed Settlement Agreement has been provided to all identified potentially responsible parties.

Copies of the Settlement Agreement may be obtained by providing a written Freedom of Information request to the South Carolina Department of Health and Environmental Control at:

Mr. Jody Hamm
Freedom of Information Office
South Carolina Department of Health and Environmental Control
2600 Bull Street
Columbia, SC 29201-1708

Any comments must be submitted in writing, postmarked no later than June 27, 2005, and addressed to:

Ms. Pat Vincent
Bureau of Land & Waste Management
South Carolina Department of Health and Environmental Control
2600 Bull Street
Columbia, SC 29201

UPON FINAL EXECUTION OF THE SETTLEMENT AGREEMENT, ANY AND ALL CLAIMS BY ANY AND ALL PERSONS AGAINST THE UNITED STATES SEEKING CONTRIBUTION FOR MATTERS ENCOMPASSED BY THE SETTLEMENT AGREEMENT SHALL BE FORECLOSED.

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
Bureau of Land and Waste Management
Philip Services Corporation Site, York County

NOTICE OF SETTLEMENT

PLEASE TAKE NOTICE that the South Carolina Department of Health and Environmental Control ("SCDHEC") intends to enter into a Cost Recovery Settlement Agreement with Caraustar Industrial and Consumer Products Group, Inc., the successor of Star Paper Tube, Inc. and its affiliate Rock Hill Paper Tube Plant #414 (jointly referred to as "Caraustar"). Prior to final execution by SCDHEC, the Cost Recovery Settlement Agreement is subject to a 30-day public comment period, consistent with the Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA") Section 122, 42 U.S.C. Section 9622 and the South Carolina Hazardous Waste Management Act ("SCHWMA") S.C. Code Ann. Section 44-56-200 (2002).

The Cost Recovery Settlement Agreement relates to the release, and threatened release, of hazardous substances, pollutants, or contaminants at the Philip Services Corporation Site (the "Site"), located at 2324 Vernsdale Road, Rock Hill, South Carolina. The Cost Recovery Settlement Agreement provides for recovery of response costs from Caraustar in the amount of $5,000.00. In consideration of the foregoing, the Cost Recovery Settlement Agreement provides for a release of Caraustar from further liability related to the matters covered by the Cost Recovery Settlement Agreement and confers contribution protection upon Caraustar pursuant to CERCLA Section 113, 42 U.S.C. Section 9613.

Copies of the Cost Recovery Settlement Agreement may be obtained by providing a written Freedom of Information request to the South Carolina Department of Health and Environmental Control at:

Mr. Jody Hamm
Freedom of Information Office
South Carolina Department of Health and Environmental Control
2600 Bull Street
Columbia, SC 29201-1708

Any comments must be submitted in writing, postmarked no later than June 27, 2005, and addressed to:

Ms. Pat Vincent
Bureau of Land & Waste Management
South Carolina Department of Health and Environmental Control
2600 Bull Street
Columbia, SC 29201

UPON FINAL EXECUTION OF THE COST RECOVERY SETTLEMENT AGREEMENT, ANY AND ALL CLAIMS BY ANY AND ALL PERSONS AGAINST CARAUSTAR SEEKING CONTRIBUTION FOR MATTERS ENCOMPASSED BY THE COST RECOVERY SETTLEMENT AGREEMENT SHALL BE FORECLOSED.

DEPARTMENT OF LABOR, LICENSING AND REGULATION
BUILDING CODES COUNCIL

NOTICE OF GENERAL PUBLIC INTEREST

Notice is hereby given that, in accordance with Section 6-9-40 of the 1976 Code of Laws of South Carolina, as amended, the South Carolina Building Codes Council intends to update the National Electrical Code, 2002 Edition to the National Electrical Code, 2005 Edition.

The Council specifically requests comments concerning sections of this edition, which may be unsuitable for enforcement in South Carolina. Written comments may be submitted to Gary F. Wiggins, Board Administrator, at 110 Centerview Drive, 1st Floor, Columbia, SC, 29211-1329, (803) 896-4620, on or before October 20, 2005.

The South Carolina Building Codes Council will accept comments for 180 days and, if appropriate, convene a study committee pursuant to Section 6-9-40 for the consideration of the comments regarding the 2005 Edition of the National Electrical Code.

CLEMSON UNIVERSITY

CHAPTER 27

Statutory Authority S. C. Code Section 47-4-30

Notice of Drafting:

The State Livestock-Poultry Health Commission is considering amending Regulations 27-1010, 27-1013, 27-1015 and proposing new regulations regarding required official identification of sheep and goats moving both interstate and intrastate. Interested persons should submit their views in writing to Dr. Parr, Clemson LPHD, P.O. Box 102406, Columbia, SC 29224-2406. To be considered comments should be received no later than June 27, 2005, the close of the drafting comment period.

Synopsis:

The proposed amendments and new regulations will change the requirements for official identification of sheep and goats moving interstate and intrastate to make them consistent with federal requirements for Scrapie Consistent State Status.

The amendments and regulation will require legislative action.

DEPARTMENT OF NATURAL RESOURCES

CHAPTER 123

Statutory Authority: 1976 Code Sections 50-15-30, 50-15-40, 50-15-50 and 50-15-70

Notice of Drafting:

The South Carolina Department of Natural Resources is proposing to amend the existing regulations that list endangered species and non-game species in need of management in South Carolina. The Department will also amend the existing regulation for management of non-game wildlife in South Carolina.

Any person interested may submit written comments to D. Breck Carmichael, Jr., Deputy Director, Wildlife & Freshwater Fisheries Division, S.C. Department of Natural Resources, Post Office Box 167, Columbia, SC 29202.

Synopsis:

The proposed amendments will change the composition of both the list of species in need of management and the endangered species list for South Carolina. The Department proposes to remove the indigo snake from the list of endangered species, and add the southern hognose snake to the list of species in need of management. The Department will amend the Spotted Turtle Program regulation to change the reporting time for permits from annual reports to reporting every five (5) years. In addition the Department will correct several names of currently listed species to reflect recent changes in their taxonomy.

DEPARTMENT OF REVENUE
CHAPTER 117
Statutory Authority: 1976 Code Section 12-4-320

Notice of Drafting:

The South Carolina Department of Revenue is considering amending SC Regulation 117-335 concerning the sales and use tax and manufactured and modular homes to address a change in the law in 2004 as to how modular homes are taxed and to address the issue of furniture and appliances sold with manufactured and modular homes. The portion of the proposal concerning the taxation of furniture and appliances sold with manufactured and modular homes is consistent with present Department of Revenue policy.

Interested persons may submit written comments to Meredith F. Cleland, South Carolina Department of Revenue, Legislative Services, P. O. Box 125, Columbia, SC 29214. To be considered, comments must be received no later than 5:00 p.m. on June 28, 2005.

Synopsis:

The South Carolina Department of Revenue is considering amending SC Regulation 117-335 concerning the sales and use tax and manufactured and modular homes to address a change in the law in 2004 as to how modular homes are taxed and to address the issue of furniture and appliances sold with manufactured and modular homes. The portion of the proposal concerning the taxation of furniture and appliances sold with manufactured and modular homes is consistent with present Department of Revenue policy.

Document No. 2980
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61
Statutory Authority: S.C. Code Section 48-1-10 *et seq.*

Regulation 61-62, *Air Pollution Control Regulations and Standards,* and the South Carolina State Implementation Plan

Preamble:

The United States Environmental Protection Agency (EPA) promulgates amendments to 40 CFR Parts 60, 61 and 63 throughout each calendar year. Recent Federal amendments include clarification, guidance and technical amendments regarding New Source Performance Standards (NSPS), National Emission Standards For Hazardous Air Pollutants (NESHAP) and National Emission Standards for Hazardous Air Pollutants (NESHAP) for Source Categories. The Department proposes to amend Regulations 61-62.60, *South Carolina Designated Facility Plan and New Source Performance Standards;* 61-62.61, *National Emission Standards For Hazardous Air Pollutants (NESHAP)* and 61-62.63, *National Emission Standards for Hazardous Air Pollutants (NESHAP) for Source Categories* to incorporate recent Federal amendments promulgated during the period from January 1, 2004, through December 31, 2004. The Department also proposes to amend R. 61-62.1, *Definitions and General Requirements*, to incorporate amendments to the definition of Volatile Organic Compounds (VOCs) promulgated by the EPA on November 29, 2004.

The proposed amendments to Regulation 61-62, *Air Pollution Control Regulations and Standards,* are necessary to maintain consistency with Federal rules and will not require legislative review.

A Notice of Drafting for these proposed changes was published in the *State Register* on January 28, 2005. Since this amendment is consistent with Federal law, neither a preliminary fiscal impact statement nor a preliminary assessment report is required.

Discussion of Proposed Revisions:

SECTION CITATION:	EXPLANATION OF CHANGE:
R. 61-62.1	Amend Section I - Definition of VOC.
R. 61-62.60	Tables in Subparts A, Cb, and GG are amended.
R. 61-62.60	Subparts B, C and BBBB are added.
R. 61-62.61	Subpart A is added.
R. 61-62.61	Tables in Subpart M and Appendix B to Part 61 are amended.
R.61-62.63	Subparts C, D, E, DDDD, EEEE, IIII, MMMM, PPPP, YYYY, ZZZZ, AAAAA, DDDDD, and EEEEE are added.
R. 61-62.63	Tables in Subparts A, N, Q, LL, MM, EEE, JJJ, PPP, RRR, UUU, GGGG, HHHH, OOOO, and CCCCC are amended.
R. 61-62.63 (Subpart UUU)	Add "and as subsequently amended upon publication in the *Federal Register*" to introductory paragraph.

R. 61-62.63 (Subpart HHHH)	Add "and as subsequently amended upon publication in the *Federal Register*" to introductory paragraph.

Notice of Staff Informational Forum:

Staff of the Department of Health and Environmental Control invites interested members of the public to attend a staff-conducted informational forum to be held on June 27, 2005 at 10:00 a.m. in room 2280 at the Department of Health and Environmental Control, 2600 Bull Street, Columbia, SC. The purpose of the forum is to receive comments from interested persons on the proposed amendments to Regulation 61-62, *Air Pollution Control Regulations and Standards*.

Interested persons are also provided an opportunity to submit written comments to Anthony T. Lofton at the South Carolina Department of Health and Environmental Control, Bureau of Air Quality, 2600 Bull Street, Columbia, SC 29201. To be considered, comments must be received no later than 5:00 p.m. on June 27, 2005. Comments received shall be submitted to the Board in a Summary of Public Comments and Department Responses.

Copies of the proposed regulation for public notice and comment may be obtained by contacting Anthony T. Lofton at the South Carolina Department of Health and Environmental Control, Bureau of Air Quality, 2600 Bull Street, Columbia, SC 29201, or by calling (803) 898-7217.

Notice of Public Hearing and Opportunity for Public Comment Pursuant to S.C. Code Sections 1-23-110 and 1-23-111:

Interested members of the public and regulated community are invited to comment on the proposed amendments to Regulation 61-62, *Air Pollution Control Regulations and Standards* at a public hearing to be conducted by the Board of Health and Environmental Control at its regularly-scheduled meeting on August 11, 2005. The public hearing is to be held in room 3420 (Board Room) of the Commissioner's Suite, third floor, Aycock Building of the Department of Health and Environmental Control, 2600 Bull Street, Columbia, SC. The Board meeting commences at 10:00 a.m. at which time the Board will consider items on its agenda in the order presented. The order of presentation for public hearings will be noted in the Board's agenda to be published by the Department twenty-four hours in advance of the meeting. Persons desiring to make oral comments at the hearing are asked to limit their statements to five minutes or less, and as a courtesy are asked to provide written copies of their presentation for the record.

Interested persons are also provided an opportunity to submit comments on the proposed amendments to Anthony T. Lofton at the South Carolina Department of Health and Environmental Control, Bureau of Air Quality, Regulatory Development Section, 2600 Bull Street, Columbia, SC 29201, or by calling (803) 898-7217. To be considered, comments must be received no later than 5:00 p.m. on June 27, 2005. Comments received shall be considered by the staff in formulating the final proposed regulation for public hearing on August 11, 2005, as noticed above. Comments received shall be submitted to the Board in a Summary of Public comments and Department Responses.

Statement of Need and Reasonableness:

This statement of need and reasonableness was determined by staff analysis pursuant to S.C. Code Section 1-23-115(C)(1)-(3) and (9)-(11).

DESCRIPTION OF REGULATION: Amendments to Regulation 61-62, *Air Pollution Control Regulations and Standards,* and the South Carolina State Implementation Plan.

Purpose of Regulation: These amendments and corrections will maintain conformity with Federal requirements and ensure compliance with Federal standards.

Legal Authority: The legal authority for Regulation 61-62, *Air Pollution Control Regulations and Standards*, and the South Carolina State Implementation Plan is S.C. Code Section 48-1-10 *et seq.*

Plan for Implementation: The proposed amendments will take effect upon approval and adoption by the South Carolina Board of Health and Environmental Control and publication in the *State Register.*

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

The United States Environmental Protection Agency (EPA) promulgates amendments to 40 CFR Parts 60, 61 and 63 throughout each calendar year. Recent Federal amendments include clarification, guidance and technical amendments regarding New Source Performance Standards (NSPS), National Emission Standards For Hazardous Air Pollutants (NESHAP) and National Emission Standards for Hazardous Air Pollutants (NESHAP) for Source Categories. The Department proposes to amend Regulations 61-62.60, *South Carolina Designated Facility Plan and New Source Performance Standards*; *R.* 61-62.61, *National Emission Standards For Hazardous Air Pollutants (NESHAP)*; and 61-62.63, *National Emission Standards for Hazardous Air Pollutants (NESHAP) for Source Categories* to incorporate recent Federal amendments promulgated during the period from January 1, 2004, through December 31, 2004. The Department also proposes to amend R. 61-62.1, *Definitions and General Requirements*, to incorporate amendments to the definition of Volatile Organic Compounds (VOCs) promulgated by the EPA on November 29, 2004.

DETERMINATION OF COSTS AND BENEFITS:

There will be no increased cost to the State or its political subdivisions as a result of these amendments. The standards to be adopted are already effective and applicable to the regulated community as a matter of Federal law. The proposed amendments will benefit the regulated community by clarifying the regulations and increasing their ease of use.

UNCERTAINTIES OF ESTIMATES:

EPA has provided the estimated costs and benefits for these standards in the *Federal Register* notices that are cited within this document.

EFFECT ON ENVIRONMENT AND PUBLIC HEALTH:

Adoption of the recent changes in Federal law through the proposed amendments to Regulation 61-62, *Air Pollution Control Regulations and Standards*, and the South Carolina State Implementation Plan will provide continued protection of the environment and public health.

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATIONS ARE NOT IMPLEMENTED:

While there is no specific detrimental effect on the environment and public health, the State's authority to implement Federal requirements, which are believed to be beneficial to the public health and environment, would be compromised if these amendments are not adopted in South Carolina.

Text:

The full text of this regulation is available on the South Carolina General Assembly Home Page: **http://www.scstatehouse.net/regnsrch.htm.** Full text may also be obtained from the promulgating agency.

Document No. 2930
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61
Statutory Authority: S.C. Code Sections 44-1-140(1); 1-23-10; -110

R. 61-41. Hotel – Motel Sanitation.

Synopsis:

R.61-41 was last revised in 1984. The requirements and need for R.61-41 are outdated and obsolete. Due to dwindling resources and prioritization of programs, the Department has not routinely inspected hotels and motels under this regulation in over 10 years; the Department continues to investigate complaints in hotels and motels. Furthermore, the hotel – motel industry has become largely self-regulating; the business is very customer-driven and competition dictates that facilities be maintained and operated properly. The public health concerns that the R.61-41 was intended to address can be addressed through other department regulations, such as R.61-56, Individual Sewage Treatment and Disposal Systems, and R.61-46, Nuisances. Since this regulation is no longer needed, and in the interest of good government and efficiency, the Department proposes repeal of R.61-41.

See Statement of Need and Reasonableness herein.

Instructions: Delete R.61-41 in its entirety.

Text of Repeal:

R.61-41**.** Hotel-Motel Sanitation.

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Section I. Definitions

A. APPROVED--means acceptable to the Health Authority based on relevant regulations, standards, and good public health practices.
B. DURABLE AND EASILY CLEANABLE--means material of sound construction, readily accessible and of such finish and so fabricated that residue may be completely removed by normal cleaning methods.
C. EXISTING FACILITY--means any facility which has been operated as a hotel-motel for any part of the year immediately prior to the adoption of this Regulation, or a facility upon which construction was commenced prior to the adoption of this Regulation and has progressed to a stage where modification is impracticable.
D. HEALTH AUTHORITY--means the authorized representative of the South Carolina Department of Health and Environmental Control.
E. HOTEL-MOTEL--means any building, part of a building, or group of buildings, containing rooms or units where overnight sleeping accommodations are available; provided, that the term shall not apply to private clubs, or to apartments, boarding homes, rooming houses, or portions thereof, where single night accommodations are not available.
F. NEW FACILITY--means any facility not encompassed in the definition of an existing facility.
G. PERMIT--means the document issued by the Health Authority indicating that a hotel-motel complies with this Regulation.
H. PERMIT HOLDER--means the owner or authorized agent.
I. SINGLE-SERVICE ITEMS--mean cups, containers, plastic liners, utensils and similar products constructed of paper, plastic foil, or similar materials, which are intended by the manufacturer and generally recognized as items to be used only once and then discarded.

Section II. Purpose

The purpose of this Regulation is to ensure that every hotel-motel permitted in this State shall be operated in a sanitary manner, free of any conditions which constitute a substantial hazard to the public's health.

Section III. Employees

HEALTH AND DISEASE CONTROL--All employees engaged in cleaning services, porterage, or other customer-contact services, shall wear clean outer garments and keep their hands clean. No person who is afflicted with boils, infected wounds, sores or any acute respiratory infection accompanied by fever, shall be engaged in the services described above.

Section IV. Conditions of Building

A. ROOMS AND UNITS--All rooms and units, furnishings and equipment therein shall be constructed of a durable and easily cleanable material, and be maintained in a sanitary condition.

B. TOILETS, LAVATORIES AND BATHING FACILITIES:

1. All new facilities shall provide toilets, lavatories and bathing facilities in each room or unit.

2. Toilets, lavatories, showers, and tubs shall be constructed of durable and easily cleanable material, shall be maintained in good repair, and shall be cleaned and disinfected daily.

3. The floors and walls of all toilets and bathrooms shall be of a durable and easily cleanable material and shall be kept clean.

4. Hot and cold water under pressure shall be provided to each lavatory. New facilities shall provide mixing faucets at each lavatory.

C. SERVICE SINK AND HOSE BIBBS--New facilities shall provide a service sink in each work room or janitor's closet. Back flow preventers shall be provided on all hose bibb faucets.

D. DRINKING FOUNTAINS--Drinking fountains shall be constructed of impervious material with an angle-jet nozzle protected by a non-oxidizing guard above the overflow rim of the bowl. Drinking fountains shall be equipped with a pressure regulating valve and be maintained in a sanitary manner.

E. VENTILATION:

1. Toilets and bathrooms shall be ventilated. Where the bathroom is mechanically vented into a pipe raceway, the raceway shall be ventilated to the exterior of the building.

2. Rooms or units shall have an operable window or transom area for ventilation or a mechanical system capable of exhausting 20 cfm of air, not including the bathroom vent.

3. Laundry rooms and other employee work areas shall be adequately ventilated.

4. Heating systems using combustion-type fuels shall be vented to the exterior of the building.

F. KITCHENETTES:

1. Kitchenettes and efficiency cooking equipment shall be constructed of durable and easily cleanable material, and maintained in a sanitary condition.

2. No enamelware, or cracked or chipped utensils shall be provided for use in kitchenettes.

3. The walls within the food preparation and service area of a kitchenette shall be constructed of a durable and easily cleanable material, washable up to the level of splash.

4. Garbage containers and single-service liners shall be provided.

G. LIGHTING: Adequate lighting shall be provided as follows:

1. At beds and/or other general areas, a minimum of ten foot candles, 30"' from the floor.

2. In laundry rooms, linen rooms, glass washing areas, kitchenettes or other work areas, a minimum of twenty foot candles, 30"' from the floor.

Section V. Linen, Bedding, and Toilet Supplies

1. Blankets, sheets, pillows, pillow cases, towels, wash cloths and bath mats shall be provided, and laundered, stored, and distributed in a sanitary manner. All body-contact linen shall be changed at least twice weekly and with every new occupant. Blankets shall be maintained in a clean condition.

2. Mattresses shall be covered with a washable mattress pad or water-proof material. Rubber sheets or water-proof backing on mattresses are acceptable for use under the mattress pad. All mattresses and covers or mattress pads shall be kept clean and maintained in good repair.

3. Non-washable pillows shall have an easily removable inner case between the pillow case and the pillow ticking. The inner case and/or washable pillow shall be kept clean and maintained in good repair.

4. Baskets or bins used to collect dirty lien shall not be used to redistribute clean linens to the rooms unless protected by single-service liner which is utilized only once and then discarded.

5. Toilet Supplies--Adequate toilet tissue and soap shall be provided for each occupant.

Section VI. Glasses, Ice Storage and Dispensing

A. GLASSES:

1. Multi-use glasses shall be collected daily, washed, rinsed, sanitized, and wrapped in a sanitary manner before being replaced in the room. Single-service drinking containers are acceptable for use, provided used containers are discarded daily and replaced with a new supply. All drinking containers shall be stored so as to prevent contamination.

2. Drinking glasses shall be cleaned in a manner acceptable to the Health Authority, such as:

a. Washing in a properly operating commercial dish machine with a 180°F. or chemical bactericide rinse
cycle, or

b. Washing, rinsing and sanitizing in a three compartment sink (lavatories, mop sinks, plastic buckets, or similar compartments are not acceptable for washing glasses).

B. ICE:

1. All ice shall be purchased from a source permitted by the Health Authority or produced and stored at the hotel-motel in a clean and sanitary manner.

2. Ice Buckets:

a. Plastic, plastic lined or glass ice containers shall be collected from the rooms and washed, rinsed and sanitized for each new guest.

b. Single-service ice buckets, such as wax-coated paper ice buckets, unless lined with single-service liners, shall be maintained in a sanitary condition or discarded and replaced for each new guest.

Section VII. Refuse and Vermin Control

A. REFUSE--Refuse shall be stored, collected and disposed of in a manner which prevents the breeding of flies and other vermin.

B. VERMIN CONTROL--All hotels-motels shall be free of vermin. Number sixteen mesh screens shall be installed and properly maintained on all operable windows.

Section VIII. Water and Sewage

A. WATER--Water shall be provided from a source permitted by the Health Authority, or otherwise meet all relevant Health Authority regulations.

B. SEWAGE--Sewage shall be disposed of in a manner permitted by the Health Authority, or otherwise meet all relevant Health Authority regulations.

Section IX. Food Service and Swimming Pools

All food services and swimming pools operated in conjunction with a hotel-motel must obtain applicable permits from the Health Authority.

Section X. Permitting and Enforcement Provisions

A. PERMITS

1. It shall be unlawful to operate a hotel-motel within the State of South Carolina without a valid permit issued to the operating entity by the Health Authority. Only a hotel-motel which complies with the requirements of this Regulation and is operated in a sanitary manner, free of any conditions which constitute a substantial hazard to the public's health, shall be permitted. Permits shall not be transferable from one operating entity to another operating entity. A valid permit shall be posted in every hotel-motel at a place designated by the Health Authority.

2. Any entity desiring to operate a hotel-motel shall make written application to the Health Authority for a permit.

3. Upon receipt of an application, the Health Authority shall make an inspection of the hotel-motel to determine compliance with this Regulation. When inspection reveals that the requirements of this Regulation have been met and that the hotel-motel is sanitary and free of any conditions which constitute a substantial hazard to the public's health, a permit shall be issued to the entity by the Health Authority.

B. INSPECTIONS AND NOTICES

1. The Health Authority shall inspect each hotel-motel located in the State of South Carolina prior to the issuance of a permit, and shall make inspections thereafter as necessary for the enforcement of this Regulation.

2. The Health Authority, after proper identification, shall be allowed to enter, at any reasonable time, any hotel-motel for the purpose of making inspections to determine compliance with this Regulation.

3. Whenever the Health Authority makes an inspection of a hotel-motel, it shall record the findings on an inspection report form and shall furnish a copy of such inspection report form to the permit holder.

4. Notice shall be deemed to have been properly served when a copy of the inspection form or other notice has been delivered personally to the permit holder, a responsible agent, or such notice has been sent by certified mail to the last known address of the permit holder. A copy of such notice shall be filed with the Health Authority.

C. SUSPENSION AND REVOCATION

1. The Health Authority may suspend or revoke a permit for repeated violation of any of the requirements of this Regulation, for the continuing existence of unsanitary conditions or other conditions which constitute a substantial hazard to the public's health, or for interference with the Health Authority in the performance of its duties under this Regulation. Prior to such action, the Health Authority shall notify the permit holder, in writing, stating the basis for suspension or revocation and advising that the permit shall be suspended or revoked on the fifteenth day following the mailing of the written notification, unless a request for a hearing is filed with the Health Authority by the permit holder within the fifteen day period.

2. A permit may be summarily suspended by the Commissioner of the Department of Health and Environmental Control or his designee, pending a hearing as herein provided if conditions exist which pose an immediate and serious threat to the public's health. In the case of a summary suspension, the permit holder shall be given a hearing, if requested, as soon as possible.

3. All hearings shall be conducted in accordance with the South Carolina Administrative Procedures Act.

D. ENFORCEMENT INTERPRETATION

This Regulation is issued under the authority of Section 44-1-140, Code of Laws of South Carolina, 1976, and subsequent legislation. It shall be enforced by the Health Authority in accordance with the best practices of public health as determined by the Board of Health and Environmental Control, and any conditions which have not been covered in this Regulation shall be handled in a like manner.

E. PENALTIES

Violation of this Regulation shall be a misdemeanor punishable under Section 44-1-150, Code of Laws of South Carolina, 1976, by fine not exceeding One Hundred Dollars or imprisonment not exceeding Thirty Days; and each day of continued violation after notice shall be a separate offense.

F. CONSTITUTIONALITY

If any part or provisions of this Regulation is declared unconstitutional or invalid for any reason, the remainder of the Regulation shall not be affected thereby.

G. REPEAL/AMENDMENT

The regulation dealing with this subject matter and filed in the Office of the Secretary of State on February 17, 1944, was repealed in its entirety by the regulation approved by the Legislature on April 22, 1979. The amendments to the April 22, 1979, regulation were approved by the Legislature on July 27, 1984.

H. PERMIT FEES

1. If a fee system is hereafter established by the Health Authority, proof of payment of the fee shall accompany each initial application and shall be furnished to the county health department within 30 days after the renewal date. If such proof is not so presented, the permit shall be immediately suspended until such proof is received, notwithstanding the sanitary conditions of the establishment.

2. Upon receipt of an application for a permit to operate a hotel-motel, accompanied by the required fee receipt, the local health department shall issue a permit if the establishment meets the requirements of this Regulation.

I. EFFECTIVE DATE

This Regulation shall become effective as provided by Section 1-23-120, Code of Laws of South Carolina, 1976.

Fiscal Impact Statement:

The Department estimates there will be no costs imposed on the State or its political subdivisions by this regulation repeal.

Statement of Need and Reasonableness and Rationale:

The Statement of Need and Reasonableness was determined by staff analysis pursuant to S.C. Code Section 1-23-115(C)(1)-(3) and (9)-(11):

DESCRIPTION OF REGULATION:

Purpose: The purpose of this action is to repeal in entirety R.61-41, Hotel-Motel Sanitation.
Legal Authority: The legal authority for R.61-41 is Section 44-1-140(4) et seq., S.C. Code of Laws.
Plan for Implementation: None.

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

The requirements and need for R.61-41 are outdated and obsolete. Due to dwindling resources and prioritization of programs, the Department has not routinely inspected hotels and motels under this regulation in over 10 years. The public health concerns that the R.61-41 was intended to address can be addressed through other department regulations, such as R.61-56, Individual Sewage Treatment and Disposal Systems, and R.61-46, Nuisances. Since this regulation is no longer needed, and in the interest of good government and efficiency, the Department proposes repeal of R.61-41.

DETERMINATION OF COSTS AND BENEFITS: There are no anticipated costs or benefits associated with the repeal of this regulation. The hotel – motel industry has become largely self-regulating; the business is very customer-driven and competition dictates that facilities be maintained and operated properly.

UNCERTAINTIES OF ESTIMATES: None.

EFFECT ON ENVIRONMENT AND PUBLIC HEALTH: There will be no effect on the environment or public health.

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATION IS NOT IMPLEMENTED: There will be no detrimental effect on the environment or public health by the repeal of R.61-41.

Statement of Rationale:

This regulation is no longer needed, and in the interest of good government and efficiency, the Department proposes repeal of R.61-41.

Document No. 2926
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61
Statutory Authority: S.C. Code Sections 44-1-140(3); 1-23-10; -110

R. 61-34.1. Pasteurized Milk And Milk Products

Synopsis:

R.61-34.1 ensures that consumers are receiving safe, high quality Grade "A" milk and milk products. The Regulation was amended last in 1993. These amendments will bring the Regulation into compliance with the latest guidelines of the Interstate Milk Shipments Conference Pasteurized Milk Ordinance and assure consumers that the latest sanitation requirements are being met by the dairy industry. Also, the United States Public Health Service, Food and Drug Administration (FDA) requires that South Carolina's dairy regulation be at least as stringent as the Pasteurized Milk Ordinance in order for South Carolina milk producers to ship their products in interstate commerce and market their product as Grade "A" milk products; the FDA has previously cited the South Carolina program for not meeting this requirement. Amendments will also insure that the regulation complies with the requirements of the federal Nutrition Labeling and Education Act, the federal Food, Drug and Cosmetic Act, and the South Carolina Administrative Procedures Act, and is compatible with R.61-36, *Frozen Desserts*. Other related editorial and stylistic changes were included to improve the overall quality of the regulation.

See Summary of Revisions below and Statement of Need and Reasonableness herein.

Summary of Revisions:

SECTION / REVISION

Contents Table of Contents revised

61-34.1 I.A. Twenty definitions added, nomenclature of one definition changed and thirteen definitions revised to be consistent with the current Pasteurized Milk Ordinance (PMO).

61-34.1 I. B. All specific product standards being deleted due to new federal regulations allowing for extensive flexibility in labeling. Product standards are now covered by reference to 21 Code of Federal Regulations, Chapter 1 - Parts 130-131 and Appendix L. of the current PMO. Standards added for whey products to be consistent with the current PMO.

61-34.1 II.A.6. Drug residue adulteration violations revised, reconditioning of adulterated milk added, and drug avoidance control measures revised to be consistent with the current PMO.

61-34.1 III.A.2. Language added to grant exemption to agents, brokers, etc.

61-34.1 III.A.3. Language added to require separate permits for non-Grade "A" condensed or dry milk products.

61-34.1 III.A.4. Language changed to clarify reasons for permit suspension.

61-34.1 III.B.1. Permit requirement added for milk tank truck cleaning facilities to be consistent with the current PMO.

61-34.1 III.B.2.a. The term "growth inhibitors (drugs)" changed to "drug residue standards".

61-34.1 III.B.2.b. Added specific requirement to stop all manufacturing operations immediately upon permit suspension added to be consistent with the current PMO.

61-34.1 III.B.2.c. Language changed to clarify hearing process.

61-34.1 III.B.3.a. Language added to clarify process for permit reinstatement.

61-34.1 III.B.3.c. Additional sentence added for compliance with somatic cell violations to be consistent with the current PMO.

61-34.1 III.B.4. Language added to allow DHEC to deny an application for a new permit based on past history.

61-34.1 IV.A.1. Labeling references changed to be consistent with the current PMO.

61-34.1 IV.A.2.a. Labeling requirements changed to be consistent with the current PMO.

61.34.1. IV.A.2.b. The words "condensed and/or dried" added to be consistent with the current PMO.

61-34.1 IV.A.2.d. Requirements for reconstituting or recombining of condensed and dry milk products added to the consistent with the current PMO.

61-34.1 IV.A.2.f. The term "UHT" deleted to be consistent with the current PMO.

61-34.1 IV.A.2.g. Changed from "goat" or "sheep" to "hooved mammal" to be consistent with the current PMO.

61-34.1 IV.A.4. Changed to be consistent with the current PMO - proper identification and sealing of tank trucks.

61-34.1 IV.A.4.a. Additional requirements for proper tanker identification added to be consistent with the current PMO.

61-34.1 IV.A.4.h. Specific temperature requirement added to be consistent with the current PMO.

61-34.1 IV.A.4.j. Wording added to be consistent with the current PMO.

61-34.1 IV.A.4.l. Sealing requirement added to be consistent with the current PMO.

61-34.1 IV.A.5. Milk tank truck identification information changed to be consistent with the current PMO.

61-34.1 IV.A.6. Unnecessary milk shipping required information deleted to be consistent with the current PMO.

61-34.1 IV.B.2. Condensing and/or drying" added to be consistent with the current PMO.

61-34.1 IV.B.2.a. Additional plant product identification added to be consistent with the current PMO.

61-34.1 IV.B.3. Dry milk product labeling requirements and the objection to using descriptive labeling terms added to be consistent with the current PMO.

61-34.1 V.A.1. Requirement added for a DHEC inspection of a milk tank truck cleaning facility to be consistent with the current PMO.

61-34.1 V.A.1.a. Name change to be consistent with the current PMO.

61-34.1 V.A.1.b. Name change and requirement added for an inspection of dairy plant and industry plant samplers to be consistent with the current PMO.

61-34.1 V.A.1.c. Deleted current inspection criteria of a transfer station to be in compliance with the current PMO.

61-34.1 V.A.1.d. Hazard Analysis Critical Control Point (HACCP) based regulatory inspections added to be consistent with the current PMO.

61-34.1 V.A.1.e. Inspection requirements added for milk tank truck cleaning facilities and transfer stations to be consistent with the current PMO.

61-34.1. V.A.2. Penalties revised on second inspections/audits to be consistent with the current PMO.

61-34.1 V.A.3. This section moved to 61-34.1 V.A.2. to correct punctuation and to be consistent with the current PMO.

61-34.1 V.A.4. This section moved to 61-34.1 V.A.2. to be consistent with the current PMO.

61-34.1 V.A.4.(new) This section added to be consistent with the current PMO regarding inspections and investigations.

61-34.1 V.A.5. This was previously 61.34.1 V.A.6. and reworded to be consistent with the PMO.

61-34.1 V.B.1. Nomenclature changed, inspection frequencies added, and audit frequencies added to be consistent with the current PMO.

61-34.1 V.B.2. Title of section added.

61-34.1. V.B.3. Terminology changed and additional facilities subject to permit suspensions and/or court actions added for repeated violations to be consistent with the current PMO.

61-34.1 V.B.3.a. Terminology changed and additional permit holders subject to penalty actions added to be consistent with the current PMO.

61-34.1 V.B.3.b. Terminology changed, additional permit holders subject to penalty actions added and a time period added before regulatory actions can be taken to be consistent with the current PMO.

61-34.1 V.B.5. Terminology changed and new criteria added for certified industry inspections to be consistent with the current PMO.

61-34.1 V.B.6. Criteria for audit reports to be filed added and report retention time increased from 12 to 24 months to be consistent with the current PMO.

61-34.1 VI.A.1. Terminology changed to consistent with the current PMO.

61-34.1 VI.A.2. Revised sampling criteria to be consistent with the current PMO.

61-34.1. VI.A.3. Revised sampling criteria, including drug testing, to be consistent with the current PMO.

61-34.1 VI.A.4. Terminology changed and criteria added for averaging samples to be consistent with the current PMO.

61-34.1 VI.A.7. Criteria added for drug residue testing to be consistent with the current PMO.

61-34.1 VI.A.9. Terminology changed, allowances made for the use of in-line samplers, HACCP requirements added, additional criteria added and a requirement for vitamin testing laboratories to be certified added to be consistent with the current PMO.

61-34.1 VI.B.2. Terminology changed to be consistent with the current PMO.

61-34.1 VI.B.3. Laboratory testing procedures, standards and methods revised to be consistent with the current PMO.

61-34.1 VI.B.4. Laboratory reference made to the "Standard Methods for the Examination of Dairy Products" to be consistent with the current PMO.

61-34.1 VI.B.5. Reference made to App. B of the current PMO for milk hauling program requirements.

61-34.1 VII.A.2. Terminology and standards revised and/or added to be consistent with the current PMO. Specific requirements added for processing heat-treated cream, whey and buttermilk products.

61-34.1 VII.B.1.a. Abnormal milk terminology changed to be consistent with the current PMO. Reference made to Appendix Q of the current PMO for automatic milking installations.

61-34.1 VII.B.1.b. Terminology changed and requirement to properly maintain milking equipment used on animals with abnormalities added to be consistent with the current PMO.

61-34.1 VII.B.2.a.(1) Specific requirements added for convalescent pens to be consistent with the current PMO.

61-34.1 VII.B.2.b.(8) Feed storage requirements moved to 61-34.1 VII.B.3.a. to be consistent with the current PMO.

61-34.1. VII.B.3.a. Feed storage requirements moved from 61-34.1 VII.B.2.b.(8) to this section to be consistent with the current PMO.

61-34.1. VII.B.3.b.(8) Requirements moved from 61-34.1 VII.B.15 to be consistent with the current PMO.

61-34.1 VII.B.4. Terminology changed, cooling ponds allowed, and explanation of cow yard sanitation criteria added to be consistent with the current PMO.

61-34.1 VII.B.5.a.(5) Parlor added as an area that cannot connect directly to an area used for domestic purposes; allowances made for a single or double acting door; and additional allowances for screen vents added to be consistent with the current PMO.

61-34.1 VII.B.5.a.(8) Terminology changed and criteria added for the use of transportation tanks for cooling and storage of milk on a dairy farm.

61-34.1 VII.B.5.b.(6) 220 lux added to be consistent with the current PMO.

61-34.1 VII.B.5.b.(11) Parlor added as an area that cannot connect directly to an area used for domestic purposes; allowances made for a simple or double acting door; and additional allowances for screen vents added to be consistent with the current PMO.

61-34.1 VII.B.5.b.(13) Criteria added for allowing milk to be transferred from a bulk milk tank to a bulk milk pickup tanker by stubbing the milk transfer and associated mechanically cleaned lines outside the milk house wall to be consistent with the current PMO.

61-34.1 VII.B.5.b.(16) Requirement for a second wash vat made optional with DHEC approval to be consistent with the current PMO.

61-34.1 VII.B.5.b.(17) Requirement for a shelter over a transportation tank made optional and criteria added for the use of a milk tank truck for cooling and storage of milk on a dairy farm.

61-34.1 VII.B.7. "Flies" changed to "insects" to be consistent with the current PMO.

61-34.1 VII.B.8.b.(7) Sampling criteria for hauled water changed to be consistent with the current PMO.

61-34.1 VII.B.9.b.(6) Terminology changed to be consistent with the current PMO.

61-34.1 VII.B.9.b.(7) Terminology changed to be consistent with the current PMO.

61-34.1 VII.B.9.b.(10) Specific criteria not allowed in product contact surface areas added to be consistent with the current PMO.

61-34.1 VII.B.9.b.(13) Specific criteria for use of flexible, plastic hoses added to be consistent with the current PMO.

61-34.1 VII.B.9.b.(14) Specific criteria for use of transparent flexible plastic tubing added to be consistent with the current PMO.

61-34.1 VII.B.9.b.(15) Requirements for Automatic Milking Installations (AMIs) added to be consistent with the current PMO. Association name change in "Note" to be consistent with the current PMO.

61-34.1 VII.B.10 Additional criteria added for cleaning utensils and equipment to be consistent with the current PMO.

61-34.1 VII.B.11.(2) Sanitization criteria revised to be consistent with the current PMO.

61-34.1 VII.B.12.a. "Meters" added as equipment allowed to be stored in parlor to be consistent with the current PMO.

61-34.1 VII.B.12.b.(1) Additional criteria added for allowing seasonally enclosed holding areas to be consistent with the current PMO.

61-34.1 VII.B.13(old) Section deleted to be consistent with the numbering in current PMO and corresponding inspection report. Items previously in this Section covered under other "utensils and equipment" sections.

61-34.1 VII.B.13(new) Renumbered to be consistent with the current PMO and corresponding inspection report.

61-34.1 VII.B.13.a. "Cows" changed to "lactating animals" to be consistent with the current PMO. This change consistent throughout the revised regulation.

61-34.1 VII.B.13.b.(4) Udder and teat preparation revised to be consistent with the current PMO.

61-34.1 VII.B.15(old) Section deleted to be consistent with the current PMO. Criteria for sursingle milk stools and anti-kickers covered under other sections.

61-34.1 VII.B.16(old) Renumbered to be consistent with the current PMO.

61-34.1 VII.B.14.a.(new) Renumbered to be consistent with the current PMO and corresponding inspection report. Product contact surface and vehicle protection from contamination criteria moved to this section for consistency with the current PMO.

61-34.1 VII.B.14.b.(4) Wording changed to be consistent with the current PMO.

61-34.1 VII.B.14.b.(5) "Stable or parlor" added for clarification purposes to be consistent with the current PMO.

61-34.1 VII.B.14.b.(8) Reference to Appendix H. of the current PMO added for air criteria specifications.

61-34.1 VII.B.14.b.(9-11)(Old) Moved to VII.B.15 to be consistent with the current PMO.

61-34.1 VII.B.14.b.(9-10)(New) Moved from old VII.B.13. to be consistent with the current PMO.

61-34.1 VII.B.14.b.(11-14) Moved from old VII.B.20. to be consistent with the current PMO.

61-34.1 VII.B.15.(new) Chemical storage and drug storage and use criteria revised to be consistent with the current PMO.

61-34.1 VII.B.16(new) Info was previously in VII.B.17., but renumbered to be consistent with the current PMO.

61-34.1 VII.B.16.a.&b.(2) A requirement to have both hot and cold or warm running water at handwash sink added to be consistent with the current PMO.

61-34.1 VII.B.17.(new) Info was previously in VII.B.18, but renumbered to be consistent with the current PMO.

61-34.1 VII.B.17.b.(1) "Other approved hand drying device" added to be consistent with VII.B.17.a.

61-34.1 VII.B.17.b.(2) Terminology changed to be consistent with the current PMO.

61-34.1 VII.B.18.(new) In current regulation, but renumbered to be consistent with the current PMO and corresponding inspection report.

61-34.1 VII.B.18.a.&b. Specific raw milk cooling criteria, including recording thermometers, added to be consistent with the current PMO.

61-34.1 VII.B.19(new) In current regulation, but renumbered to be consistent with the current PMO and corresponding inspection report.

61-34.1 VII.B.19.a.&b.(9-10) Specific criteria for the storage of feed added to this section to be consistent with the current PMO.

61-34.1 VII.B.19.b.(7) Reference added to Appendix C of the current PMO for insect and rodent control measures.

61-34.1 VII.B.20.(old) Deleted after moving requirements to VII.B.14 to be consistent with the current PMO and corresponding inspection report.

61-34.1 VII.B.21.(old) Deleted after moving criteria to VII.B.19. to be consistent with the current PMO and corresponding inspection report.

61-34.1 VII.C. Two paragraphs added for plants desiring to be regulated under a Hazard Analysis Critical Control Point (HACCP) system.

61-34.1 VII.C.1. Floor structure criteria also applied to plants manufacturing dry milk or mild products so as to be consistent with the current PMO.

61-34.1 VII.C.2.a. The word "packaged" added to be consistent with the current PMO.

61-34.1 VII.C.2.b.(1) Wording simplified and structural requirements applied for plants manufacturing dry milk or milk products so as to be consistent with the current PMO.

61-34.1 VII.C.3.e. "Flies" changed to "insects" to be consistent with the current PMO.

61-34.1 VII.C.4.a. Requirements for lighting and ventilation also applied to rooms where milk is packaged to be consistent with the current PMO.

61-34.1 VII.C.4.b.(1) Another acceptable way to measure light levels (lux) added to be consistent with the current PMO.

61-34.1 VII.C.4.b.(4) Ventilation requirement added for plants condensing and/or drying milk and milk products to be consistent with the current PMO.

61-34.1 VII.C.5.a. Section modified to include additional activities required to be done in separate rooms to be consistent with the current PMO.

61-34.1 VII.C.5.b.(1) Section rewritten to include additional activities in a plant that are required to be done in separate rooms to be consistent with the current PMO.

61-34.1 VII.C.5.b.(5) Note added as reference to requirements for facilities cleaning and sanitizing milk tank trucks to be consistent with the current PMO.

61-34.1 VII.C.6.b.(2) Processing rooms for condensed or dried products added to areas in which toilet room doors cannot open to be consistent with the current PMO.

61-34.1 VII.C.7.b.(2) Specific criteria added for individual water source criteria to meet the requirements of DHEC's R.61-58.

61-34.1 VII.C.7.b.(3) Air gap criteria added to be consistent with the current PMO.

61-34.1 VII.C.7.b.(5) "Milk products" added to be consistent with the current PMO.

61-34.1 VII.C.7.b.(7) Water frequency determination criteria added to be consistent with the current PMO.

61-34.1 VII.C.7.b.(10) Steam vacuum evaporation potable water supply criteria added to be consistent with the current PMO.

61-34.1 VII.C.9.a.&b.(1) Additional areas with equipment limitations added to be consistent with the current PMO.

61-34.1 VII.C.9.b.(5) Product dust control measures added to be consistent with the current PMO.

61-34.1 VII.C.10.a. Additional criteria for piping, fittings and connections added to be consistent with the current PMO.

61-34.1 VII.C.10.b.(2)(d) Section separated from (c) above to be consistent with the current PMO.

61-34.1 VII.C.10.b.(5)(a) Specific welded pipeline inspection criteria deleted to be consistent with the current PMO.

61-34.1 VII.C.10.b.(5)(b) "Pipe" added before "line" to be consistent with the current PMO.

61-34.1 VII.C.10.b.(8) Threaded or welded exception made for pipelines in drying chambers to be consistent with the current PMO.

61-34.1 VII.C.11.b.(3) Additional criteria for joints, unacceptability of tile floors in dryers and condition that grease and oil be kept out of milk and milk products added to be consistent with the current PMO.

61-34.1 VII.C.11.b.(4) "Distributor" changed to "similar equipment" to be consistent with the current PMO.

61-34.1 VII.C.11.b.(5) Additional criteria and exceptions made for product contact surfaces to be in compliance with the current PMO.

61-34.1 VII.C.11.b.(6) Exception made to allow threaded connections for safety purposes in high pressure lines to be in compliance with the current PMO.

61-34.1 VII.C.11.b.(8) "Dry whey" added to be consistent with the current PMO.

61-34.1 VII.C.11.b.(10) The word "Closures" added in name of Guidelines and criteria added for condensed and dry milk and milk product packaging.

61-34.1 VII.C.11.b.(11) Construction criteria for dry milk product sifters added, and Association name changed in "Note" to be consistent with the current PMO.

61-34.1 VII.C.12. Cleaning and sanitizing criteria for containers and equipment changed to be consistent with the current PMO. Specifically, requirements added for milk condensers, dryers and milk tank trucks; requirements added for allowances of extended runs; requirements added for recording devices for tanks; updates make for laboratory testing of multi-use and single-service containers and closures; and requirements updated for plants using multi-use plastic containers for pasteurized milk and milk products.

61-34.1 VII.C.13. Additional criteria for storage of multi-use containers, equipment and utensils added to be consistent with the current PMO.

61-34.1 VII.C.14. "Liners and bags" added to list of single-service material that must meet certain criteria to be consistent with the current PMO.

61-34.1 VII.C.15. The section contains many changes of which all are being made to be consistent with the current PMO. The minor changes include such things as adding "Grade A" before milk and milk products, revising nomenclature of "transport tankers" and Grade "A" dairy products, and adding "and milk products" after the word "milk" in several locations. Major changes include the allowances for sampling milk while the milk tank truck manhole is not adequately covered, adding criteria for air systems used on milk drying equipment, adding criteria for adequate separation of different types of products and adding specific objections for handling products in a milk plant that may create a public health hazard.

61-34.1 VII.C.16. New criteria listed for aseptic processing and handling milk or milk products by using reverse osmosis (RO), ultra-filtration (UF) evaporating and/or condensing equipment to be consistent with the current PMO.

61-34.1 VII.C.16.c. Batch pasteurizer criteria revised to be consistent with the current PMO.

61-34.1 VII.C.16.d. High-Temperature-Short-Time Pasteurizer criteria revised to be consistent with the current PMO.

61-34.1 VII.C.16.e. Aseptic Processing System criteria revised to be consistent with the current PMO.

61-34.1 VII.C.16.f. Criteria revised for pasteurizers and aseptic processing systems employing regenerative heating to be consistent with the current PMO.

61-34.1 VII.C.16.g. Pasteurization and aseptic processing records, equipment tests and examinations revised, including testing and temporarily sealing pasteurization equipment by trained plant employees, to be consistent with the current PMO.

61-34.1 VII.C.17. Cooling criteria for whey and whey products and additional criteria for use of re-circulated cold water added to be consistent with the current PMO.

61-34.1 VII.C.18. Additional criteria and wording added for mechanical packaging operations, including those for condensed and dry milk products, to be consistent with the current PMO.

61-34.1 VII.C.19. Section revised to include additional acceptable sealing processes and practices for milk and milk products, including dry milk products, to be consistent with the current PMO.

61-34.1 VII.C.20. Additional criteria added or revised to include the prohibited use of tobacco products in milk processing and handling areas and the need to provide and use specific protective clothing in milk drying chambers to be consistent with the current PMO.

61-34.1 VII.C.21. Additional criteria added or revised for milk tank cars, milk tank trucks, and portable shipping bins used to transport milk and milk products to be consistent with the current PMO.

61-34.1 VII.C.22.b.(5.) Criteria for keeping dry milk plant roofs clean added to be consistent with the current PMO.

61-34.1 VIII. Section revised to be consistent with the animal health criteria now required in the current PMO.

61-34.1 IX. Additional criteria added to ensure that only Grade "A" milk and milk products are sold to plants for the commercial preparation of Grade "A" milk and milk products to be consistent with the current PMO.

61-34.1 X.2. Deleted because no longer required by DHEC's regulation governing food establishments.

61-34.1 XI. Requirements for selling milk and milk products in South Carolina from outside manufacturers extended to condensed and dried products, added criteria to allow milk and milk products to be sold in South Carolina from plants operating under a HACCP regulatory program and updated reciprocity requirements of the NCIMS program to be consistent with the current PMO.

61-34.1 XII. Added the requirement for DHEC to review plans for milk tank truck cleaning facilities to be consistent with the current PMO.

61-34.1 XIII. Revised and added criteria relating to personnel health for those employed by a milk plant to be consistent with the current PMO.

61-34.1 XIV. Revised actions that must be taken when employees who handle milk or milk products are found to have or highly suspected to have contagious infections to be consistent with the current PMO.

Instructions: Replace R.61-34.1 in entirety with this amendment**.**

Text of Amendments

R. 61-34.1. PASTEURIZED MILK AND MILK PRODUCTS

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SECTION I. DEFINITIONS AND STANDARDS

A. Definitions

The following definitions shall apply in the interpretation and the enforcement of this Regulation:

1. ABNORMALITIES OF MILK means

a. Abnormal Milk: Milk that is visibly changed in color, odor and/or texture.

b. Undesirable Milk: Milk that, prior to the milking of the animal, is known to be unsuitable for sale, such as colostrum.

c. Contaminated Milk: Milk that is un-saleable or unfit for human consumption following treatment of the animal with veterinary products, i.e. antibiotics, which have withhold requirements, or treatment with medicines or insecticides not approved for use on dairy animals by the U.S. Food and Drug Administration (FDA) or the U.S. Environmental Protection Agency (EPA).

2. AND/OR means "and" shall apply where appropriate, otherwise "or" shall apply.

3. ASEPTICALLY PROCESSED MILK AND MILK PRODUCTS means the products hermetically sealed in a container and so thermally processed in conformance with 21 CFR 113 and the provisions of this Regulation so as to render the product free of microorganisms capable of reproducing in the product under normal non-refrigeration conditions of storage and distribution. The product shall be free of viable microorganisms (including spores) of public health significance.

4. ASEPTIC PROCESSING means the milk product has been subjected to sufficient heat processing, and packaged in a hermetically sealed container, to conform to the applicable requirements of 21 CFR 113 and the provisions of Section VII.C.16. of this Regulation and maintain the commercial sterility of the product under normal non-refrigerated conditions.

5. AUTOMATIC MILKING INSTALLATION (AMI) means the entire installation of one or more automatic milking units, including the hardware and software utilized in the operation of individual automatic milking units, the animal selection system, the automatic milking machine, the milk cooling system, the system for cleaning and sanitizing the automatic milking unit, the teat cleaning system, and the alarm systems associated with the process of milking, cooling, cleaning and sanitation.

6. BULK MILK HAULER/SAMPLER means any person who collects official samples and may transport raw milk from a farm and/or raw milk products to or from a milk plant, receiving station or transfer station and has in their possession a permit from any State to sample such products.

7. BULK MILK PICKUP TANKER means a vehicle including the truck, tank and those appurtenances necessary for its use, used by a milk hauler/sampler to transport bulk raw milk for pasteurization from a dairy farm to a transfer station, receiving station or milk plant.

8. BUTTERMILK means the fluid product resulting from the manufacture of butter from milk or cream. It contains not less than 8.25 percent of milk solids not fat. It shall also include:

a. Grade “A” Dry Buttermilk - dry buttermilk which complies with the applicable provisions of the Pasteurized Milk Ordinance (PMO)

b. Grade “A” Dry Buttermilk Products - dry buttermilk products which comply with the applicable provisions of the PMO.

c. Concentrated (Condensed) Buttermilk - the product resulting from the removal of a considerable portion of water from buttermilk.

d. Grade "A" Concentrated (Condensed) and Dry Buttermilk and Buttermilk Products - concentrated (condensed) or dry buttermilk and buttermilk products which comply with the applicable provisions of the PMO. The words "concentrated (condensed) and dry milk products" shall be interpreted to include concentrated (condensed) and dry buttermilk and buttermilk products.

9. CLEAN means direct product contact surfaces that have had the effective and thorough removal of product and/or contaminants.

10. CODE OF FEDERAL REGULATIONS (CFR) means the 2003 Code of Federal Regulations.

11. COMMON NAME means the generic term commonly used for domestic animals, i.e., cattle, goats, sheep, horses, water buffalo, etc.

12. COFFEE LIGHTENER, COFFEE WHITENER, COFFEE MILK, OR MILK FOR COFFEE means a milk product consisting of at least 5 percent but no more than 10.5 percent milkfat, to which approved ingredients may have been added.

13. CONCENTRATED (CONDENSED) MILK means the fluid product, unsterilized and unsweetened, resulting from the removal of a considerable portion of the water from the milk, which, when combined with potable water in accordance with instructions printed on the container label, results in a product conforming with the milkfat and milk solids not fat levels of milk.

14. CONCENTRATED (CONDENSED) MILK PRODUCTS means homogenized concentrated (condensed) milk, concentrated (condensed) skim milk, concentrated (condensed), reduced fat or lowfat milk, and similar concentrated (condensed) products made from concentrated (condensed) milk or concentrated (condensed) skim milk which when combined with potable water in accordance with instructions printed on the container label, conform with the definitions of the corresponding milk products in this section.

15. CONCENTRATED (CONDENSED) SKIM MILK (GRADE "A") means concentrated (condensed) skim milk, which complies with the applicable provisions of the PMO.

16. COOLING POND MEANS a man-made structure designed for the specific purpose of cooling cows.

17. CREAM means the liquid milk product high in fat which is separated from milk which may have been adjusted by adding thereto: milk, concentrated milk, dry whole milk, skim milk, concentrated skim milk, or nonfat dry milk. Cream contains not less than 18 percent milkfat.

18. DAIRY FARM means any place or premises where one or more lactating animals (cows, goats, sheep water buffalo, or other hooved mammal) are kept for milking purposes, and from which a part or all of the milk or milk product(s) is provided, sold, or offered for sale to a milk plant, transfer station, or receiving station.

19. DAIRY PLANT SAMPLER means a person responsible for the collection of official samples for regulatory purposes outlined in Section 6 of the PMO. This person is an employee of DHEC and is evaluated at least once every two-year period by a State Sampling Surveillance Officer.

20. DRUG means (A) articles recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any articles specified in clause (A), (B), or (C), but does not include devices or their components, parts, or accessories.

21. EGGNOG OR BOILED CUSTARD means the product defined in 21 CFR 131.170.

22. FOOD ALLERGENS mean proteins in foods that are capable of inducing an allergic reaction or response in some individuals. There is scientific consensus that the following foods account for more than 90% of all food allergies: peanuts, soybeans, milk, eggs, fish, crustaceans, tree nuts, and wheat.

Reference: FDA Compliance Policy Guide 555.250 - Statement of Policy for Labeling and Preventing Cross-Contact of Common Food Allergens available on the Internet at:
http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg555-250.htm

23. FROZEN MILK CONCENTRATE means a frozen milk product with a composition of milkfat and milk solids not fat in such proportions that when a given volume of concentrate is mixed with a given volume of water the reconstituted product conforms to the milkfat and milk solids not fat requirements of whole milk. In the manufacturing process, water may be used to adjust the primary concentrate to the final desired concentration. The adjusted primary concentrate is pasteurized, packaged, and immediately frozen. This product is stored, transported, and sold in the frozen state.

24. GOAT MILK means the normal lacteal secretion, practically free of colostrum, obtained by the complete milking of one or more healthy goats. Goat milk sold in retail packages shall contain not less than 2.5 percent milkfat and not less than 7.5 percent milk solids not fat. Goat milk shall be produced according to the sanitary standards of this Regulation. The word "milk" shall be interpreted to include goat milk.

25. GRADE A DRY MILK AND WHEY PRODUCTS means the products which have been produced for use in Grade A pasteurized or aseptically processed milk products and which have been manufactured under the provisions of the PMO.

26. HAZARD ANALYSIS CRITICAL CONTROL POINT (HACCP) DEFINITIONS FOR USE IN CONJUNCTION WITH APPENDIX K OF THE PMO:

a. AUDIT means an evaluation of the entire milk plant, receiving station or transfer station facility and National Conference on Interstate Milk Shipments (NCIMS) HACCP System to ensure compliance with the NCIMS HACCP System and other NCIMS regulatory requirements.

b. CENTRALIZED DEVIATION LOG means a centralized log or file identifying data detailing any deviation of critical limits and the corrective actions taken as required in Appendix K of the PMO.

c. CONTROL means:

(1) To manage the conditions of an operation to maintain compliance with established criteria.

(2) The state where correct procedures are being followed and criteria are being met.

d. CONTROL MEASURE means any action or activity that can be used to prevent, eliminate, or reduce a significant hazard that is managed at a Critical Control Point.

e. CORRECTIVE ACTION means procedures followed when a deviation occurs.

f.. CRITICAL CONTROL POINT (CCP) means a step at which control can be applied and is essential to prevent or eliminate a milk or milk product safety hazard or reduce it to an acceptable level.

g. CRITICAL LIMIT (CL) means a maximum and/or minimum value to which a biological, chemical, or physical parameter must be controlled at a CCP to prevent, eliminate, or reduce to an acceptable level the occurrence of a milk or milk product safety hazard.

h. CRITICAL LISTING ELEMENT (CLE) means an item on the Milk Plant, Receiving Station or Transfer Station NCIMS HACCP System Audit Report identified with a double star (**). The marking of a CLE by a State Rating Officer or FDA auditor, indicates a condition that constitutes a major dysfunction likely to result in a potential compromise to milk or milk product safety, or that violate NCIMS requirements regarding drug residue testing and traceback or raw milk sources, whereby a listing may be denied or withdrawn.

i. DAIRY HACCP CORE CURRICULUM shall consist of:

(1) Basic HACCP training; plus

(2) An orientation to the requirements of the NCIMS HACCP Program.

j. DEFICIENCY means an element inadequate or missing from the requirements of the HACCP System or Appendix K of the PMO.

k. DEVIATION means a failure to meet a CL.

l. HAZARD ANALYSIS CRITICAL CONTROL POINT (HACCP) means a systematic approach to the identification, evaluation, and control of significant milk or milk product safety hazards.

m. HACCP PLAN means the written document, which is based upon the principles of HACCP and delineates the procedures to be followed.

n. HACCP SYSTEM means the implemented HACCP Plan and Prerequisite Program, including other applicable NCIMS requirements.

o. HACCP TEAM means the group of people who are responsible for developing, implementing, and maintaining the HACCP System.

p. HAZARD means a biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control.

q. HAZARD ANALYSIS means the process of collecting and evaluating information on hazards associated with the milk under consideration, to decide which are reasonably likely to occur and must be addressed in the HACCP Plan.

r. MONITOR means to conduct a planned sequence of observations or measurements to assess whether a CCP is under control or to assess the conditions and practices of all required Prerequisite Programs.

s. NON-CONFORMITY means a failure to meet specified requirements of the HACCP System as described in Appendix K of the PMO.

t. POTENTIAL HAZARD means any hazard to be evaluated by the hazard analysis.

u. PREREQUISITE PROGRAMS (PPs) mean procedures, including Good Manufacturing Practices (GMPs), which address operational conditions that provide the foundation for the HACCP System. The required PPs specified in Appendix K. of the PMO are sometimes called Sanitary Standard Operating Procedures (SSOPs) in other HACCP Systems.

v. VALIDATION means the element of verification focused on collecting and evaluating scientific and technical information to determine whether the HACCP Plan, when properly implemented, will effectively control the hazards.

w. VERIFICATION means those activities, other than monitoring, that determine the validity of the HACCP Plan and that the HACCP System is operating according to the plan.

27. HERMETICALLY SEALED CONTAINER means a container that is designed and intended to be secure against the entry of microorganisms and thereby maintain the commercial sterility of its contents after processing.

28. HOMOGENIZED means the milk or a milk product has been treated to insure breakup of the fat globules to such an extent that after 48 hours of quiescent storage at 4.4°C (40°F), no visible cream separation occurs on the milk; and the fat percentage of the top 100 milliliters of milk in a quart, or of proportionate volumes in containers of other sizes, does not differ by more than 10 percent from the fat percentage of the remaining milk as determined after thorough mixing.

29. HOOVED MAMMALS MILK means the normal lacteal secretion, practically free of colostrum, obtained by the complete milking of one or more healthy hooved mammals. This product shall be produced according to the sanitary standards of this Regulation.

30. INDUSTRY PLANT SAMPLER means a person responsible for the collection of official samples for regulatory purposes at a milk plant, receiving station or transfer station as outlined in Appendix N of the PMO. This person is an employee of the milk plant, receiving station or transfer station and is evaluated at least once every two year period by a State Sampling Surveillance Officer or a properly delegated Sampling Surveillance Regulatory Official.

31. LACTOSE-REDUCED MILK, LACTOSE-REDUCED REDUCED FAT MILK, LACTOSE-REDUCED LOWFAT MILK, OR LACTOSE-REDUCED SKIM MILK means the product resulting from the treatment of milk, reduced fat milk, low fat milk, or skim milk as defined in this Regulation by the addition of safe and suitable enzymes to convert sufficient amounts of the lactose to glucose and/or galactose so that the remaining lactose is less than 30 percent of the lactose in milk, reduced fat milk, lowfat milk or skim milk.

32. LOW-SODIUM MILK, LOW-SODIUM REDUCED FAT MILK, LOW-SODIUM LOWFAT MILK OR LOW-SODIUM SKIM MILK means the product resulting from the treatment of milk, reduced fat milk, lowfat milk, or skim milk as defined in the Regulation by a process of passing the milk, reduced fat milk, lowfat milk. or skim milk through an ion exchange resin process or any other process which has been recognized by the Food and Drug Administration that effectively reduces the sodium content of the product to less than 10 milligrams in 100 milliliters.

33. MILK DISTRIBUTOR means any person who offers for sale or sells to another any milk or milk products.

34. MILK HAULER means any person who transports raw milk and/or raw milk products to or from a milk plant, receiving station or transfer station.

35. MILK PLANT means any place, premises, or establishment where milk or milk products are collected, handled, processed, stored, pasteurized, ultra-pasteurized, aseptically processed, condensed, dried, packaged, or prepared for distribution.

36. MILK PRODUCER means any person who operates a dairy farm and provides, sells, or offers milk for sale to a milk plant, receiving station, or transfer station.

37. MILK PRODUCTS include cream, light cream, light whipping cream, heavy cream, heavy whipping cream, whipped cream, whipped light cream, sour cream, acidified sour cream, cultured sour cream, half-and-half, sour half-and-half, acidified sour half-and-half, cultured sour half-and-half, reconstituted or recombined milk and milk products, concentrated (condensed) milk, concentrated (condensed) milk products, concentrated (condensed) and dry milk products, nonfat (skim) milk, reduced fat or lowfat milk, frozen milk concentrate, eggnog, buttermilk, buttermilk products, whey, whey products, cultured milk, cultured reduced fat or lowfat milk, cultured nonfat (skim) milk, yogurt, lowfat yogurt, nonfat yogurt, acidified milk, acidified reduced fat or lowfat milk, acidified nonfat (skim) milk, low-sodium milk, low-sodium reduced fat or lowfat milk, low-sodium nonfat (skim) milk, lactose-reduced milk, lactose-reduced reduced fat or lowfat milk, lactose-reduced nonfat (skim) milk, aseptically processed and packaged milk and milk products as defined in this Section, milk, reduced fat, lowfat milk or nonfat (skim) milk with added safe and suitable microbial organisms and any other milk product made by the addition or subtraction of milkfat or addition of safe and suitable optional ingredients for protein, vitamin or mineral fortification of milk products defined herein.

Milk products also include those dairy foods made by modifying the federally standardized products listed in this Section in accordance with 21 CFR 130.10-Requirements for foods named by use of a nutrient content claim and a standardized term.

This Definition shall include those milk and milk products, as defined herein, which have been aseptically processed and then packaged.

Milk and milk products which have been retort processed after packaging or which have been concentrated (condensed) or dried are included in this Definition only if they are used as an ingredient to produce any milk or milk product defined herein or if they are labeled as Grade "A" as described in Section IV.

Powdered dairy blends may be labeled Grade "A" and used as ingredients in Grade "A" dairy products, such as cottage cheese dressing mixes or starter media for cultures used to produce various Grade "A" cultured products, if they meet the requirements of this Regulation. If used as an ingredient in Grade "A" products, such as those listed above, blends of dairy powders must be blended under conditions, which meet all applicable Grade "A" requirements. Grade "A" powder blends must be made from Grade "A" powdered dairy products, except that small amounts of functional ingredients, (total of all such ingredients shall not exceed 5% by weight of the finished blend) which are not Grade "A" are allowed in Grade "A" blends when the finished ingredient is not available in Grade "A" form, i.e., sodium caseinate. This is similar to the existing FDA position that such dairy ingredient in small cans of freeze-dried starter culture need not be Grade "A".

This definition is not intended to include dietary products (except as defined herein), infant formula, ice cream or other frozen desserts, butter or cheese. It does, however, include:

DRY MILK PRODUCTS - products resulting from the drying of milk or milk products and any product resulting from the combination of dry milk products with other wholesome dry ingredients.

GRADE "A" DRY MILK PRODUCTS - dry milk products, which comply with the applicable provisions of this Regulation.

38. MILK SHAKE MIX means the fluid product made only from Grade A pasteurized milk with the addition of harmless flavoring, sugar, stabilizer, and milk solids. The product shall contain not less than 3.25 percent milkfat and not less than 25 percent and not more than 30 percent total solids.

39. MILK TANK TRUCK means a bulk milk pickup tanker and a milk transport tank.

40. MILK TANK TRUCK CLEANING FACILITY means any place, premises, or establishment, separate from a milk plant, receiving station or transfer station, where a milk tank truck is cleaned and sanitized.

41. MILK TANK TRUCK DRIVER means a person who transports raw or pasteurized milk or milk products to or from a milk plant, receiving station or transfer station. Any transportation of a direct farm pickup requires the milk tank truck driver to have responsibility for accompanying official samples.

42. MILK TRANSPORT TANK means a vehicle including the truck and tank used by a milk hauler/sampler to transport bulk shipments of milk from a transfer station, receiving station or milk plant to another transfer station, receiving station or milk plant.

43. MILK TRANSPORTATION COMPANY means the person responsible for a milk tank truck(s).

44. MISBRANDED MILK AND MILK PRODUCTS means any milk or milk products are deemed to be misbranded when:

a. The product's container bears or accompanies any false or misleading written, printed, or graphic matter;

b. The milk and milk products do not conform to the definitions as contained in this Regulation; and

c. The products are not labeled in accordance with Section IV of this Regulation.

d. Violation of Chapter 403 of the Federal Food, Drug, and Cosmetic Act as amended (21 U.S.C. 342) will be considered as a violation of this Regulation.

45. OFFICIALLY DESIGNATED LABORATORY means a commercial laboratory authorized to do official work by DHEC, or a milk industry laboratory officially designated by DHEC for the examination of producer samples of Grade A raw milk for pasteurization and commingled milk tank truck samples of raw milk for drug residues and bacterial limits.

46. OFFICIAL LABORATORY means a biological, chemical, or physical laboratory which is under the direct supervision of DHEC.

47. OPTIONAL INGREDIENTS means ingredients used in milk products approved by DHEC.

48. PASTEURIZATION means the process of heating every particle of milk or milk product in properly designed and operated equipment, to one of the temperatures given in the following table and held continuously at or above that temperature for at least the corresponding specified time:

Temperature	Time
*63ºC (145ºF)	30 minutes
*72ºC (161ºF)	15 seconds
89ºC (191ºF)	1.0 second
90ºC (194ºF)	0.5 second
94ºC (201ºF)	0.1 second
96ºC (204ºF)	0.05 second
100ºC (212ºF)	0.01 second

*If the fat content of the milk product is 10 percent or more, or if it contains added sweeteners, or if it is concentrated (condensed), the specified temperature shall be increased by 3°C (5°F): Provided, that eggnog shall be heated to at least the following temperature and time specifications:

Temperature	Time
69ºC (155ºF)	30 minutes
80ºC (175ºF)	25 seconds
83ºC (180ºF)	15 seconds

Provided further, that nothing in this definition shall be construed as barring any other pasteurization process which has been recognized by the Food and Drug Administration to be equally efficient and which is approved by DHEC.

49. PASTEURIZED MILK ORDINANCE (PMO) means the Grade "A" Pasteurized Milk Ordinance, 2003 Revision, promulgated by the National Conference on Interstate Milk Shipments (NCIMS) and endorsed by the United States Department of Health and Human Services, Public Health Service, Food and Drug Administration for regulating the production, transportation, processing, handling, sampling, examination, labeling and sale of all Grade "A" milk and milk products sold and consumed in the United States.

50. PERSON means any individual, milk plant operator, partnership, corporation, company, firm, trustee, association or institution.

51. RECEIVING STATION means any place, premises, or establishment where raw milk is received, collected, handled, stored or cooled and prepared for further transporting.

52. RECONSTITUTED OR RECOMBINED MILK AND MILK PRODUCTS means milk or milk products defined in this section which result from reconstituting or recombining of milk constituents with potable water when appropriate.

53. REGULATORY AUTHORITY means the authorized representative of the South Carolina Department of Health and Environmental Control, hereinafter known as DHEC.

54. SANITIZATION means the application of any effective method or substance to a clean surface for the destruction of pathogens, and of other organisms as far as is practicable. Such treatment shall not adversely affect the equipment, the milk or milk product or the health of consumers, and shall be acceptable to DHEC.

55. SHEEP MILK means the normal lacteal secretion practically free of colostrum, obtained by the complete milking of one or more healthy sheep. Sheep milk shall be produced according to the sanitary standards of this Regulation. The word "milk" shall be interpreted to include sheep milk.

56. STERILIZED means the condition achieved by application of heat, chemical sterilant(s) or other appropriate treatment that renders the piping, equipment and containers free of viable microorganisms.

57. TRANSFER STATION means any place, premises, or establishment where milk or milk products are transferred directly from one milk tank truck to another.

58. ULTRA-PASTEURIZED means that a dairy product shall have been thermally processed at or above 138ºC (280ºF) for at least two seconds, either before or after packaging, so as to produce a product which has an extended shelf life under refrigerated conditions. (Refer to 21 CFR 131.3)

59. WATER BUFFALO MILK means the normal lacteal secretion, practically free of colostrum, obtained by the complete milking of one or more healthy water buffalo. Water buffalo milk shall be produced according to the sanitary standards of this Regulation. The word "milk" shall be interpreted to include water buffalo milk.

60. WHEY PRODUCTS mean any fluid product removed from whey; or made by the removal of any constituent from whey; or by the addition of any wholesome substance to whey or parts thereof.

a. GRADE “A” WHEY PRODUCTS mean any fluid product removed from whey; or made by the removal of any constituent from whey; or by the addition of any wholesome substance to whey or parts thereof which have been manufactured under the provisions of this Regulation.

b. DRY WHEY PRODUCTS mean products resulting from the drying of whey or whey products and any product resulting from the combination of dry whey products with other wholesome dry ingredients.

GRADE “A” CONCENTRATED (CONDENSED) AND DRY WHEY AND WHEY PRODUCTS mean concentrated (condensed) or dry whey and whey products, which complies with the applicable provisions of this Regulation. The words "concentrated (condensed) and dry milk products" shall be interpreted to include concentrated (condensed) and dry whey and whey products.

B. Standards

1. The Grade A milk and milk products covered by this Regulation include cream, light cream, light whipping cream, heavy cream, heavy whipping cream, whipped cream, whipped light cream, sour cream, acidified sour cream, cultured sour cream, half-and-half, sour half-and-half, acidified sour half-and-half, cultured sour half-and-half, reconstituted or recombined milk and milk products, concentrated (condensed) milk, concentrated (condensed) milk products, concentrated (condensed) and dry milk products, nonfat (skim) milk, reduced fat or lowfat milk, frozen milk concentrate, eggnog, buttermilk, buttermilk products, whey, whey products, cultured milk, cultured reduced fat or lowfat milk, cultured nonfat (skim) milk, yogurt, lowfat yogurt, nonfat yogurt, acidified milk, acidified reduced fat or lowfat milk, acidified nonfat (skim) milk, low-sodium milk, low-sodium reduced fat or lowfat milk, low-sodium nonfat (skim) milk, lactose-reduced milk, lactose-reduced reduced fat or lowfat milk, lactose-reduced nonfat (skim) milk, aseptically processed and packaged milk and milk products, milk, reduced fat, lowfat milk or nonfat (skim) milk with added safe and suitable microbial organisms and any other milk product made by the addition or subtraction of milkfat or addition of safe and suitable optional ingredients for protein, vitamin or mineral fortification of milk products defined herein.

Milk products also include those dairy foods made by modifying the federally standardized products listed in this Section in accordance with 21 CFR 130.10-Requirements for foods named by use of a nutrient content claim and a standardized term.

Milk and milk products,which have been aseptically processed and then packaged are also covered by this Regulation.

Milk and milk products which have been retort processed after packaging or which have been concentrated (condensed) or dried are included only if they are used as an ingredient to produce any milk or milk product defined herein or if they are labeled as Grade “A.”

Powdered dairy blends may be labeled Grade “A” and used as ingredients in Grade “A” dairy products, such as cottage cheese dressing mixes or starter media for cultures used to produce various Grade “A” cultured products, if they meet the requirements of this Regulation. If used as an ingredient in Grade “A” products, such as those listed above, blends of dairy powders must be blended under conditions, which meet all applicable Grade “A” requirements. Grade “A” powder blends must be made from Grade “A” powdered dairy products, except that small amounts of functional ingredients, (total of all such ingredients shall not exceed 5% by weight of the finished blend) which are not Grade “A” are allowed in Grade “A” blends when the finished ingredient is not available in Grade “A” form, i.e., sodium caseinate. Examples: small cans of freeze-dried starter culture not labeled as Grade “A.”

This Regulation is not intended to include dietary products (except as defined herein), infant formula, ice cream or other frozen desserts, butter or cheese.

2. All Grade A milk and milk products shall meet the definitions and standards for milk and cream products as set for in Parts 131 and 133 (for cottage cheese products) of 21 CFR and Appendix L. of the PMO.

3. All Grade "A" raw milk or milk products for pasteurization, ultra-pasteurization, or aseptic processing and all Grade "A" pasteurized, ultra-pasteurized or aseptically processed milk and milk products, shall be produced, processed**,** manufactured and pasteurized, ultra-pasteurized, or aseptically processed to conform to the following chemical, physical, bacteriological and temperature standards and the sanitation requirements of this Section.

No process or manipulation other than pasteurization, ultra-pasteurization or aseptic processing; processing methods integral therewith; and appropriate refrigeration shall be applied to milk and milk products for the purpose of removing or deactivating microorganisms. Provided, that in the bulk shipment of cream, nonfat (skim) milk or reduced fat or lowfat milk, the heating of the raw milk, one time, to temperatures greater than 52ºC (125ºF) but less than 72ºC (161ºF), for separation purposes, is permitted when the resulting bulk shipment(s) of cream, nonfat (skim) milk or reduced fat or lowfat milk are labeled heat-treated. In the case of heat-treated cream, the cream may be further heated to less than 75ºC (166ºF) in a continuing heating process and immediately cooled to 7ºC (45ºF) or less when necessary for enzyme deactivation (such as lipase reduction) for a functional reason.

Milk plants, receiving stations and transfer stations participating in the NCIMS HACCP Program, shall also comply with the requirements of Appendix K. of the PMO.

Whey shall be from cheese made from Grade "A" raw milk for pasteurization as provided in this Regulation.

Buttermilk shall be from butter made from Grade "A" cream, which has been pasteurized prior to use in accordance with the pasteurizing and aseptic processing requirements of this Regulation. Provided, that this requirement shall not be construed as barring any other heat treatment process which has been recognized by the FDA to be equally efficient in the destruction of staphylococcal organisms and which is approved by DHEC.

Buttermilk and whey used in the manufacture of Grade "A" milk and milk products shall be produced in an approved milk/cheese plant.

Whey shall be from:

a. Cheese made from Grade "A" raw milk for pasteurization, which has been pasteurized prior to use, in accordance with the pasteurizing and aseptic processing requirements of this Regulation, or

b. Cheese made from Grade "A" raw milk for pasteurization, which has been heat-treated to a temperature of at least 64^{o}C (147^{o}F) and held continuously at that temperature for at least twenty-one seconds or to at least 68^{o}C (153^{o}F) and held continuously at that temperature for at least fifteen seconds, in equipment meeting the pasteurization requirements provided for in this Regulation. Provided, that this requirement shall not be construed as barring any other heat treatment process which has been recognized by the FDA to be equally efficient in the destruction of staphylococcal organisms and which is approved by DHEC.

SECTION II. ADULTERATED OR MISBRANDED MILK OR MILK PRODUCTS

A. General

1. No person shall, within the State of South Carolina or its jurisdiction, produce, provide, sell, offer, or expose for sale, or have in possession with intent to sell any milk or milk product which is adulterated or misbranded: provided, that in an emergency, the sale of pasteurized milk and milk products which have not been graded, or the grade of which is unknown, may be authorized by DHEC in which case such products shall be labeled "ungraded".

2. Any adulterated or misbranded milk or milk product may be impounded by DHEC and disposed of in accordance with applicable laws or regulations.

3. Milk and milk products shall be examined by DHEC as often as may be necessary to determine freedom from adulteration or misbranding. DHEC may, upon written notice to the owner or person in charge, place a hold order on any milk or milk product which it determines, or has probable cause to believe, to be unwholesome or otherwise adulterated or misbranded. Under a hold order, milk or milk products shall be permitted to be suitably stored. It shall be unlawful for any person to remove or alter a hold order, notice, or tag placed on milk or milk products by DHEC, and neither such milk or milk products nor the containers thereof shall be relabeled, repacked, reprocessed, altered, disposed of, or destroyed without permission of DHEC, except on order by a court of competent jurisdiction.

4. When the freezing point of milk and milk products, other than cultured products, is greater than 31ºF. (-0.525ºC.), the farm or plant owner or manager shall be notified that apparently the milk or milk product contains added water. If a second violation of this freezing point standard occurs within two years, an observed milking or operation of processing shall be conducted and samples analyzed. The freezing point obtained from milk collected during the observation shall be used to determine a definite freezing point from the individual farm or plant. A violation of the determined freezing point for a specific operation by over 3 percent within two years of setting the standard shall call for a two-day permit suspension or equivalent.

5. A cryoscope shall be used to determine adulteration by water.

6. When milk is found to be adulterated by the presence of drugs, pesticides, herbicides, or other poisonous substances, it shall be impounded and additional samples analyzed. Milk found to be adulterated shall be disposed of until analysis shows the product not to be adulterated. If testing reveals milk positive for drug residues, the milk shall be disposed of in a manner that removes it from the human or animal food chain, except where acceptably reconditioned under FDA Compliance Policy Guide (CPG 7126.20). DHEC shall determine the producer(s) responsible for the drug residue violation and immediately suspend the producer’s Grade "A” permit or equally effective measures shall be taken to prevent the sale of milk containing drug residues and a penalty shall be imposed. Future pick-ups are prohibited until subsequent testing reveals the milk is free of drug residue. The penalty shall be for the value of all milk on the contaminated load plus any costs associated with the disposition of the contaminated load. DHEC may accept certification from the violative producer’s milk marketing cooperative or purchaser of milk as satisfying the penalty requirements. The Grade “A” producer’s permit may be reinstated, or other action taken, to allow the sale of milk for human food, when a representative sample taken from the producer’s milk, prior to commingling with any other milk, is no longer positive for drug residue. Whenever a drug residue test is positive, an investigation shall be made to determine the cause. The farm inspection is completed by DHEC to determine the cause of the residue and actions taken to prevent future violations including:

a. On-farm changes in procedures necessary to prevent future occurrences as recommended by DHEC.

b. Discussion and education on the Drug Residue Avoidance Control measures outlined in

Appendix C. of the PMO.

After a third violation in a twelve-month period, DHEC shall initiate administrative procedures pursuant to the revocation of the producer's Grade "A" permit under the authority of Section III.of this Regulation, due to repeated violations.

7. When pasteurized milk or milk products are found to be adulterated by drugs, pesticides, herbicides, or other poisonous substances, the adulterated products shall be removed from the market, disposed of, and sale stopped until analysis proves the product to be free from adulteration.

B. Administrative Procedures

1. This section of the Regulation shall be used in impounding the product, preferring charges against persons who adulterated or misbrand their milk or milk products, or label them with any grade designation not authorized by DHEC under the terms of this Regulation, or who sell or deliver ungraded milk or milk products except as may be permitted under this section in an emergency. An emergency is defined as a general and acute shortage in the milkshed, not simply one distributor's shortage.

2. When two of the last four samples of a pasteurized product are in violation of the milkfat or milk solids not fat standard for that product a warning letter will be issued. When three of the last five samples are in violation the permit will be suspended in accordance with the South Carolina Administrative Procedures Act, Sections 1-23-310 et. seq., 1976 Code of Laws of South Carolina as amended.

SECTION III. PERMITS

A. General

1. It shall be unlawful for any person who does not possess a permit from DHEC to manufacture, bring into, send into, or receive into South Carolina or its jurisdiction; have in storage, sell or offer for sale therein, or or offer to give away any milk or milk products defined in this Regulation. Grocery stores, restaurants, soda fountains, and similar establishments where milk or milk products are served or sold at retail, but not processed, may be exempt from the requirements of this section.

2. Only a person who complies with the requirements of this Regulation shall be entitled to receive and retain such a permit. Permits shall not be transferable with respect to persons and/or locations. Brokers, agents, and distributors representing, buying from, and/or selling condensed and dry milk from, or to, a permitted milk plant are not required to have a separate permit.

3. DHEC shall suspend such permit, whenever it has reason to believe that a public health hazard exists; or whenever the permit holder has violated any of the requirements of this Regulation; or whenever the permit holder has interfered with DHEC in the performance of its duties provided that DHEC shall, in all cases except where the milk or milk product involved creates, or appears to create, an imminent hazard to the public health; or in any case of a willful refusal to permit authorized inspection, serve upon the holder a written notice of intent to suspend permit, which notice shall specify with particularity the violation(s) in question and afford the holder such reasonable opportunity to correct such violation(s) as may be agreed to by the parties, or in the absence of agreement, fixed by DHEC before making any order of suspension effective. A suspension of permit shall remain in effect until the violation has been corrected to the satisfaction of DHEC.

3. It shall be unlawful for any person to manufacture, package, and/or store non-Grade "A" condensed or dry milk products in a permitted Grade "A" milk plant in South Carolina without a separate DHEC permit for those specific products. All non-Grade "A" condensed or dry milk products shall be plainly identified, and processed, packaged and stored separately from all Grade "A" products.

4. a. DHEC shall suspend such permit whenever:

(1) it has reason to believe that a public health hazard exists;

(2) the permit holder has violated any of the requirements of this Regulation, including willful refusal to allow an authorized inspection/audit;

(3) the permit holder has interfered with DHEC in the performance of its duties; or

(4) the milk or milk product involved creates, or appears to create, an imminent hazard to the public health, as defined in Section III.B.2.a. below.

b. A suspension of permit shall remain in effect until the violation has been corrected to the satisfaction of DHEC.

5. Upon repeated violation(s) and/or suspension(s), DHEC may revoke such permit following reasonable notice to the permit holder and an opportunity for a hearing, pursuant to the South Carolina Administrative Procedures Act, Sections 1-23-310 et. seq, 1976 Code of Laws of South Carolina as amended.

B. Administrative Procedures

1. Issuance of Permits - Every milk producer, milk distributor, milk hauler, bulk milk pickup tanker, and each milk plant, receiving station, milk tank truck cleaning facility, transfer station operator, and milk transportation company shall hold a valid permit. Milk producers who transport milk or milk products only from their own dairy farms and employees of a milk distributor or milk plant operator who possesses a valid permit and employees of a milk transportation company that possesses a valid permit and transports milk or milk products from a milk plant, receiving station or transfer station shall not be required to possess a bulk milk hauler/sampler's permit. Grocery stores, restaurants, soda fountains, and similar establishments where milk and milk products are served or sold at retail but not processed, may be exempt from the requirements of this section.

2. Suspension of Permits

a. When the permit suspension is due to violations other than bacterial, coliform, somatic cell, cooling temperature, or drug residue test standards, the permit holder, manager or other authorized representative is notified by certified mail or hand delivery of the intent to suspend the permit in thirty days unless a written request for a hearing is filed with DHEC. If no request is made in thirty days, the permit is suspended until the violations are corrected. If a written request for a hearing is made within thirty days, a hearing will be provided. If the hearing upholds the findings of DHEC, the permit shall be suspended until the reasons for the suspension have been corrected.

b. DHEC may without warning, notice, or hearing suspend a permit when an imminent health hazard exists. An imminent health hazard includes, but is not limited to, violations of bacterial, coliform, somatic cell, cooling temperature, or drug residue test standards. Following permit suspension, all manufacturing operations shall immediately cease. DHEC shall promptly notify, in writing by certified mail or hand delivery, the specific reasons for which the permit was suspended and that an opportunity for a hearing will be provided if a written request is filed with DHEC by the permit holder within thirty days. If no written request is filed within thirty days, the suspension is sustained. During the hearing process, the permit shall remain suspended unless the imminent health hazard has been corrected.

c. Hearings on suspension of permits provided for in this section shall be conducted in accordance, where applicable, with the South Carolina Administrative Procedures Act, Sections 1-23-310 et. seq., 1976 Code of Laws of South Carolina as amended.

3. Reinstatement of Permits

a. Any producer, distributor, bulk milk hauler/sampler, bulk milk pickup tanker, or milk plant operator, receiving station, milk tank truck cleaning facility, transfer station operator, and milk transportation company, whose permit has been suspended may apply for the reinstatement of his permit. Any application for the reinstatement of a suspended permit must be in writing and must address all violations underlying the suspension and explain the steps taken to correct those violations. Within one week of the receipt of such application, DHEC shall make an inspection of the applicant's establishment, and as many additional inspections thereafter as are deemed necessary, to determine that the applicant's establishment is complying with the requirements. When the findings justify, the permit shall be reinstated.

b. When the permit suspension has been due to a violation of any of the bacteriological, coliform, somatic cell, cooling temperature, or drug residue test standards, DHEC, within one week after the receipt of application for reinstatement of permit, may issue a temporary permit after determining by an inspection of the facilities and operating methods that the conditions responsible for the violation have been corrected.

c.When a permit suspension has been due to a violation of the somatic cell count standard, DHEC may issue a temporary permit whenever resampling of the herd’s milk supply indicates the milk supply to be within acceptable limits as prescribed in Section VII. Samples shall then be taken at the rate of not more than two per week on separate days within a three-week period, and DHEC shall reinstate the permit upon compliance with the appropriate standards as determined in accordance with Section VI of this Regulation.

4. When a permit has been revoked, the holder of the revoked permit may make written application for a new permit; however, DHEC may deny a new permit based upon past history.

SECTION IV. LABELING

A. General

1. All bottles, containers, and packages enclosing milk or milk products defined in Section I of this Regulation shall be labeled in accordance with the applicable requirements of the Federal Food, Drug and Cosmetic Act as amended, the Nutrition Labeling and Education Act (NLEA) of 1990 and regulations developed thereunder, the Code of Federal Regulations, and in addition shall comply with the applicable requirements of this section as follows:

2. All bottles, containers, and packages enclosing milk or milk products except milk tank trucks, storage tanks, and cans of raw milk from individual dairy farms shall be conspicuously marked with:

a. The words "Grade A" on the exterior surface. Acceptable locations shall include the principal display panel, the secondary or informational panel, or the cap/cover.

b. The identity of the plant where pasteurized, ultra-pasteurized, aseptically processed, condensed and/or dried.

c. The word "reconstituted" or "recombined" if the product is made by reconstitution or recombination.

d. The volume or proportion of water to be added for reconstituting or recombining in the case of concentrated milk or milk products.

e. In the case of condensed or dry milk products, the following shall also apply:

(1) The identity of the Regulatory Agency issuing such permit; and if distributed by another party, the name and address of the distributor shall be shown by a statement, such as "Distributed by."

(2) A code or lot number identifying the contents with a specific date, run, or batch of the product, and the quantity of the contents of the container.

f. The words "keep refrigerated after opening" in the case of aseptically processed milk and milk products.

g. The common name of the hooved mammal producing the milk shall precede the name of the milk or milk product when the product is or is made from other than cattle's milk. As an example, "Goat," "Sheep," "Water Buffalo," or "Other Hooved Mammal" milk or milk products respectively.

3. All vehicles and milk tank trucks containing milk or milk products shall be legibly marked with the name and address of the milk plant or hauler in possession of the contents.

4. Milk tank trucks transporting raw, heat-treated or pasteurized milk and milk products to a milk plant from another milk plant, receiving or transfer station are required to be marked with the name and address of the milk plant or hauler and shall be sealed; in addition, for each such shipment, a shipping statement shall be prepared containing at least the following information:

a. Shipper's name, address, and permit number. Each milk tank truck containing milk shall include the IMS Bulk Tank Unit (BTU) Identification Number(s) or the IMS Listed Milk Plant Number for farm groups listed with a milk plant, on the weigh ticket or manifest.

b. Permit identification of hauler, if not employee of shipper.

c. Point of origin of shipment.

d. Tanker identity number.

e. Name of product.

f. Weight of product.

g. Grade of product.

h. Temperature of product when loaded.

i. Date of shipment.

j. Name of supervising regulatory agency at the point of origin of shipment.

k. Whether the contents are raw, pasteurized, or in the case of cream, lowfat, or skim milk whether it has been heat-treated.

l. Seal number on inlet, outlet, wash connections and vents.

5. Each milk tank truck containing milk shall be accompanied by documentation, weigh ticket or manifest, which shall include the IMS BTU Identification Number(s) or the IMS Listed Milk Plant Number, for farm groups listed with a milk plant.

6. All cans of raw milk from individual dairy farms shall be identified by the name or number of the individual milk producer.

B. Administrative Procedures - Emergency Supplies

The purpose of this Section is to require labeling that will permit easy identification of the milk and milk product and its origin. It is required that the milk or milk product be designated by its common or usual name.

1. Labeling - When the sale of ungraded milk or milk products is authorized during emergencies, under the terms of Section II, the label must bear the designation "ungraded". When such labeling is not available, DHEC shall take immediate steps to inform the public that the particular supply is ungraded, and that the supply will be properly labeled as soon as the distributor can obtain the required labels.

2. Identity Labeling - "Identity" as used in this section is defined as the name and address or permit number of the milk plant at which the pasteurization, ultra-pasteurization, aseptic processing, or condensing and/or drying takes place. It is recommended that the voluntary national uniform coding system for identification of pasteurization plants at which milk and milk products are packaged, be adopted in order to provide a uniform system of codes throughout the country.

a. In cases where several plants are operated by one firm, the common firm name may be utilized on milk bottles, containers, or packages provided that the location of the plant at which the contents were pasteurized, ultra-pasteurized, aseptically processed, condensed and/or dried is also shown, either directly or by a code. This requirement is necessary in order to enable DHEC to identify the source of the pasteurized, ultra-pasteurized, aseptically processed, condensed and/or dried milk or milk products. The street address of the plant need not be shown when only one plant of a given name is located within the municipality.

b. The identity labeling requirement may be interpreted as permitting plants and persons to purchase and distribute, under their own label milk and milk products processed and packaged at another plant provided that the label reads, "Processed at ... (name and address)", or that the processing and packaging plant is identified by a proper code.

3. Misleading Labels - DHEC shall not permit the use of any misleading marks, words, or endorsements upon the label. DHEC may permit the use of registered trade designs or similar terms on the bottle cap or label when, in their opinion, they are not misleading and are not so used as to obscure the labeling required by the Regulation. For dry milk products, the outer bag must be preprinted Grade “A” before filling. The use of super grade designations shall not be permitted. However, this should not be construed as prohibiting the use of official grade designations awarded to dry milk products by the United States Department of Agriculture (USDA). Grade designations such as "Grade AA Pasteurized", "Selected Grade A Pasteurized", "Special Grade A Pasteurized", etc., give the consumer the impression that such a grade is significantly safer than Grade “A.” Such an implication is false, because the Regulation requirements for Grade “A” pasteurized, ultra-pasteurized or aseptically processed milk when properly enforced, will ensure that this grade of milk will be as safe as milk can practicably be made. Descriptive labeling terms must not be used in conjunction with the Grade “A” designation or name of the milk or milk product and must not be false or misleading.

SECTION V. INSPECTION OF DAIRY FARMS AND MILK PLANTS

A. General

1. Each dairy farm, milk plant, receiving station, transfer station, and milk tank truck cleaning facility whose milk or milk products are intended for consumption within South Carolina or its jurisdiction and each bulk milk hauler/sampler who collects samples of raw milk for pasteurization, for bacterial, chemical or temperature standards and hauls milk from a dairy farm to a milk plant, transfer station or receiving station and his bulk milk pickup tank and its appurtenances shall be inspected by DHEC prior to the issuance of a permit. Following the issuance of a permit, DHEC shall:

a. Inspect each bulk milk pickup tanker and its appurtenances used by a bulk milk hauler/sampler who collects samples of raw milk for pasteurization for bacterial, chemical or temperature standards and hauls milk from a dairy farm to a milk plant, transfer station or receiving station at least every twelve months;

b. Inspect each such bulk milk hauler/sampler's, dairy plant sampler's and industry plant sampler's pickup and sampling procedures at least once every twenty-four months;

c. Inspect each dairy farm at least once every three months;

d. Inspect each milk plant and receiving station at least once every three months, except that, for those milk plants and receiving stations that have HACCP Systems, which are regulated under the NCIMS HACCP Program, regulatory audits shall replace the regulatory inspections described in this Section. The requirements and minimum frequencies for these regulatory audits are specified in Appendix K of the PMO.

e. Inspect each milk tank truck cleaning facility and transfer station at least once every six months, except that, for those transfer stations that have HACCP Systems, which are regulated under the NCIMS HACCP Program, regulatory audits shall replace the regulatory inspections described in this Section. The requirements and minimum frequencies for these regulatory audits are specified in Appendix K of the PMO.

2. Should a violation of any requirement set forth in Section VII, or in the case of a bulk milk hauler/sampler, industry plant sampler or milk tank truck also Section VI and Appendix B of the PMO, be found to exist on an inspection/audit, a second inspection/audit shall be required after the time deemed necessary to remedy the violation, but not before three days. This second inspection/audit shall be used to determine compliance with the requirements of Section VII or in the case of a bulk milk hauler/sampler, industry plant sampler or milk tank truck also Section VI and Appendix B of the PMO. Any violation of the same requirement of Section VII, or in the case of a bulk milk hauler/sampler or milk tank truck also Section VI and Appendix B of the PMO, on such second inspection/audit, shall call for permit suspension in accordance with Section III and/or court action or in the case of an industry plant sampler, shall cease the collection of official regulatory samples until successfully re-trained and re-evaluated by DHEC. Provided, that when DHEC finds that a critical processing element violation involving:

a. Proper pasteurization, whereby every particle of milk or milk product may not have been heated to the proper temperature and held for the required time in properly designed and operated equipment;

b. A cross-connection exists whereby direct contamination of pasteurized milk or milk product is occurring; or

c. Conditions exist whereby direct contamination of pasteurized milk or milk product is occurring,

DHEC shall take immediate action to prevent further movement of such milk or milk product until such violations of critical processing element(s) have been corrected. Should correction of such critical processing element(s) not be accomplished immediately, DHEC shall take prompt action to suspend the permit as provided

for in Section III of this Regulation. Provided, that in the case of milk plants producing aseptically processed milk and milk products, when an inspection of the milk plant and its records reveal that the process used has been less than the required scheduled process, it shall be considered an imminent hazard to public health and DHEC shall take immediate action to suspend the permit of the milk plant for the sale of aseptically processed milk and milk products in conformance with Section III of this Regulation.

3. One copy of the inspection report shall be handed to the operator, or other responsible person, or be posted in a conspicuous place on an inside wall of the establishment. Said inspection/audit report shall not be defaced and shall be made available to DHEC upon request. An identical copy of the inspection/audit report shall be filed with the records of DHEC.

4. DHEC shall also make such other inspections and investigations as are necessary for the enforcement of this Regulation.

5. Every permit holder shall, upon request of DHEC, allow access of officially designated persons to all parts of the permitted establishment or facilities to determine compliance with the provision of this Regulation. A distributor or plant operator shall furnish DHEC, upon request, for official use only, a true statement of the actual quantities of milk and milk products of each grade purchased and sold, and a list of all sources of such milk and milk products, records of inspections, tests, and pasteurization time and temperature records.

6. It shall be unlawful for any person who, in an official capacity, obtains any information under the provisions of this Regulation which is entitled to protection as a trade secret (including information as to the quantity, quality, source or disposition of milk or milk products, or results of inspections or tests thereof) to use such information to his/her own advantage or to reveal it to any unauthorized person.

B. Administrative Procedures

1. Inspection Frequency - One bulk milk tank truck inspection every twelve months or bulk milk hauler/sampler or industry plant sampler pickup and sampling procedures inspection each twenty-four months or one producer inspection or one milk plant or receiving station inspection every three months or one transfer station or milk tank truck cleaning facility inspection every six months is not a desirable frequency; it is instead a legal minimum. Bulk milk hauler/samplers, industry plant samplers, milk tank truck cleaning facilities, dairy farms, milk plants, receiving stations and transfer stations experiencing difficulty meeting requirements should be visited more frequently. Milk plants that condense and/or dry milk or milk products and which operate for a short duration of time or intermittent periods of time should also be inspected more frequently. For the purposes of determining the inspection frequency for dairy farms, milk plants, and receiving stations, the interval shall include the designated three-month period in addition to the remaining days of the month in which the inspection is due. For the purposes of determining the inspection frequency for receiving stations, the interval shall include the designated six-month period in addition to the remaining days of the month in which the inspection is due. Inspections of dairy farms shall be made at milking time as often as possible, and of milk plants at different times of the day, in order to ascertain if the processes of equipment assembly, sanitizing, pasteurization, cleaning, and other procedures comply with the requirements of this Regulation. For the purpose of determining the minimum audit frequency for milk plants, receiving stations and transfer stations regulated under the NCIMS HACCP Program the interval shall include the remaining days of the month in which the audit is due.

2. Inspection Notification - It is preferable that the inspector advise the owner or other responsible person of the intent to inspect upon arrival of the premises.

3. Enforcement Procedure - This section provides that a dairy farm, bulk milk hauler/sampler, milk tank truck, milk tank truck cleaning facility, milk plant, receiving station, transfer station, or distributor, except those processing aseptically processed milk and milk products, shall be subject to suspension of permit, and/or court action, if two successive inspections disclose violation of the same requirement.

a. Experience has demonstrated that strict enforcement of the Regulation leads to a better and friendlier relationship between DHEC and the milk industry than does a policy of enforcement which seeks to excuse violations and to defer penalty thereof. The sanitarian's criterion of satisfactory compliance should be neither too lenient nor unreasonably stringent. When a violation is discovered, the sanitarian should point out to the milk producer, bulk milk hauler/sampler, industry plant sampler, responsible person for the milk tank truck, milk tank truck cleaning facility, milk plant, receiving station, transfer station, or distributor the requirement that has been violated, discuss a method for correction, and set a time for correcting the violated requirement.

b. The penalties of suspension or revocation of permit, and/or court action, are provided to prevent continued violation of the provisions of this Regulation, but are worded to protect the dairy industry against unreasonable or arbitrary action. When a condition is found which constitutes an imminent health hazard, prompt action is necessary to protect the public health; therefore, DHEC is authorized, in Section III, to suspend the permit immediately. However, except for such emergencies, no penalty is imposed on the milk producer, bulk milk hauler/sampler, responsible person for the milk tank truck, milk tank cleaning facility, milk plant, receiving station, transfer station, or distributor upon the first violation of any of the sanitation requirements listed in Section VII. A milk producer, bulk milk hauler/sampler, responsible person for the milk tank truck, milk tank cleaning facility, milk plant, receiving station, transfer station, or distributor found violating any requirement must be notified in writing and given a reasonable time to correct the violation(s) before a second inspection is made, but not before three days. The requirement of giving written notice shall be deemed to have been satisfied by the handing to the operator or by the posting of an inspection report, as required by this section. After receipt of a notice of violation, but before the allotted time has elapsed, the milk producer, bulk milk hauler/sampler, responsible person for the milk tank truck, milk tank cleaning facility, milk plant, receiving station, transfer station, or distributor shall have an opportunity to appeal the sanitarian's interpretation to DHEC or for an extension of the time allowed for correction.

4. Enforcement Procedure - Aseptic Processing Milk Plants - Because aseptically processed milk and milk products are stored at room temperature and not refrigerated after processing, they must be considered an imminent hazard to public health whenever it is revealed by an inspection or a review of the processing records that the process is less than the required scheduled process and the products produced have not maintained their commercial sterility. Prompt action by DHEC to suspend the permit must be initiated in order to protect the public health. DHEC shall stop the sale of all under-processed product and follow at least the minimum requirements of 21 CFR 113.89 before releasing any product.

5. Certified Industry Inspection - DHEC may certify industry personnel, with their consent, to carry out cooperatively the provisions of this Regulation with respect to the supervision of dairy farms, bulk milk hauler/sampler's pickup and sampling procedures, and/or milk tank trucks. Industry personnel shall be certified every three years by DHEC. In order for DHEC to utilize certified industry inspections, it shall have on file and available for review, a written program that describes how the requirements of this Regulation and related documents shall be implemented. Delegation of the inspection and evaluation of bulk milk hauler/sampler's pickup and sampling procedures shall be done by the Sampling Surveillance Officer in accordance with the *Evaluation of Milk Laboratories* (EML). Reports of all inspections conducted by such personnel to determine compliance with the provisions of this Regulation shall be maintained by the industry at a location acceptable to DHEC. The Certified Industry Inspector may perform all punitive actions and all inspections for the issuance or reinstatement of permits.

Initial inspections and change of market inspections are required and shall be conducted by DHEC in conjunction with the Certified Industry Inspector. When a producer changes market, the producer records for the preceding twenty-four months shall be transferred with the producer, through DHEC, and will continue to be a part of the producer's record. Industry personnel shall be certified every three years by DHEC.

At least annually, the Certified Industry Inspector shall attend an educational seminar provided by DHEC, or equivalent training acceptable to DHEC.

At least once in each six month period, DHEC shall inspect the records maintained by the Industry for the Certified Industry Inspection Program and conduct farm field work to assure the program meets the provisions of DHEC's written plan and requirements of this Regulation and related documents.

Initial certification by DHEC shall not be made during the course of an official inspection. Re-certification by DHEC may be conducted during the course of an official inspection.

PURPOSE OF CERTIFICATION: The purpose of certification is to have the applicant formally demonstrate their inspection ability to apply proper interpretations of this Regulation, related documents, and DHEC's procedures.

DESIGNATION OF INDIVIDUALS TO BE CERTIFIED: Candidates shall submit requests for certification to DHEC. The applicant for certification shall have had experience in the field of milk sanitation, and shall be an employee of a milk plant, a producer association, officially designated laboratory or shall be employed on a consulting basis.

RECORDING OF QUALIFICATION DATA: Prior to conducting the certification procedure, background information shall be secured on the applicant. This shall include academic training, experience in milk sanitation and related fields, in-service courses attended, etc. This information is to be retained by DHEC as part of the applicant's file, along with appropriate records of the applicant's performance during the certification examination.

FIELD PROCEDURE: Only one applicant shall be certified at a time. The certification is to be conducted without prompting from DHEC or comparison of inspection results in any way until the entire procedure is completed. Initial certification shall not be made during the course of an official inspection by DHEC. At least twenty-five randomly selected dairy farms and/or five milk tank trucks shall be visited. After the necessary inspections have been completed, DHEC shall compare their results with those of the candidate. The percentage agreement for each item of sanitation shall be determined by dividing the number of agreements by the total number of dairy farms and/or milk tank trucks inspected.

CRITERIA FOR CERTIFICATION: In order to be certified, an industry inspector shall agree with DHEC eighty percent of the time on individual items of sanitation and shall further agree to comply with the administrative procedures established by DHEC for the program of dairy farm and/or milk tank truck supervision. DHEC should allow sufficient time to discuss the findings with the applicant.

DURATION OF CERTIFICATION: Certification of industry inspection personnel shall be for a period not exceeding three years from the date of formal certification or re-certification, unless revoked.

RE-CERTIFICATION: DHEC shall notify the certified industry inspector of the need for certification renewal at least sixty days prior to its expiration. If re-certification is desired, the inspector will make appropriate arrangements for the renewal procedure. Re-certification can be made for the succeeding three year period, by following the procedures outlined above. Provided, that re-certification may be conducted during the course of an official inspection by DHEC.

REPORTS AND RECORDS: Upon satisfactory completion of certification or re-certification, the certified industry inspector shall be issued a certificate. The milk plant(s) or officially designated laboratory(ies) employing the inspector shall be formally notified by letter of the certification. The letter shall outline the purpose of the certification and the conditions under which the certification may be retained. A copy of the notification letter, together with a copy of the qualification data above and a resume of the percentage agreement on individual items, shall be retained by DHEC.

REVOCATION OF CERTIFICATION: The certification of an industry inspector may be revoked by DHEC upon a finding that the inspector is:

a. Not in agreement with DHEC at least eighty percent of the time on Items of sanitation in a field examination conducted as described in the FIELD PROCEDURE outlined above; or

b. Not complying with the established administrative procedures of DHEC; or

c. Failing to carry out the provisions of this Regulation in the course of the inspector's work.

6. INSPECTION/AUDIT REPORTS**:** A copy of the inspection/audit report shall be filed by DHEC and retained for at least twenty-four months. The results shall be entered on appropriate ledger forms. The use of a computer or other information retrieval system may be used.

SECTION VI. THE EXAMINATION OF MILK AND MILK PRODUCTS

A. General

1. It shall be the responsibility of the bulk milk hauler/sampler to collect a representative sample of milk from each farm bulk tank prior to transferring milk from a farm bulk tank, truck, or other container. All samples shall be collected and delivered to a milk plant, receiving station, transfer station, or other location approved by DHEC.

2. During any consecutive six months, at least four samples of raw milk for pasteurization, shall be collected in at least four separate months, except when three months show a month containing two sampling dates separated by at least twenty days, and delivered in accordance with this section, from each producer. These samples shall be obtained under the direction of DHEC or shall be taken from each producer under the direction of DHEC and delivered in accordance with this section. During any consecutive six months, at least four samples of raw milk for pasteurization, ultra-pasteurization or aseptic processing, collected in at least four separate months, except when three months show a month containing two sampling dates separated by at least twenty days, shall be taken, by DHEC, from each milk plant after receipt of the milk by the milk plant and prior to pasteurization, ultra-pasteurization or aseptic processing. During any consecutive six months, at least four samples of heat treated milk products, from plants offering such products for sale, shall be collected in at least four separate months, except when three months show a month containing two sampling dates separated by at least twenty days, by DHEC. During any consecutive six months, at least four samples of pasteurized milk, flavored milk, flavored reduced fat or lowfat milk, flavored nonfat skim milk, each fat level of reduced fat or lowfat milk and each milk product defined in this Regulation, including aseptically processed milk and milk products for drug residue tests, shall be collected in at least four separate months, except when three months show a month containing two sampling dates separated by at least twenty days, from every milk plant by DHEC. If the production of any Grade “A” condensed or dry milk product as defined in this Regulation is not on a yearly basis, at least five samples shall be taken within a continuous production run. Samples of milk and milk products shall be taken while in the possession of the producer or distributor at any time prior to delivery to the store or consumer. Samples of milk and milk products from dairy retail stores, food service establishments, grocery stores, and other places where milk and milk products are sold shall be examined periodically as determined by DHEC; and the results of such examination shall be used to determine compliance with Sections II, IV, and X. Proprietors of such establishments shall furnish DHEC, upon request, with the names of all distributors from whom milk or milk products are obtained.

3. Required bacterial counts, somatic cell counts, and cooling temperature checks shall be performed on raw milk for pasteurization. In addition, drug tests on each producer's milk shall be conducted at least four times during any consecutive six months. Required bacterial counts, drug tests, except those products for which there are no approved drug test kits available, coliform determinations, phosphatase, and cooling temperature

determinations shall be performed on Grade "A" pasteurized milk and milk products. Required drug residue tests shall be performed on all aseptically processed milk and milk products.

NOTE: When multiple samples of the same milk or milk products, except for aseptically processed milk and milk products, are collected from the same producer or processor from multiple tanks or silos on the same day, the laboratory results are averaged arithmetically by DHEC and recorded as the official results for that day. This is applicable for bacterial (standard plate count and coliform), somatic cell count and temperature determinations only.

4. Whenever two of the last four consecutive bacterial counts (except those for aseptically processed milk and milk products), somatic cell count, coliform determinations, or cooling temperatures, taken on separate days, exceed the standard for the milk and/or milk products as defined in this Regulation, DHEC shall send a certified or hand delivered written notice thereof to the person concerned. This notice shall be in effect so long as two of the last four consecutive samples exceed the standard. An additional sample shall be taken within twenty-one days of the sending of such notice, but not before the lapse of three days. Immediate suspension of permit in accordance with Section III, and/or court action shall be instituted whenever the standard is violated by three of the last five bacterial counts (except those for aseptically processed milk and milk products), coliform determinations, cooling temperatures or somatic cell counts.

5. Whenever a phosphatase test is positive, the cause shall be determined. Where the cause is improper pasteurization, it shall be corrected and any milk or milk product involved shall not be offered for sale.

6. Whenever a pesticide residue test is positive, an investigation shall be made to determine the cause, and the cause shall be corrected. An additional sample shall be taken and tested for pesticide residues and no milk or milk products shall be offered for sale until it is shown by a subsequent sample to be free of pesticide residues or below the actionable levels established for such residues.

7. Whenever a drug residue test is confirmed positive, an investigation shall be made to determine the cause, and the cause shall be corrected in accordance with the provisions of Appendix N of the PMO.

8. Whenever a container or containers of aseptically processed milk or milk product is found to be non-sterile due to under-processing, DHEC shall consider this to be an imminent hazard to public health and shall suspend the permit of the milk plant for the sale of aseptically processed milk and milk products. No aseptically processed milk and milk product shall be sold until it can be shown that the processes, equipment and procedures used are suitable for consistent production of a sterile product. All product from the lot that was found to contain one or more non-sterile units shall be recalled and disposed of as directed by DHEC.

9. Samples shall be analyzed at an official or appropriate officially designated laboratory. All sampling procedures, including the use of approved in-line samplers, and required laboratory examinations shall be in substantial compliance with the current edition of Standard Methods for the Examination of Dairy Products (SMEDP) of the American Public Health Association, and the current edition of Official Methods of Analysis of AOAC International (OMA). Such procedures, including the certification of sample collectors, and examinations shall be evaluated in accordance with the Evaluation of Milk Laboratories. Aseptically processed milk and milk products packaged in hermetically sealed containers shall be tested in accordance with the FDA's Bacteriological Analytical Manual (BAM).

Each milk plant regulated under the NCIMS HACCP Program shall adequately document its response to each regulatory sample test result that exceeds any maximum level specified in Section VII of this Regulation. DHEC will monitor and verify that appropriate action(s) was taken by the milk plant.
Examinations and tests to detect adulterants, including pesticides, shall be conducted as DHEC requires. When the Commissioner of the FDA determines that a potential problem exists with animal drug residues or other contaminants in the milk supply, samples shall be analyzed for the contaminant by a method(s) determined by FDA to be effective in determining compliance with actionable levels or established tolerances. This testing will

continue until such time that the Commissioner of the FDA is reasonably assured that the problem has been corrected. The determination of a problem is to be based upon:

a. Sample survey results;

b. USDA tissue residue data from cull and veal dairy animals;

c. Animal drug disappearance and sales data;

d. State feed back; and

e. Other relevant information.

Assays of milk and milk products to which vitamin(s) A and/or D have been added, shall be made at least annually in a laboratory which has been accredited by FDA and which is acceptable to DHEC using test methods acceptable to FDA or other official methodologies, which give statistically equivalent results to the FDA methods.

Vitamin testing laboratories are accredited if they have one or more certified analysts and meet the quality control requirements of the program established by FDA. Laboratory accreditation and analyst certification parameters are specified in the *EML* manual. In addition, all facilities fortifying milk or milk products with vitamins must keep volume control records. These volume control records must cross reference the form and amount of vitamin D, vitamin A and/or vitamins A and D used with the amount of products produced and indicate a percent of expected use, plus or minus.

B. Administrative Procedures

1. Enforcement Procedures - All violations of bacteria, coliform, confirmed somatic cell counts, and cooling temperature standards should be followed promptly by inspection to determine and correct the cause.

2. Aseptically Processed Milk and Milk Product Enforcement Procedure - Aseptically processed milk and milk products packaged in hermetically sealed containers are exempt from the refrigerated storage requirements of this Regulation. Therefore, whenever a breakdown in the processing or packaging of these products occurs an imminent hazard to public health exists. Prompt action is needed by DHEC. Milk plants aseptically processing milk and milk products in hermetically sealed containers should be encouraged to perform bacterial and other quality tests on each lot of aseptically processed milk and milk product produced in order to ascertain that these products have been properly processed and have not been rendered non-sterile after aseptic processing and packaging. DHEC may utilize industry records, of each lot of aseptically processed milk and milk products, to determine when lots can be released for sale after a violation of bacterial standards has existed.

3. Laboratory Techniques - Procedures for the collection, including the use of approved in-line samplers, and holding of samples; the selection and preparation of apparatus, media and reagents; and the analytical procedures, incubation, reading and reporting of results, shall be in substantial compliance with FDA 2400 Series forms, SMEDP and OMA.

a. The procedures shall be those specified therein for:

(1) Standard plate count at 32ºC (Agar or Petrifilm Method).

(2) Alternate methods, including Plate Loop Count and the Bacto Scan FC for viable counts for raw milk and the Petrifilm method, for pasteurized milk and milk products, at 32ºC.

(3) Coliform test with solid media or Petrifilm method at 32ºC for all milk and milk products, and the Petrifilm High Sensitivity Coliform Count Method for all milk and milk products, except unflavored whole, reduced or low fat and non fat (skim) milk.

(4) A viable bacterial count of nonfat dry milk and dry whey shall be made in accordance with the procedures in *SMEDP* for the Standard Plate Count of Dry Milk, except agar plates shall be incubated for 72 hours.

5) Beta lactam methods which have been independently evaluated or evaluated by FDA and have been found acceptable by FDA for detecting drug residues in raw milk, or pasteurized milk, or that particular type of pasteurized milk product at current safe or tolerance levels, shall be used for each drug of concern, except those products for which there are not any approved drug test kits available. Regulatory action shall be taken on all confirmed positive results. (Refer to Appendix N of the PMO.) A result shall be considered positive if it has been obtained by using a method, which has been evaluated and deemed acceptable by FDA and accepted by the NCIMS at levels established in memoranda transmitted periodically by FDA as required by Section IV of Appendix N of the PMO.

(6) Screening and confirmatory methods for the detection of abnormal milk: The results of the screening test or confirmatory test shall be recorded on the official records of the dairy farm and a copy of the results sent to the milk producer. When a warning letter has been sent, because of excessively high somatic cell counts, an official inspection of the dairy should be made by DHEC personnel or certified industry personnel. This inspection should be made during milking time.

(a) Milk (Non-Goat): Any of the following confirmatory or screening tests shall be used: Direct Microscopic Somatic Cell Counting Single Strip Procedure, Electronic Somatic Cell Counting or Flow Cytometry/Opto-Electronic Somatic Cell Counting.

(b) Goat Milk: In addition to the above mentioned tests, the Wisconsin Mastitis Test or California Mastitis Test may be used for screening raw goat milk samples, to indicate a range of somatic cell levels, as long as the somatic cell standard for goat milk remains 1,000,000/mL. Laboratories using the Wisconsin Mastitis Test or California Mastitis Test for goat milk shall confirm samples of herd milk that exceeds 18mm, or a value of one, respectively. Any of the following confirmatory or screening tests shall be used: Direct Microscopic Somatic Cell Counting Single Strip Procedure, Electronic Somatic Cell Counting or Flow Cytometry/Opto-Electronic Somatic Cell Counting. Pyronine Y-Methyl green stain or "New York modification" shall be used in the confirmatory test for Direct Microscopic Somatic Cell Counts in goat milk.

(7) American Public Health Association (APHA), Association of Official Analytical Chemists (AOAC), or Electronic Phosphatase Tests: The phosphatase test is an index of the efficiency of the pasteurization process. In the event the laboratory phosphatase test is positive, the cause shall be determined immediately. Where the cause is improper pasteurization, it shall be corrected. When a laboratory phosphatase test is positive, or if any doubt should arise as to the compliance of the equipment, standards or methods outlined in Section VII.C.16., DHEC should immediately conduct field phosphatase test at the milk plant. (Refer to Appendix G. of the PMO).

(8.) Vitamin testing shall be performed using test methods acceptable to FDA or other official methodologies, which give statistically equivalent results to the FDA methods.

(9) Any other tests which have been approved by the Food and Drug Administration to be equally accurate, precise, and practical.

(10) All standards used in the development and use of drug residue detection methods designed for Grade "A" PMO monitoring programs will be referenced to a United States Pharmacopeia (USP) standard when available. When a USP standard is not available, then the original method must define the standard to be used.

(11) Procedural or reagent changes for official tests must be submitted to the Food and Drug Administration for acceptance prior to being used by certified NCIMS milk laboratories.

4. Sampling Procedures - SMEDP contains guidance for sampling of milk and milk products. However, when samples of raw milk for pasteurization are taken at a milk plant prior to pasteurization, they shall be drawn following adequate agitation from randomly selected storage tanks.

a. When bacterial counts except for aseptically processed milk and milk products and temperature determinations are made of several samples of the same milk or milk products collected from the same supply or processor, on the same day, these values are averaged arithmetically, and the results recorded as the count or temperature determinations of the milk or milk product for that day. All counts and temperatures should be recorded on a milk-ledger form for dairy farms or milk plants as soon as reported by the laboratory.

b. A computer or other information retrieval system may be used.

5. Farm Bulk Milk Hauling - The farm bulk milk hauler/sampler occupies a unique position in the producer-processor-DHEC relationship. The bulk milk hauler/sampler is a critical factor in the current structure of milk marketing. As a weigher and sampler, he stands as the official and frequently the only judge of milk volumes bought and sold. As the milk receiver, the hauler/sampler's operating habits directly affect the quality of milk committed to his care. When the bulk milk hauler/sampler's obligations include the collection and delivery of samples to the laboratory for analysis, he becomes a vital part of the quality control and regulatory programs. Any deviation from acceptable practices by the bulk milk hauler/sampler may result in the suspension and/or revocation of his permit. Refer to Appendix B. of the PMO for reference to farm bulk milk hauling programs regarding training, licensing/permitting, routine inspection and the evaluation of sampling procedures.

6. Sampling Raw Milk - When samples of raw milk are taken, they shall be randomly drawn following adequate agitation. Sampling procedures shall be in such a manner as to not contaminate the sample of remaining milk in the tank or other type of container. Each sample shall be labeled. The label shall contain identification, temperature when collected, and date and hour collected. The sample shall be immediately placed under refrigeration. Samples shall not be submerged in a coolant or handled in any manner which may cause contamination. All samples shall be maintained at 40°F (4°C) or below until analyzed. At no time shall the period of time between collection and analysis exceed forty eight (48) hours. Samples shall be collected by personnel who have been certified as sample collectors by Certified State Milk Sanitation Rating Officers.

SECTION VII. STANDARDS FOR MILK AND MILK PRODUCTS

A. General

1. All Grade "A" raw milk for pasteurization, ultra-pasteurization or aseptic processing; and all Grade "A" pasteurized, ultra-pasteurized or aseptically processed milk and milk products shall be produced, processed, and pasteurized, ultra pasteurized or aseptically processed to conform with the following chemical, bacteriological, and temperature standards, and the sanitation requirements of this section.

2. No process or manipulation other than pasteurization, ultra pasteurization or aseptic processing, processing methods integral therewith, and appropriate refrigeration shall be applied to milk and milk products for the purpose of removing or deactivating microorganisms provided that in the bulk shipment of cream, nonfat (skim) milk, reduced fat, or lowfat milk, the heating of the raw milk, one time, to temperatures greater than 52ºC (125ºF) but less than 72ºC (161ºF) for separation purposes is permitted when the resulting bulk shipments of cream, nonfat (skim) milk, and/or reduced fat or low fat milk are labeled heat-treated.

In the case of heat-treated cream, the cream may be further heated to less than 75ºC (166ºF) in a continuing heating process and immediately cooled to 7ºC (45ºF) or less when necessary for enzyme deactivation (such as lipase reduction) for a functional reason.

Milk plants, receiving stations and transfer stations participating in the NCIMS HACCP Program, shall also comply with the requirements of Appendix K. of the PMO.

Whey shall be from cheese made from Grade "A" raw milk for pasteurization as provided in this Regulation.

Buttermilk shall be from butter made from Grade "A" cream, which has been pasteurized prior to use in accordance with Section VII.C.16 of this Regulation. Provided, that this requirement shall not be construed as barring any other heat treatment process which has been recognized by the FDA to be equally efficient in the destruction of staphylococcal organisms and which is approved by DHEC.
Buttermilk and whey used in the manufacture of Grade "A" milk and milk products shall be produced in a milk/cheese plant that complies with Section VII.C.1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 17, 20, 21 and 22 as provided in this Regulation.
Whey shall be from:

a. Cheese made from Grade "A" raw milk for pasteurization, which has been pasteurized prior to use, in accordance with Section VII.C.16 of this Regulation, or

b. Cheese made from Grade "A" raw milk for pasteurization, which has been heat-treated to a temperature of at least 64°C (147°F) and held continuously at that temperature for at least twenty-one seconds, or to at least 68°C (153°F) and held continuously at that temperature for at least fifteen seconds, in equipment meeting the pasteurization requirements provided for in this Regulation. This requirement shall not be construed as barring any other heat treatment process which has been recognized by the FDA to be equally efficient in the destruction of staphylococcal organisms and which is approved by DHEC.

Table 1. Chemical, Physical, Bacteriological, and Temperature Standards

GRADE "A" RAW MILK AND MILK PRODUCTS FOR PASTEURIZATION, ULTRA-PASTEURIZATION OR ASEPTIC PROCESSING	Temperature.....	Cooled to 10ºC (50ºF) or less within four hours or less, of the commencement of the first milking, and to 7°C (45ºF) or less within two hours after milking, provided, that the blend temperature after the first and subsequent milkings does not exceed 10ºC (50ºF).
	Bacterial Limits.....	Individual producer milk not to exceed 100,000 per mL prior to commingling with other producer milk. Not to exceed 300,000 per mL as commingled milk prior to pasteurization.
	Drugs.....……	No positive results on drug residue detection methods as referenced in Section VI - Laboratory Techniques.
	Somatic Cell Count*...	Individual producer milk not to exceed 750,000 per mL.
GRADE "A" PASTEURIZED MILK AND MILK PRODUCTS AND BULK SHIPPED HEAT-TREATED MILK PRODUCTS	Temperature.....	Cooled to 7ºC (45ºF) or less and maintained thereat.
	Bacterial Limits**…....	20,000 per mL, or gm.***
	Coliform****.....	Not to exceed 10 per mL. Provided, that in the case of bulk milk transport tank shipments, shall not exceed 100 per mL.

	Phosphatase*****.....	Less than 350 milliunits/L for fluid products and other milk products by the Fluorometer or Charm ALP or equivalent.
	Drugs**.....….	No positive results on drug residue detection methods as referenced in Section 6 - Laboratory Techniques which have been found to be acceptable for use with pasteurized and heat-treated milk and milk products.
GRADE "A" PASTEURIZED CONCENTRATED (CONDENSED) MILK AND MILK PRODUCTS	Temperature……	Cooled to 7°C (45°F) or less and maintained thereat unless drying is commenced immediately after condensing.
	Coliform……	Not to exceed 10 per gram. *Provided,* that in the case of bulk milk transport tank shipments shall not exceed 100 per ml.
GRADE "A" ASEPTICALLY PROCESSED MILK AND MILK PRODUCTS	Temperature.....	None.
	Bacterial Limits.....	Refer to 21 CFR 113. 3(e)(1)******
	Drugs**.....	No positive results on drug residue detection methods as referenced in Section 6 - Laboratory Techniques that have been found to be acceptable for use with aseptically processed milk and milk products.
GRADE "A" NONFAT DRY MILK	Butterfat…… Moisture…… Titratable Acidity…….. Solubility Index…… Bacterial Estimate……. Coliform……... Scorched Particles disc B……	No More Than: 1.25% 4.00% 0.15% 1.25mL. 30,000 per gram 10 per gram 15.0 per gram
GRADE "A" WHEY FOR CONDENSING	Temperature……	Maintained at a temperature of 45°F (7°C) or less, or 63°C (145°F) or greater, except for acid-type whey with a titratable acidity of 0.40% or above, or a pH of 4.6 or below.
GRADE "A" PASTEURIZED CONDENSED WHEY AND WHEY PRODUCTS	Temperature……..	Cooled to 7°C (45°F) or less during crystallization, within 48 hours of condensing.
	Coliform Limit……..	Not to exceed 10 per gram
GRADE "A" DRY WHEY, GRADE "A" DRY WHEY PRODUCTS, GRADE "A" DRY BUTTERMILK, AND GRADE "A" DRY BUTTERMILK PRODUCTS	Coliform Limit……..	Not to exceed 10 per gram

* Goat Milk 1,000,000 per mL
** Not applicable to acidified or cultured products.
*** Results of the analysis of dairy products which are weighed in order to be analyzed will be reported in # per gm. (Refer to the current edition of the *SMEDP*)
**** Not applicable to bulk shipped heat-treated milk products.

***** Not applicable to bulk shipped heat-treated milk products; UP products that have been thermally processed at or above 138^0C (280^0F) for at least two seconds to produce a product which has an extended shelf life (ESL) under refrigerated conditions; and condensed products.
****** 21 CFR 113.3(e)(1) contains the definition of "COMMERCIAL STERILITY."

B. Sanitation Requirements For Grade A Raw Milk For Pasteurization, Ultra-Pasteurization, or Aseptic Processing

1. Milk with Abnormalities

a. General - Lactating animals which show evidence of the secretion of milk with abnormalities in one or more quarters, based upon bacteriological, chemical or physical examination, shall be milked last or with separate equipment and the milk shall be discarded. Lactating animals producing contaminated milk, that is, lactating animals which have been treated with, have consumed chemical, medicinal or radioactive agents, which are capable of being secreted in the milk and which, in the judgment of DHEC, may be deleterious to human health, shall be milked last or with separate equipment and the milk disposed of as DHEC may direct. (For applicability to automatic milking installations (AMI's), refer to Appendix Q of the PMO.)

b. Administrative Procedures - This item is deemed to be satisfied when:

(1) Milk from lactating animals being treated with medicinal agents, which are capable of being secreted in the milk, is not offered for sale for such period as is recommended by the attending veterinarian or as indicated on the package label of the medicinal agent.

(2) Milk from lactating animals treated with or exposed to insecticides not approved for use on dairy animals by the U.S. Environmental Protection Agency is not offered for sale.

(3) DHEC may require such additional tests for the detection of milk with abnormalities as they deem necessary.

(4) Bloody, stringy, off-colored milk, or milk that is abnormal to sight or odor, is so handled and disposed of as to preclude the infection of other lactating animals and the contamination of milk utensils.

(5) Lactating animals secreting milk with abnormalities are milked last or in separate equipment which effectively prevents the contamination of the wholesome supply. Milking equipment used on animals with abnormalities in their milk is maintained clean to reduce the possibility of re-infecting or cross infection of the dairy animals.

(6) Equipment, utensils, and containers used for the handling of milk with abnormalities are not used for the handling of milk to be offered for sale, unless they are first cleaned and effectively sanitized.

(7) Processed animal waste derivatives, used as a feed ingredient for any portion of the total ration of the lactating dairy animal, have been:

(a) Properly processed in accordance with at least those requirements contained in the Model Regulations for Processed Animal Wastes developed by the Association of American Feed Control Officials; and

(b) Do not contain levels of deleterious substances, harmful pathogenic organisms, or other toxic substances which are secreted in the milk at any level which may be deleterious to human health.

(8) Unprocessed poultry litter and unprocessed recycled animal body discharges are not fed to lactating dairy animals.

2. Milking Barn, Stable or Parlor Construction

a. General - A milking barn, stable, or parlor shall be provided on all dairy farms in which the milking herd shall be housed during milking time operations. The areas used for milking purposes shall:

(1) Have floors constructed of concrete or equally impervious material; provided, convalescent (maternity) pens located in milking areas of stanchion-type barns may be used when they comply with the guidelines specified in Appendix C. III. of the PMO;

(2) Have walls and ceiling which are smooth, painted or finished in an approved manner, in good repair, and ceiling dust-tight;

(3) Have separate stalls or pens for horses, calves, and bulls;

(4) Be provided with natural and/or artificial light, well distributed for day and/or night milking;

(5) Provide sufficient air space and air circulation to prevent condensation and excessive odors;

(6) Not be overcrowded; and

(7) Have dust-tight covered boxes or bins, or separate storage facilities for ground, chopped, or concentrated feed.

b. Administrative Procedures - This item is deemed to be satisfied when:

(1) A milking barn, stable, or parlor is provided on all dairy farms.

(2) Gutters, floors, and feed troughs are constructed of good quality concrete or equally impervious material. Floors shall be easily cleaned (brushed surfaces permitted) and shall be graded to drain and maintained in good repair and free of excessive breaks or worn areas that may create pools.

(3) Walls and ceilings are finished with wood, tile, smooth-surfaced concrete, cement plaster, brick, or other equivalent materials with light colored surfaces. Walls, partitions, doors, shelves, windows, and ceilings shall be kept in good repair; and surfaces shall be refinished whenever wear or discoloration is evident. Whenever feed is stored overhead, ceilings shall be constructed to prevent the sifting of chaff and dust into the milking barn, stable or parlor. If a hay opening is provided from loft into the milking portion of the barn, such opening shall be provided with a dust-tight door which shall be kept closed during milking operations.

(4) Bull pens, maternity and calf stalls, and horse stalls are partitioned from the milking portion of the barn. Such portions of the barn that are not separated by tight partitions shall comply with all requirements of this item.

(5) The milking barn is provided with natural and/or artificial light to insure that all surfaces and particularly the working areas will be plainly visible. The equivalent of at least ten foot-candles (110 lux) of light in all working areas shall be provided.

(6) Air circulation is sufficient to minimize odors and to prevent condensation upon walls and ceilings.

(7) Overcrowding is not evidenced by the presence of calves, cows, or other barnyard animals in walks or feed alleys. Inadequate ventilation and excessive odors may also be evidence of an overcrowded barn. It is recommended that pit areas in parlors should be at least six feet in width from overhang when cows are milked on two sides, and six feet working areas when single row of stalls. Ceiling height shall be at least seven feet in areas where cows stand.

(8) A dust-tight partition, provided with doors that are kept closed except when in actual use, shall separate the milking portion of the barn from any feed room or silo in which feed is ground or mixed, or in which sweet feed is stored.

(9) When conditions warrant, DHEC may approve a barn without four walls extending from floor to roof, or a shed-type barn provided the requirement of Section VII.B.3. prohibiting animals and fowl from entering the barn is satisfied. Lactating animal-housing areas (stables without stanchions, such as loose housing stables, pen stables, resting barns, free stall barns, holding barns, loafing sheds, wandering sheds) may be of shed-type construction, provided no milking is conducted therein. (They are classified as part of the cowyard under Section VII.B.4.)

3. Milking Barn, Stable or Parlor Cleanliness

a. General - The interior shall be kept clean. Floors, walls, ceilings, windows, pipelines, and equipment shall be free of filth and/or litter, and shall be clean. Swine and fowl shall be kept out of the milking area. Feed shall be stored in a manner that will not increase the dust content of the air or interfere with the cleaning of the floor (as in covered, dust-tight boxes or bins). For applicability to AMIs, refer to Appendix Q of the PMO. Open feed dollies or carts may be used for distributing the feed, but not storing food, in the milking area. Surcingles, or belly straps, milk stools and antikickers shall be kept clean and stored above the floor.

b. Administrative Procedures - This item is deemed to be satisfied when:

(1) The interior of the milking barn, stable, or parlor is kept clean.

(2) Leftover feed in feed mangers appears fresh and is not wet or soggy.

(3) The bedding material, if used, does not contain more manure than has accumulated since the previous milking.

(4) Outside surfaces of pipeline systems located in the milking barn, stable, or parlor are reasonably clean.

(5) Gutter cleaners are reasonably clean.

(6) All pens, calf stalls, and bull pens, if not separated from the milking barn, stable, or parlor, are clean.

(7) Swine and fowl are kept out of the milking area.

(8) Milk stools are not padded and are constructed to be easily cleaned. Milk stools, surcingles and antikickers are kept clean and are stored above the floor in a clean place in the milking barn, stable, parlor or milkhouse, when not in use.

4. COWYARD

a. General - The cowyard shall be graded and drained and shall have no standing pools of water or accumulations of organic wastes: Provided, that in loafing or lactating animal housing areas, lactating animal droppings and soiled bedding shall be removed, or clean bedding added, at sufficiently frequent intervals to prevent the soiling of the lactating animals' udder and flanks. Cooling ponds shall be allowed provided they are constructed and maintained in a manner that does not result in the visible soiling of flanks, udders, bellies, and tails of lactating animals exiting the pond. Waste feed shall not be allowed to accumulate. Manure packs shall be properly drained and shall provide a reasonably firm footing. Swine shall be kept out of the cowyard.

b. Administrative Procedures - This item is deemed to be satisfied when:

(1) The cowyard, which is interpreted to be the enclosed or unenclosed area approximately adjacent to the milking barn in which the lactating animals may congregate, including animal-housing areas and feed lots, is graded and drained; depressions and soggy areas are filled; and lactating animal lanes are reasonably dry. This area is; therefore, particularly apt to become filthy with manure droppings, which may result in the soiling of the lactating animal's udders and flanks. The grading and drainage of the cowyard, as far as is practicable, is required because wet conditions are conducive to fly breeding and make it difficult to keep manure removed and the lactating animals clean. If manure and barn sweepings are allowed to accumulate in the cowyard, fly breeding will be promoted, and the lactating animals, because of their habit of lying down, will be more apt to have manure-soiled udders. Lactating animals should not have access to piles of manure, in order to avoid the soiling of udders and the spread of diseases among dairy animals.

(2) Approaches to the barn door and the surroundings of stock watering and feed stations are solid to the footing of the animal.

(3) Wastes from the barn or milkhouse are not allowed to pool in the cowyard. Cowyards which are muddy due to recent rains should not be considered as violating this item.

(4) Manure, soiled bedding, and waste feed are not stored or permitted to accumulate therein in such a manner as to permit the soiling of lactating animals' udders and flanks. Animal-housing areas (stables without stanchions, such as loose-housing stables, pen stables, resting barns, holding barns, loafing sheds, wandering sheds, free-stall housing) shall be considered as part of the cowyard. Manure packs shall be solid to the footing of the animal.

(5) Cowyards are kept reasonably free of animal droppings. Animal droppings shall not be allowed to accumulate in piles that are accessible to the animals.

5. Milkhouse or Room - Construction and Facilities

a. General

(1) A milkhouse or room of sufficient size shall be provided, in which the cooling, handling, and storing of milk and the washing, sanitizing, and storing of milk containers and utensils shall be conducted: Except as provided for in Section VII.B.12. of this section.

(2) The milkhouse shall be provided with a smooth floor constructed of concrete or equally impervious material graded to drain and maintained in good repair. Liquid waste shall be disposed of in a sanitary manner; all floor drains shall be accessible and shall be trapped if connected to a sanitary sewer system.

(3) The walls and ceilings shall be constructed of smooth material, in good repair, well painted, or finished in an equally suitable manner.

(4) The milkhouse shall have adequate natural and/or artificial light and be well ventilated.

(5) The milkhouse shall be used for no other purpose than milkhouse operations; there shall be no direct opening into any barn, stable, parlor, or into a room used for domestic purposes: Provided, that a direct opening between the milkhouse and milking barn, stable, or parlor is permitted when a tight-fitting self-closing solid door(s) hinged to be single or double acting is provided and opens outward from the milkroom. Screened vents in the wall between the milkhouse and a breezeway, which separates the milkhouse from the milking parlor, are permitted, provided animals are not housed within the milking facility.

(6) Water under pressure shall be piped into the milkhouse.

(7) The milkhouse shall be equipped with a two-compartment wash vat and adequate hot water heating facilities.

(8) When a transportation tank is used for the cooling and/or storage of milk on the dairy farm, such tank shall be provided with a suitable shelter for the receipt of milk. Such shelter shall be adjacent to, but not a part of, the milkhouse and shall comply with the requirements of the milkhouse with respect to construction, lighting, drainage, insect and rodent control, and general maintenance. In addition, the following minimum criteria shall be met:

(a) An accurate, accessible temperature recording device shall be installed in the milk line downstream from an effective cooling device, which cools the milk to 7°C (45°F) or less. An indicating thermometer shall be installed as close as possible to the recording device for verification of recording temperatures. This indicating thermometer shall comply with all applicable requirements in Appendix H of the PMO. This thermometer shall be used to check the recording thermometer during the regulatory inspection and the results recorded on the recording chart.

(b) The milk shall be sampled at the direction of DHEC in a manner so as to preclude contaminating the milk tank truck or sample, by a permitted milk sample collector.

(c) The milk tank truck shall be effectively agitated in order to collect a representative sample.

When DHEC determines conditions exist whereby the milk tank truck can be adequately protected and sampled without contamination, a shelter need not be provided if the following minimum criteria are met:

(d) The milk hose connection is accessible to, and made from within, the milkhouse. The milk hose connection to the milk tank truck is completely protected from the outside environment at all times.

(e) To assure continued protection of the milk, the milk tank truck manhole must be sealed after the truck has been cleaned and sanitized.

(f) The milk tank truck shall be washed and sanitized at the permitted milk plant, receiving station, or transfer station receiving the milk, or at a permitted milk tank truck cleaning facility.

(g) An accurate, accessible temperature-recording device shall be installed in the milk line downstream from an effective cooling device, which cools the milk to 7°C (45°F) or less. An indicating thermometer shall be installed as close as possible to the recording device for verification of recording temperatures. This indicating thermometer shall comply with all applicable requirements in Appendix H of the PMO. This thermometer shall be used to check the recording thermometer during the regulatory inspection and the results recorded on the recording chart.

(h) The milk shall be sampled at the direction of DHEC, in a manner so as to preclude

contaminating the milk tank truck or sample, by a permitted milk sample collector. The milk in the milk tank truck shall be effectively agitated in order to collect a representative sample.

(i) The milk tank truck shall be parked on a self-draining concrete or equally impervious surface during filling and storage.

b. Administrative Procedures - This item is deemed to be satisfied when:

(1) A separate milkhouse of sufficient size is provided for the cooling, handling, and storing of milk and the washing, sanitizing, and storing of milk containers and utensils: Except as provided for in Section VII.B.12. of this section.

(2) The floors of all milkhouses are constructed of good quality concrete (float finish permissible), or equally impervious tile, or brick laid closely with impervious material, or metal surfacing with impervious joints, or other material the equivalent of concrete and maintained free of breaks, depressions, and surface peelings.

(3) The floor slopes to drain so that there are no pools of standing water. The joints between the floor and the walls shall be watertight.

(4) The liquid wastes are disposed of in a sanitary manner; all floor drains are accessible and are trapped if connected to a sanitary sewer.

(5) Walls and ceilings are constructed of smooth dressed lumber or similar material, well painted with a light-colored washable paint, and are in good repair. Surfaces and joints shall be tight and smooth. Sheet metal, tile, cement block, brick, concrete, cement plaster, or similar materials of light color may be used; the surfaces and joints shall be smooth.

(6) A minimum of twenty foot-candles (220 lux) of light is provided at all working areas from natural and/or artificial light for milkhouse operations.

(7) Windows and solid doors are closed during dusty weather.

(8) The milkhouse is adequately ventilated to minimize odors and condensation on floors, walls, ceilings, and clean utensils.

(9) Vents, if installed, and lighting fixtures are installed in a manner to preclude the contamination of bulk milk tanks or clean utensil storage areas.

(10) The milkhouse is used for no other purpose than milkhouse operations.

(11) There is no direct opening into any barn, stable, parlor, or room used for domestic purposes; except that an opening between the milkhouse and milking barn, stable, or parlor is permitted when a tight-fitting, self-closing solid door(s) hinged to be single or double acting and open outward from the milkhouse or milkroom is provided; except that screened vents are permitted in the wall between the milkhouse and breezeway, which separates the milkhouse from the milking parlor, provided animals are not housed within the milking facility.

(12) A vestibule, if used, complies with the applicable milkhouse construction requirements.

(13) The transfer of milk from a bulk milk tank to a bulk milk pickup tanker is through a hose port located in the milkhouse wall. The port shall be fitted with a tight door, which shall be in good repair. It shall be kept closed except when the port is in use. An easily cleanable surface shall be constructed under the hose port, adjacent to the outside wall, sufficiently large to protect the milk hose from contamination. Provided, milk can be transferred from a bulk milk tank to a bulk milk pickup tanker by stubbing the milk transfer and associated mechanically cleaned lines outside the milkhouse wall, provided:

(a) A concrete slab of adequate size, to protect the transfer hose, shall be provided under the stubbed sanitary milk and mechanically cleaned lines.

(b) The outside wall of the milkhouse, where the sanitary piping and concrete slab are located, shall be properly maintained and kept in good repair.

(c) The sanitary piping, stubbed outside the milkhouse, shall be properly sloped to assure complete drainage and the ends of the piping, which are located outside, shall be capped when the transfer hose is disconnected.

(d) After the completion of milk transfer, the milk lines and transfer hose shall be properly mechanically cleaned.

(e) After the mechanical cleaning process has been completed; the transfer hose shall be disconnected, drained and stored in the milkhouse. Proper storage of the transfer hose includes capping the ends and storing the entire hose up off the floor. The sanitary piping outside the milkhouse shall be capped at all times, except when transferring milk or being mechanically cleaned. When the caps are not being used, they shall be properly cleaned and sanitized after each use and stored in the milkhouse to protect them from contamination. A transfer hose manufactured with permanent hose end fittings, attached in such a manner that will assure a crevice-free joint between the hose and the fitting, may be stored outside of the milkhouse, provided it is mechanically cleaned; the stubbed piping and hose length are of sufficient design to allow complete drainage after cleaning and sanitizing; and the hose remains connected to the stubbed piping when not in use.

(f) Means shall be provided to sanitize the milk-contact surfaces of the transfer hose and bulk milk pickup tanker fittings prior to the connection of the transfer hose to the bulk milk pickup tanker.

(g) At all times, the bulk milk pickup tanker manhole openings(s) shall remain closed, except for brief periods for sampling and examination when environmental conditions permit.

(14) Water under pressure is piped into the milkhouse.

(15) Each milkhouse is provided with facilities for heating water in sufficient quantity and to such temperatures for the effective cleaning of all equipment and utensils.

(16) The milkhouse is equipped with a wash-and-rinse vat having at least two compartments. Each compartment must be of sufficient size to accommodate the largest utensil or container used. The upright wash vat for milk pipelines and milk machines may be accepted as one part of the two-compartment vat: Provided, that the stationary wash rack, in or on the vat, and the milking machines inflations and appurtenances are completely removed from the vat during the washing, rinsing, and/or sanitizing of other utensils and equipment. Where mechanical cleaning/recirculated systems eliminate the need for handwashing of equipment, the presence of the second wash vat compartment may be optional if so determined by DHEC on an individual farm basis.

(17) A transportation tank, with or without overhead protection, may be used for cooling and/or storing milk on a dairy farm. If a suitable shelter is provided for a transportation truck used for cooling and/or storing milk, such shelter shall be adjacent to, but not a part of, the milkhouse and shall comply with the requirements of the

milkhouse with respect to construction, lighting, drainage, insect and rodent control, and general maintenance. In addition, the following minimum criteria shall be met:

(a) An accurate, accessible temperature-recording device shall be installed in the milk line downstream from an effective cooling device that cools the milk to 7°C (45°F) or less. An indicating thermometer shall be installed as close as possible to the recording device for verification of recording temperatures. This indicating thermometer shall comply with all applicable requirements in Appendix H of the PMO. This thermometer shall be used to check the recording thermometer during the regulatory inspection and the results recorded on the recording chart.

(b) The milk shall be sampled at the direction of DHEC in a manner so as to preclude contaminating the milk tank truck or sample, by an acceptable milk sample collector.

(c) The milk tank truck shall be effectively agitated in order to collect a representative sample.

When DHEC determines conditions exist whereby the milk tank truck can be adequately protected and sampled without contamination, a shelter need not be provided if the following minimum criteria are met:

(d) The milk hose connection is accessible to, and made from within, the milkhouse. The milk hose connection to the milk tank truck is completely protected from the outside environment at all times.

(e) To assure continued protection of the milk, the milk tank truck manhole must be sealed after the truck has been cleaned and sanitized.

(f) The milk tank truck shall be washed and sanitized at the permitted milk plant, receiving station or transfer station receiving the milk or at a permitted milk tank truck cleaning facility.

An accurate, accessible temperature-recording device shall be installed in the milk line downstream from an effective cooling device, which cools the milk to below 7°C (45°F). An indicating thermometer shall be installed as close as possible to the recording device for verification of recording temperatures. This indicating thermometer shall comply with all applicable requirements in Appendix H of the PMO. This thermometer shall be used to check the recording thermometer during the regulatory inspection and the results recorded on the recording chart.

The milk shall be sampled at the direction of DHEC, in a manner so as to preclude contaminating the milk tank truck or sample, by a permitted milk sample collector. The milk in the milk tank truck shall be effectively agitated in order to collect a representative sample.

The milk tank truck shall be parked on a self-draining concrete or equally impervious surface during filling and storage.

6. Milkhouse or Room - Cleanliness

a. General - The floors, walls, ceilings, windows, tables, shelves, cabinets, wash vats, non-product contact surfaces of milk containers, utensils and equipment and other milkhouse equipment shall be clean. Only articles directly related to milkhouse activities shall be permitted in the milkhouse. The milkhouse shall be free of trash, animals, and fowl.

b. Administrative Procedures - This item is deemed to be satisfied when:

(1) The milkhouse structure, equipment, and other facilities used in its operation or maintenance are clean at all times.

(2) Incidental articles such as desks, refrigerators, and storage cabinets may be in the milkhouse provided they are kept clean and ample space is available to conduct the normal operations in the milkhouse and will not cause contamination of the milk.

(3) Vestibules, if provided, are kept clean.

(4) Animals and fowl are kept out of the milkhouse.

7. Toilet

a. General - Every dairy farm shall be provided with one or more toilets, conveniently located and properly constructed, operated, and maintained in a sanitary manner. The waste shall be inaccessible to insects and shall not pollute the soil surfaces or contaminate any water supply.

b. Administrative Procedures - This item is deemed to be satisfied when:

(1) There is at least one flush toilet connected to a public sewer system or to an individual sewage disposal system or a chemical toilet, earth pit privy or other type of privy. Such sewage systems shall be constructed and operated in accordance with plans and instructions of DHEC.

(2) A toilet or privy is convenient to the milking barn and the milkhouse. There shall be no evidence of human defecation or urination about the premises.

(3) No privy opens directly into the milkhouse.

(4) The toilet room, including all fixtures and facilities, is kept clean and free of insects and odors.

(5) Where flush toilets are used, doors to toilet rooms are tight and self-closing. All outer openings in toilet rooms shall be screened or otherwise protected against the entrance of insects.

(6) Vents of earth pits are screened.

8. Water Supply

a. General - Water for milkhouse and milking operations shall be from a supply properly located, protected, and operated, and shall be easily accessible, adequate and of a safe, sanitary quality.

b. Administrative Procedures - This item is deemed to be satisfied when:

(1) The water supply for milkhouse and milking operations is approved as safe by DHEC.

(2) No cross-connection exists between a safe water supply and any unsafe or questionable water supply, or any other source of pollution.

(3) There are no submerged inlets through which a safe water supply may be contaminated.

(4) The well or other source of water is located and constructed in such a manner that neither underground nor surface contamination from any sewerage systems, privy, or other source of pollution can reach such water supply.

(5) New individual water supplies and water supply systems which have been repaired or otherwise become contaminated are thoroughly disinfected before being placed in use. The supply shall be made free of the disinfectant by pumping to waste before any sample for bacteriological testing shall be collected.

(6) All containers and tanks used in the transportation of water are sealed and protected from possible contamination. These containers and tanks shall be subjected to a thorough cleaning and a bacteriological treatment prior to filling with potable water to be used at the dairy farm. To minimize the possibility of contamination of the water during its transfer from the potable tanks to the elevated or groundwater storage at the dairy farm, a suitable pump, hose, and fittings shall be provided. When the pump, hose and fittings are not being used, the outlets shall be capped and stored in a suitable dust-proof enclosure so as to prevent their contamination. The storage tank at the dairy farm shall be constructed of impervious material provided with a dust and rainproof cover, and also provided with an approved-type vent and roof hatch. All new reservoirs or reservoirs which have been cleaned shall be disinfected prior to placing them into service.

(7) Samples for bacteriological examination are taken upon the initial approval of the physical structure based upon the requirements of this Regulation and when any repair or alteration of the water supply system has been made, and at least every three years: Provided, that water supplies with buried well casing seals, installed prior to the adoption of this section, shall be tested at intervals no greater than six months apart. Whenever such samples indicate either the presence of bacteria of the coliform group, or whenever the well casing, pump or seal need replacing or repair, the well casing and seal shall be brought above the ground surface and shall comply with all other applicable construction criteria of this section: Provided, That when water is hauled to the dairy farm, such water shall be sampled for bacteriological examination at the point of use and submitted to a laboratory at least four times in separate months during any consecutive six months. Bacteriological examinations shall be conducted in a laboratory acceptable to DHEC. To determine if water samples have been taken at the frequency established in this Section, the interval shall include the designated period plus the remaining days of the month in which the sample is due.

(8) Current records of water test results shall be retained on file with DHEC, or as DHEC directs.

9. Utensils and Equipment - Construction

a. General

(1) All multi-use containers, equipment, and utensils used in the handling, storage, or transportation of milk shall be made of smooth, nonabsorbent, corrosion-resistant, nontoxic materials, and shall be so constructed as to be easily cleaned. All containers, utensils, and equipment shall be in good repair. All milk pails used for hand milking and stripping shall be seamless and of the hooded type. Multiple-use woven material shall not be used for straining milk. All single-service articles shall have been manufactured, packaged, transported, and handled in a sanitary manner and shall comply with the applicable requirements of Section VII.C.11. of this section. Articles intended for single-service use shall not be reused.

(2) Farm holding/cooling tanks, welded sanitary piping, and transportation tanks shall comply with the applicable requirements of Section VII.C.10. and 11. of this section.

b. Administrative Procedures - This item is deemed to be satisfied when:

(1) All multi-use containers, equipment, and utensils which are exposed to milk or milk products, or from which liquids may drip, drain or be drawn into milk or milk products are made of smooth impervious, nonabsorbent, safe materials of the following types:

(a) Stainless steel of the AISI (American Iron and Steel Institute) 300 series; or

(b) Equally corrosion-resistant, nontoxic metal; or

(c) Heat-resistant glass; or

(d) Plastic or rubber and rubber-like materials which are relatively inert, resistant to scratching, scoring, decomposition, crazing, chipping, and distortion, under normal use conditions; are nontoxic, fat resistant, relatively nonabsorbent, relatively insoluble, do not release component chemicals or impart flavor or odor to the product, and which maintain their original properties under repeated use conditions.

(2) Single-service articles have been manufactured, packaged, transported and handled in a sanitary manner and comply with the applicable requirements of Section VII.C.11.

(3) Articles intended for single-service use are not reused.

(4) All containers, equipment and utensils are free of breaks and corrosion.

(5) All joints in such containers, equipment, and utensils are smooth and free from pits, cracks, or inclusions.

(6) Mechanically cleaned milk pipelines and return-solution lines are self-draining. If gaskets are used, they shall be self-positioning and of material meeting specifications described in (1)(d) above, and shall be of such design, finish, and application as to form a smooth, flush interior surface. If gaskets are not used, all fittings shall have self-positioning faces designed to form a smooth, flush interior surface. All interior surfaces of welded joints in pipelines shall be smooth and free of pits, cracks, and inclusions.

(7) Detailed plans for mechanically cleaned pipeline systems are submitted to DHEC for written approval prior to installation. No alteration or addition shall be made to any milk pipeline system without prior written approval of DHEC.

(8) Strainers, if used, are of perforated metal design, or so constructed as to utilize single-service strainer media.

(9) Seamless hooded pails having an opening not exceeding one-third the area of that of an open pail of the same size are used for hand milking and hand stripping.

(10) All milking machines, including heads, milk claws, milk tubing, and other milk-contact surfaces can be easily cleaned and inspected. Pipelines, milking equipment, and appurtenances which require a screw driver or special tool shall be considered easily accessible for inspection providing the necessary tools are available at the milkhouse. Milking systems shall not have components incorporated in the return solution lines, which by design do not comply with the criteria for product- contact surfaces, such as:

(a) Ball type plastic valves;

(b) Plastic tees with barbed ridges to better grip the plastic or rubber hoses; and

(c) The use of PVC water type piping for return solution lines.

(11) Milk cans have umbrella-type lids.

(12) Farm holding/cooling tanks, welded sanitary piping, and transportation tanks comply with the applicable requirements of Section VII.C.10 and 11 of this section.

(13) During filling, flexible plastic/rubber hoses may be used between the fill valves of bottom fill and top fill bulk milk storage tanks, when needed for functional purposes. Such hoses shall be drainable, be as short as practical, have sanitary fittings, and be supported to maintain uniform slope and alignment. The end fittings of such hoses shall be permanently attached in such a manner that will assure a crevice-free joint between the hose and the fitting, which can be cleaned by mechanical means. The hoses shall be included as part of a mechanical cleaning system.

(14) Transparent flexible plastic tubing (up to 150 feet in length) used in connection with milk transfer stations shall be considered acceptable if it meets the "3-A Sanitary Standards for Multiple-Use Plastic Materials Used as Product Contact Surfaces for Dairy Equipment, Number 20-" and if it remains sufficiently clear that the interior surfaces can be properly inspected. Short lengths of flexible plastic tubing (8 feet or less) may be inspected for cleanliness by sight or by use of a "rod". The transparency or opacity of such tubing under this condition is not a factor in determining cleanliness.

(15) AMIs shall comply with all applicable *Grade "A" PMO* requirements and/or 3-A standards.

NOTE: 3-A Sanitary standards for dairy equipment are promulgated jointly by the Sanitary Standards Subcommittee of the Dairy Industry Committee, the Committee on Sanitary Procedure of the International Association for Food Protection, and the Milk Safety Branch, Food and Drug Administration, Public Health Service, Center for Food Safety and Applied Nutrition, Department of Health and Human Services. Equipment manufactured in conformity with 3-A Sanitary Standards complies with the sanitary design and construction standards of this Regulation.

10. Utensils and Equipment - Cleaning

a. General - The product-contact surfaces of all multi-use containers, equipment, and utensils used in the handling, storage, or transportation of milk shall be cleaned after each usage.

b. Administrative Procedures - This item is deemed to be satisfied when:

(1) There shall be a separate wash manifold for all mechanically cleaned milk pipelines in all new or extensively remodeled facilities.

(2) The product-contact surface of all multi-use containers, equipment and utensils used in the handling, storage or transportation of milk are cleaned after each milking or once every twenty-four hours for continuous operations.

(3) There shall be no partial removal of milk from milk storage/holding tanks by the bulk milk hauler/sampler, except partial pickups may be permitted when the milk storage/holding tank is equipped with a seven day recording device complying with the specifications of Appendix H of the PMO. or other recording device acceptable to DHEC, provided the milk storage/holding tank shall be cleaned and sanitized when empty and shall be emptied at least every seventy-two hours. In the absence of a temperature-recording device, partial pickups may be permitted as long as the milk storage/holding tank is completely empty, clean and sanitized prior to the next milking. In the event of an emergency situation, such as inclement weather, natural disaster, etc., a variance may be permitted at the discretion of DHEC.

11. Utensils and Equipment - Sanitization

a. General - The product-contact surfaces of all multi-use containers, equipment and utensils used in the handling, storage, or transportation of milk shall be sanitized before each usage.

b. Administrative Procedures - This item is deemed to be satisfied when all product-contact surfaces of multi-use containers, utensils, and equipment used in the handling, storage, or transportation of milk are sanitized

before each usage by one of the following methods, or by any method which has been demonstrated to be equally effective:

(1) Complete immersion in hot water at a temperature of at least 77°C (170°F) for at least five minutes, or exposure to a flow of hot water at a temperature of at least 77°C (170°F) as determined by use of a suitable accurate thermometer (at the outlet) for at least five minutes.

(2) Certain chemical compounds are effective for the sanitization of milk utensils, containers, and equipment. These are contained in 21 CFR 178.1010 and shall be used in accordance with label directions. (Refer to Appendix F. of the PMO for further discussion of approved sanitizing procedures.)

12. Utensils and Equipment - Storage

a. General - All containers, utensils and equipment used in the handling, storage, or transportation of milk, unless stored in sanitizing solutions, shall be stored to assure complete drainage, and shall be protected from contamination prior to use: Provided, that pipeline milking equipment such as milker claws, inflations, weigh jars, meters, milk hoses, milk receivers, tubular coolers, plate coolers and milk pumps which are designed for mechanical cleaning and other equipment, as accepted by FDA, which meets these criteria may be stored in the milking barn or parlor provided this equipment is designed, installed and operated to protect the product and solution-contact surfaces from contamination at all times.

b. Administrative Procedures - This item is deemed to be satisfied when:

(1) All milk containers, utensils, and equipment, including milking machine vacuum hoses, are stored in the milkhouse in a sanitizing solution, or on racks, until used. Pipeline milking equipment such as: milker claws, inflations, weigh jars, milk hoses, milk receivers, tubular coolers, plate coolers and milk pumps which are designed for mechanical cleaning and other equipment, as accepted by FDA, which meets these criteria may be mechanically cleaned, sanitized and stored in the milking barn or parlor provided this equipment is designed, installed and operated to protect the product and solution contact surface from contamination at all times. Some of the parameters to be considered in determining protection are: proper location of equipment, proper drainage of equipment, and adequate and properly located lighting and ventilation. The milking barn or parlor must be used only for milking. Concentrates may be fed in the barn during milking but the barn shall not be used for the housing of animals. When manual cleaning of product-contact surfaces is necessary, the cleaning shall be done in the milkhouse. Provided, in the case of a milking parlor that opens directly into an enclosed housing area, through a covered holding area, the holding area may be seasonally enclosed when:

(a) There are no manure pit openings in the parlor, holding area or in the housing area close enough to affect the milking parlor.

(b) The animal holding and housing areas are maintained in good repair and reasonably clean.

(c) With respect to dust, odors, rodents and insects, the entire area meets milking parlor standards and the parlor is free of evidence of birds.

In addition, construction and cleanliness items identified above shall be evaluated in the appropriate Regulation Sections.

(2) Means are provided to effect complete drainage of equipment when such equipment cannot be stored to drain freely.

(3) Clean cans or other containers are stored in the milkhouse within a reasonable time after delivery to the dairy farm.

(4) Strainer pads, parchment papers, gaskets and similar single-service articles are stored in a suitable container or cabinet, in a location convenient to their use, and protected against contamination.

13. Milking - Flanks, Udders, and Teats

a. General - Milking shall be done in the milking barn, stable, or parlor. The flanks, udders, bellies, and tails of all milking lactating animals shall be free from visible dirt. All brushing shall be completed prior to milking. The udders and teats of all milking lactating animals shall be clean and dry before milking. Teats shall be treated with a sanitizing solution just prior to the time of milking, and shall be dry before milking. Wet hand milking is prohibited.

b. Administrative Procedures - This item is deemed to be satisfied when:

(1) Milking is done in a milking barn, stable, or parlor.

(2) Brushing is completed prior to milking.

(3) Flanks, bellies, tails, and udders are clipped as often as necessary to facilitate cleaning of these areas and are free from dirt. The hair on the udders shall be of such length that it is not incorporated with the teat in the inflation during milking.

Udders and teats of all milking animals are clean and dry before milking. Teats shall be cleaned, treated with a sanitizing solution and dry just prior to milking. Provided that the sanitizing of teats shall not be required if the udder is dry and the teats have been thoroughly cleaned (not dry wiped) and dried (manually wiped dry) prior to milking. The determination of what constitutes a dry udder and cleaned and dried teats shall be made by DHEC.

NOTE: Additional alternative udder preparation methods may also be used once they have been evaluated by FDA and found acceptable.

(5) Wet hand milking is prohibited.

14. Protection From Contamination

a. General - Milking and milkhouse operations, equipment, and facilities shall be located and conducted to prevent any contamination of milk, equipment, containers, and utensils. No milk shall be strained, poured, transferred, or stored unless it is properly protected from contamination. After sanitization, all containers, utensils and equipment shall be handled in such a manner as to prevent contamination of any product-contact surface. Vehicles used to transport milk from the dairy farm to the milk plant, receiving station or transfer station shall be constructed and operated to protect their contents from sun, freezing and contamination. Such vehicles shall be kept clean, inside and out, and no substance capable of contaminating the milk shall be transported with the milk.

b. Administrative Procedures - This item is deemed to be satisfied when:

(1) Equipment and operations are so located within the milking barn and milkhouse as to prevent overcrowding and contamination of cleaned and sanitized containers, equipment, and utensils by splash, condensation, or manual contact.

(2) During processing, pipelines and equipment used to contain or conduct milk and milk products shall be effectively separated from tanks or circuits containing cleaning and/or sanitizing solutions.

(3) All milk which has overflowed, leaked, been spilled, or improperly handled is discarded.

(4) All product-contact surfaces of containers, equipment, and utensils are covered or otherwise protected to prevent the access of insects, dust, condensation, and other contamination. All openings, including valves and piping attached to milk storage tanks, and milk tank trucks, pumps, or vats, shall be capped or otherwise properly protected. Gravity type strainers used in the milkhouse do not have to be covered. Milk pipelines used to convey milk from pre-coolers to the bulk milk tank must be fitted with effective drip deflectors.

(5) The receiving receptacle is raised above the floor (as on a dolly or cart), or placed at a distance from the lactating animals, to protect it against manure and splash when milk is poured and/or strained in the milking barn, stable or parlor. Such receptacle shall have a tight-fitting cover, which shall be closed, except when milk is being poured.

(6) Each pail or container of milk is transferred immediately from the milking barn, stable, or parlor to the milkhouse.

(7) Pails, cans, and other equipment containing milk are properly covered during transfer and storage.

(8) Whenever air under pressure is used for the agitation or movement of milk, or is directed at a milk-contact surface, it is free of oil, dust, rust, excessive moisture, extraneous materials and odor, and shall otherwise comply with the applicable standards of Appendix H of the PMO.

(9) Sanitized product-contact surfaces, including bulk milk tank openings and outlets, are protected against contact with unsanitized utensils and equipment, hands, clothing, splash, condensation and other sources of contamination.

(10) Any sanitized product-contact surface, which has been otherwise exposed to contamination, is again cleaned and sanitized before being used.

(11) Vehicles used to transport milk from the dairy farm to the milk plant, receiving station or transfer station are constructed and operated to protect their contents from sun, freezing and contamination.

(12) Vehicles have bodies with solid enclosures and tight, solid doors.

(13) Vehicles are kept clean, inside and out.

(14) No substance capable of contaminating milk is transported with the milk. (Refer to Section VII.C.10 and 11 and Appendix B of the PMO for information on the construction of milk tank trucks.)

15. Drug and Chemical Control

a. General - Cleaners and sanitizers shall be stored in properly identified, dedicated end-use containers. Animal drugs and drug administration equipment shall be stored in such a way that milk, milking equipment, wash vats and hand sinks are not subject to contamination. Animal drugs shall be properly labeled and segregated, lactating from non-lactating. Unapproved drugs shall not be used.

b. Administrative Procedures - This item is deemed to be satisfied when:

(1) Cleaners and sanitizers used on dairy farms shall be purchased in containers from the manufacturer or distributor which properly identify the contents or, if bulk cleaners and sanitizers are transferred from the manufacturer's or distributor's container, that the transfer only occurs into a dedicated end-use container which is specifically designed and maintained according to the manufacturer's specifications for that specific product. The label on the dedicated end-use container shall include the product name, chemical description, use

directions, precautionary and warning statement, first aid instructions, container storage and maintenance instructions and the name and address of the manufacturer or distributor.

(2) Equipment used to administer drugs is not cleaned in the wash vats and is stored so as not to contaminate the milk or milk-contact surfaces of equipment.

(3) Drugs intended for treatment of non-lactating dairy animals are segregated from those drugs used for lactating animals. Separate shelves in cabinets, refrigerators or other storage facilities satisfy this item.

(4) Drugs shall be properly labeled to include the name and address of the manufacturer or distributor for OTC drugs, or veterinary practitioner dispensing the product for Rx and extra label use drugs.

(5) Drug labels shall also include:

(a) Directions for use, and prescribed withholding times;

(b) Cautionary statements, if needed; and

(c) Active ingredient(s) in the drug product.

(6) Unapproved and/or improperly labeled drugs are not used to treat dairy animals and are not stored in the milkhouse, milking barn, stable or parlor.

(7) Drugs are stored in such a manner that they cannot contaminate the milk or milk product-contact surfaces of the containers, utensils or equipment.

NOTE: Topical antiseptics and wound dressings, unless intended for direct injection into the teat, vaccines and other biologics, and dosage form vitamins and/or mineral products are exempt from labeling and storage requirements, except when it is determined that they are stored in such a manner that they may contaminate the milk or milk product-contact surfaces of containers, utensils or equipment.

16. Personnel - Hand-Washing Facilities

a. General - Adequate hand-washing facilities shall be provided, including a lavatory fixture with hot and cold, or warm running water, soap or detergent, and individual sanitary towels, or other approved hand drying devices, convenient to the milkhouse, milking barn, stable, parlor and flush toilet.

b. Administrative Procedures - This item is deemed to be satisfied when:

(1) Hand-washing facilities are located convenient to the milkhouse, milking barn, stable, parlor, and flush toilet.

(2) Hand-washing facilities include soap or detergent, hot and cold, or warm running water, individual sanitary towels, or other approved hand drying devices and a lavatory fixture. Utensil wash and rinse vats shall not be considered as hand-washing facilities.

17. Personnel - Cleanliness

a. General - Hands shall be washed clean and dried with an individual sanitary towel or other approved hand drying devices immediately before milking, before performing any milkhouse function, and immediately after

the interruption of any of these activities. Milkers and milk haulers shall wear clean outer garments while milking or handling milk, milk containers, utensils, or equipment.

b. Administrative Procedures - This item is deemed to be satisfied when:

(1) Hands are washed clean and dried with an individual sanitary towel or other approved hand drying device immediately before milking, before performing any milkhouse function, and immediately after the interruption of any of these activities.

(2) Milkers and bulk milk haulers /samplers wear clean outer garments while milking or handling milk, milk containers, utensils, or equipment.

18.Cooling

a. General - Raw milk for pasteurization shall be cooled to 10ºC (50ºF) or less within four hours or less of the commencement of the first milking, and to 7ºC (45ºF) or less within two hours after the completion of milking: Provided, that the blend temperature after the first milking and subsequent milking does not exceed 10°C (50°F).

b. Administrative Procedures - This item is deemed to be satisfied when:

(1) Raw milk for pasteurization is cooled to 10ºC (50ºF) or less within four hours or less of the commencement of the first milking, and to 7ºC (45ºF) or less within two hours after the completion of milking: Provided, that the blend temperature after the first milking and subsequent milking does not exceed 10ºC (50ºF).

(2) Recirculated cold water which is used in plate or tubular coolers or heat exchangers is from a safe source and protected from contamination. Such water shall be tested semiannually and shall comply with the bacteriological standards set by DHEC.

(3) All farm bulk milk tanks manufactured after January 1, 2000 shall be equipped with an approved temperature-recording device.

(a) The recording device shall be operated continuously and be maintained in a properly functioning manner. Circular charts shall not overlap.

(b) The recording device shall be verified every six months and documented in a manner acceptable to DHEC using an accurate (+/- 1^{o}C (2^{o}F)) thermometer that has been calibrated by a traceable standard thermometer, within the past six months, with the results and date recorded and the thermometer being properly identified, or by using a traceable standard thermometer that has been calibrated within the last year.

(c) Recording thermometer charts shall maintained on the premises for a period of a minimum of six months and available to DHEC.

(d) The recording thermometer should be installed in an area convenient to the milk storage tank and acceptable to DHEC.

(e) The recording thermometer sensor shall be located to permit the registering of the temperature of the contents when the tank contains no more than ten percent of its calibrated capacity.

(f) The recording thermometer shall comply with the current technical specifications for tank recording thermometers.

(g) A recording thermometer and/or any other device that meets the intent of these

Administrative Procedures and technical specifications and is acceptable to DHEC can be used to monitor/record the bulk tank temperature.

(h) The recording thermometer charts shall properly identify the producer, date, and signature of the person removing the chart.

19. Insect and Rodent Control

a. General - Effective measures shall be taken to prevent the contamination of milk, containers, equipment, and utensils by insects and rodents and by chemicals used to control such vermin. Milkhouses shall be free of insects and rodents. Surroundings shall be kept neat, clean, and free of conditions which might harbor or be conducive to the breeding of insects and rodents. Feed shall be stored in such a manner that it will not attract birds, rodents or insects.

b. Administrative Procedures - This item is deemed to be satisfied when:

(1) Surroundings are kept neat, clean, and free of conditions which might harbor or be conducive to the breeding of insects and rodents. During fly season, manure shall be spread directly on the fields; or stored for not more than four days in a pile on the ground surface, and then spread on the fields; or stored for not more than seven days in a impervious-floored bin, or on an impervious-curbed platform and then spread; or stored in a tight-screened and trapped manure shed; or effectively treated with larvicides; or disposed of in any other manner which controls insect breeding.

(2) Manure packs in loafing areas, stables without stanchions, pen stables, resting barns, wandering sheds and free-stall housing are properly bedded and managed to prevent insect breeding.

(3) Milkhouses are free of insects and rodents.

(4) Milkhouses are effectively screened or otherwise protected against the entrance of vermin.

(5) Outer milkhouse doors are tight and self-closing. Screen doors shall open outward.

(6) Effective measures are taken to prevent the contamination of milk, containers, utensils, and equipment by insects and rodents, and by chemicals used to control such vermin. Insecticides and rodenticides not approved for use in the milkhouse shall not be stored in the milkhouse.

(7) Only insecticides and rodenticides approved for use by DHEC and/or registered with the U.S. Environmental Protection Agency are used for insect and rodent control. (Refer to Appendix C of the PMO for further information about insect and rodent control.)

(8) Insecticides and rodenticides are used only in accordance with manufacturer's label directions and are used so as to prevent the contamination of milk, milk containers, equipment, utensils, feed, and water.

(9) Covered boxes, bins or separate storage facilities for ground, chopped or concentrated feeds are provided.

(10) Feed may be stored in the milking portion of the barn only in such a manner as will not attract birds, insects or rodents. Open feed dollies or carts may be used for distributing the feed, but not storing feed, in the milking barn. Feed dollies, carts, fully automated feeding systems, or other feed containers may be exempt from the use of covers, provided they do not attract birds, insects, or rodents.

C. Sanitation Requirements for Grade A Pasteurized, Ultra-Pasteurized and Aseptically Processed Milk and Milk Products

Milk plants shall comply with all items of Section VII. C. A receiving station shall comply with Section VII.C.1 to 15, inclusive, and 17, 20, and 22, except that the partitioning requirement of VII.C.5 shall not apply.

A transfer station shall comply with Section VII.C.1, 4, 6, 7, 8, 9, 10, 11, 12, 14, 15, 17, 20, and 22; and as climatic and operating conditions require, the applicable provisions of 2 and 3: Provided, that in every case, overhead protection shall be provided. Facilities for the cleaning and sanitizing of milk tank trucks shall comply with Section VII.C.1, 4, 6, 7, 8, 9, 10, 11, 12, 14, 15, 20, and 22; and as climatic and operating conditions require, the applicable provisions of 2 and 3: Provided, that in every case, overhead protection shall be provided.

In the case of milk plants, receiving stations and transfer stations, which have HACCP Systems regulated under Appendix K. of the PMO, the HACCP System shall address the public health concerns described in this Section in a manner that provides protection equivalent to the requirements in this Section.

Milk plants that have HACCP Systems, which are regulated under the NCIMS HACCP Program, shall comply with all of the requirements of Section VII. C.1. 16. Pasteurization and Aseptic Processing of this Regulation, and pasteurization shall be managed as a CCP as described in Appendix H of the PMO - MILK AND MILK PRODUCT CONTINUOUS-FLOW (HTST AND HHST) PASTEURIZATION---CCP MODEL HACCP PLAN SUMMARY; and MILK AND MILK PRODUCT VAT (BATCH) PASTEURIZATION---CCP MODEL HACCP PLAN SUMMARY.

1. Floors - Construction

a. General - The floors of all rooms in which milk or milk products are processed, handled, or stored, or in which milk containers, equipment, and utensils are washed, shall be constructed of concrete or other equally impervious and easily cleaned material; and shall be smooth, properly sloped, provided with trapped drains, and kept in good repair: Provided, that cold-storage rooms used for storing milk and milk products need not be provided with floor drains when the floors are sloped to drain to one or more exits: Provided further, that storage rooms for storing dry ingredients, packaged dry ingredients, packaged dry milk or milk products, and/or packaging materials need not be provided with drains: and the floors may be constructed of tightly joined wood.

b. Administrative Procedures - This item is deemed to be satisfied when:

(1) The floors of all rooms in which milk is handled, processed, or stored, or in which milk containers or utensils are washed, are constructed of good quality concrete, or equally impervious tile or brick laid closely with impervious joint material, or metal surfacing with impervious joints, or other material which is the equivalent of good quality concrete. The floors of storage rooms for dry ingredients and/or packaging material may be constructed of tightly joined wood.

(2) The floor surface is smooth and sloped, so that there are no pools of standing water after flushing; and the joints between the floor and the walls are impervious.

(3) The floors are provided with trapped drains. Cold-storage rooms used for storing milk and milk products need not be provided with floor drains when the floors are sloped to drain to one or more exits. Storage rooms for dry ingredients, dry packaged milk or milk products, and/or packaging materials need not be provided with drains. Refer to Section VII.C.11. for requirements for floors of drying chambers.

2. Walls and Ceilings - Construction

a. General - Walls and ceilings of rooms in which milk or milk products are handled, processed, packaged, or stored or in which milk containers, utensils, and equipment are washed, shall have a smooth, washable, light-colored surface, in good repair.

b. Administrative Procedures - This item is deemed satisfied when:

(1) Walls and ceilings are finished with smooth, washable, light-colored impervious materials. Refer to Section VII.C.11 for requirements for walls for drying chambers. Storage rooms used for the storage of packaged dry milk or milk products are exempt from the ceiling requirements of this item.

(2) Walls, partitions, windows, and ceilings are kept in good repair and refinished as often as the finish wears off or becomes discolored.

3. Doors and Windows

a. General - Effective means shall be provided to prevent the access of insects and rodents. All openings to the outside shall have solid doors or glazed windows which shall be closed during dusty weather.

b. Administrative Procedures - This item is deemed to be satisfied when:

(1) All openings to the outer air are effectively protected by:

(a) Screening; or

(b) Effective electric screen panels; or

(c) Fans or air curtains which provide sufficient air velocity so as to prevent the entrance of insects; or

(d) Properly constructed flaps where it is impractical to use self-closing doors or air curtains; or

(e) Any effective combination of (a), (b), (c), or (d), or by any other method which prevents the entrance of insects.

(2) All outer doors are tight and self-closing. Screen doors shall open outward.

(3) All outer openings are rodent-proofed to the extent necessary to prevent the entry of rodents.

NOTE: The evidence of insects and/or rodents in the plant shall be considered under Section VII.C.9.

4. Lighting and Ventilation

a. General - All rooms in which milk or milk products are handled, processed, packaged or stored and/or in which milk containers, equipment, and/or utensils are washed shall be well lighted and well ventilated.

b. Administrative Procedures - This item is deemed to be satisfied when:

(1) Adequate light sources are provided (natural, artificial, or a combination of both) which furnish at least twenty foot-candles (220 lux) of light in all working areas. This shall apply to all rooms where milk or milk products are handled, processed, or stored, or where utensils, containers, and/or equipment are washed. Dry storage and cold storage rooms shall be provided with at least five foot-candles (55 lux) of light.

(2) Ventilation in all rooms is sufficient to keep them reasonably free of odors and excessive condensation on equipment, walls, and ceilings.

(3) Pressurized ventilating systems, if used, have a filtered air intake.

(4) For milk plants that condense and/or dry milk or milk products, ventilating systems in packaging rooms, where used, are separate systems and where possible have the ducts installed in a vertical position.

5. Separate Rooms

a. General - There shall be separate rooms for:

(1) The pasteurizing, processing, cooling, reconstitution, condensing, drying, and packaging of milk and milk products.

(2) The cleaning of milk cans and containers, bottles, cases, and dry milk or milk product containers.

(3) Cleaning and sanitizing facilities for milk tank trucks in plants receiving milk, or whey in such tanks.

(4) Receiving cans of milk and milk products in plants receiving such cans.

(5) The fabrication of containers and closures for milk and milk products.

(6) Packaging of dry milk or milk products.

Rooms in which milk or milk products are handled, processed, stored, condensed, dried and packaged, or in which containers, utensils, and/or equipment are washed or stored, shall not open directly into any stable or any room used for domestic purposes. All rooms shall be of sufficient size for their intended purposes.

Designated areas or rooms shall be provided for the receiving, handling, and storage of returned packaged milk and milk products.

b. Administrative Procedures - This item is deemed to be satisfied when:

(1) Pasteurizing, processing, reconstitution, cooling, condensing, drying and packaging of milk and milk products are conducted in a single room(s), but not in the same room(s) used for the cleaning of milk cans, portable storage bins, bottles and cases, or the unloading and/or cleaning and sanitizing of milk tank trucks, provided that these rooms may be separated by solid partitioning doors that are kept closed. Provided further, that cooling, plate or tubular, may be done in the room where milk tank trucks are unloaded and/or cleaned and sanitized. Separation/clarification of raw milk may be done in an enclosed room where milk tank trucks are unloaded and/or cleaned and sanitized.

(2) All returned packaged milk and milk products which have physically left the premises of the milk plant shall be received, handled, and stored in separate areas or rooms isolated from the Grade A dairy operations. Such separate areas or rooms shall be clearly defined and marked for such use.

(3) All bulk milk storage tanks are vented into a room used for pasteurization, processing, cooling, or packaging operations, or into a storage tank gallery room: Provided, that vents located elsewhere which are adequately equipped with air filters so as to preclude the contamination of the milk or milk product shall be considered satisfactory.

(4) Solid doors installed in required partitions are self-closing.

(5) Facilities for the cleaning and sanitizing of milk tank trucks are properly equipped for manual and/or mechanical operations. When such facilities are not provided on the milk plant premises, these operations shall be performed at a receiving station, transfer station, or separate milk tank truck cleaning installation. Items related to facilities for cleaning and sanitizing milk tank trucks are listed at the beginning of this section.

(6) Rooms in which milk or milk products are handled, processed, or stored, or in which milk containers, utensils, and/or equipment are washed or stored, do not open directly into any stable or any room used for domestic purposes.

(7) All rooms shall be of sufficient size for their intended purposes.

(8) Cottage cheese vats shall be located in a separate room, maintained free from flies and other vermin, and kept in a clean condition. Cottage cheese vats located in processing rooms shall be equipped with multi-service or single-service covers which shall be kept in place at all times during the "setting" operation.

6. Toilet-Sewage Disposal Facilities

a. General - Every milk plant shall be provided with toilet facilities conforming with State and local plumbing laws. Toilet rooms shall not open directly into any room in which milk and/or milk products are processed. Toilet rooms shall be completely enclosed and shall have tight-fitting, self-closing doors. Dressing rooms, toilet rooms and fixtures shall be kept in a clean condition, in good repair, and shall be well ventilated and well lighted. Sewage and other liquid wastes shall be disposed of in a sanitary manner.

b. Administrative Procedures - This item is deemed to be satisfied when:

(1) The milk plant is provided with toilet facilities conforming with applicable State and local plumbing laws.

(2) Toilet rooms do not open directly into any room in which milk and/or milk products are processed, condensed or dried.

(3) Toilet rooms are completely enclosed and have tight-fitting self-closing doors.

(4) Dressing rooms, toilet rooms, and fixtures are kept in a clean condition, in good repair, and are well ventilated and well lighted.

(5) Toilet tissue and easily cleanable covered waste receptacles are provided in toilet rooms.

(6) All plumbing is installed to meet the applicable provisions of the State or local plumbing code.

(7) Sewage and other liquid wastes are disposed of in a sanitary manner.

(8) Non-water-carried sewage disposal facilities are not used.

7. Water Supply

a. General - Water for milk plant purposes shall be from a supply properly located, protected, and operated and shall be easily accessible, adequate, and of a safe, sanitary quality.

b. Administrative Procedures - This item is deemed to be satisfied when:

(1) Water for milk plant purposes is from an adequate supply, properly located, protected, and operated. It shall be easily accessible and of a safe, sanitary quality.

(2) The water supply is approved as safe by DHEC, and, in the case of individual water systems, complies with at least the specification outlined by DHEC, including maximum contaminant levels of *R. 61-58, State Primary Drinking Water Regulations*, and the bacteriological standards required by DHEC.

(3) There is no cross-connection between the safe water supply and any unsafe or questionable water supply, or any source of pollution through which the safe water supply might become contaminated. A connection between the water supply piping and a make-up tank (such as for cooling or condensing), unless protected by an air gap or effective backflow preventer, constitutes a violation of this requirement. An approved air gap is defined as the unobstructed vertical distance through the free atmosphere of at least twice the diameter of the largest incoming water supply pipe or faucet to the flood level of the vessel or receptacle. The distance of the air gap is to be measured from the bottom of the potable inlet supply pipe or faucet to the top of the effective overflow, i.e., flood level rim or internal overflow, of the vessel. In no case, may the effective air gap be less than one inch (2.54 cm).

(4) Condensing water for milk or milk product evaporators, and water used to produce vacuum and/or to condense vapors in vacuum heat processing equipment, is from a source complying with (2) above: Provided, that when approved by DHEC, water from sources not complying with (2) above may be used when the evaporator or vacuum heat equipment is constructed and operated to preclude contamination of such equipment or its contents by condensing water or by water used to produce vacuum. Means of preventing such contamination are:

(a) Use of a surface type condenser in which the condensing water is physically separated from the vapors and condensate, or

(b) Use of reliable safeguards to prevent the overflow of condensing water from the condenser into the evaporator. Such safeguards include a barometric leg extending at least thirty-five feet vertically from the invert of the outgoing condensing water line to the free level at which the leg discharges, or a safety shutoff valve, located on the water feed line to the condenser, automatically actuated by a control which will shut off the in-flowing water when the water level rises above a predetermined point in the condenser. This valve may be actuated by water, air, or electricity, and shall be designed so that failure of the primary motivating power will automatically stop the flow of water into the condenser.

(5) Condensing water for all milk or milk product evaporators, complying with (2) above, and water reclaimed from milk or milk products, may be reused when all necessary means of protection are afforded and it complies with the procedures approved by DHEC.

(6) New individual water supplies and water supply systems, which have been repaired or otherwise become contaminated, are disinfected before being placed in use. The supply shall be made free of the disinfectant by pumping to waste before any sample for bacteriological testing shall be collected.

(7) Samples for bacteriological testing of individual water supplies are taken upon the initial approval of the physical structure, each six months thereafter, and when any repair or alteration of the water supply system has been made. Samples shall be taken by DHEC and examinations shall be conducted in an official laboratory. To

determine if water samples have been taken at the frequency established in this Section, the interval shall include the designated six month period plus the remaining days of the month in which the sample is due.

(8) Current records of water test results are retained on file with DHEC or as DHEC directs.

(9) Water supply outlets are provided immediately available to the cottage cheese vats. The hose for transport of water for washing cottage cheese curd shall be arranged in such a way as to preclude the possibility of the hose touching the floor or the product.

(10) A potable water supply, which meets the criteria of this section, may be connected to the product feed line of a steam vacuum evaporator, provided that the water supply is protected at the point of connection by an approved backflow prevention device.

8. Hand-Washing Facilities

a. General - Convenient hand-washing facilities shall be provided, including hot and cold and/or warm running water, soap, and individual sanitary towels or other approved hand-drying devices. Hand-washing facilities shall be kept in a clean condition and in good repair.

b. Administrative Procedures - This item is deemed to be satisfied when:

(1) Convenient hand-washing facilities are provided, including hot and cold and/or warm running water, soap, and individual sanitary towels or other approved hand-drying devices.

(2) Hand-washing facilities are convenient to all toilets and to all rooms in which milk plant operations are conducted.

(3) Hand-washing facilities are kept in a clean condition and in good repair.

(4) Steam-water mixing valves and vats for washing bottles, cans, and similar equipment are not used as hand-washing facilities.

9. Milk Plant Cleanliness

a. General - All rooms in which milk and milk products are handled, processed, or stored, and/or in which containers, utensils, or equipment are washed or stored, shall be kept clean, neat, and free of evidence of insects and rodents. Only equipment directly related to processing operations or to handling of containers, utensils, and equipment shall be permitted in the pasteurizing, processing, cooling, condensing, drying, packaging, and bulk milk or milk product storage rooms.

b. Administrative Procedures - This item is deemed to be satisfied when:

(1) Only equipment directly related to processing operations or the handling of containers, utensils, and equipment is permitted in the pasteurizing, processing, cooling, condensing, drying, packaging, and bulk milk or milk product storage rooms.

(2) All piping, floors, walls, ceilings, fans, shelves, tables, and the non-product-contact surfaces of other facilities and equipment are clean.

(3) No trash or solid waste is stored within the milk plant, except in covered containers. Waste containers at the packaging machine or bottle washer may be uncovered during operation of such equipment.

(4) All rooms in which milk and milk products are handled, processed, or stored, and/or in which containers, utensils, or equipment are washed or stored, are kept clean, neat, and free of evidence of insects and rodents.

(5) Excessive product dust shall be kept under effective control by the use of exhaust and collective systems designed for in-plant dust control. Tailings and materials collected from exhaust collective systems shall not be used for human consumption.

10. Sanitary Piping

a. General - All sanitary piping, fittings, and connections which are exposed to milk or milk products, or from which liquids may drip, drain, or be drawn into milk or milk products, shall consist of smooth, impervious, corrosion-resistant, nontoxic, easily cleanable material which is approved for milk product contact surfaces. All piping shall be in good repair. Pasteurized milk and milk products shall be conducted from one piece of equipment to another only through sanitary piping.

b. Administrative Procedures - This item is deemed to be satisfied when:

(1) All sanitary piping, fittings, and connections which are exposed to milk or milk products, or from which liquids may drip, drain, or be drawn into milk or milk products, consist of smooth, impervious, corrosion-resistant, nontoxic, easily cleanable material.

(2) All sanitary piping, connections and fittings consist of:

(a) Stainless steel of the AISI (American Iron and Steel Institute) 300 series; or

(b) Equally corrosion-resistant metal which is nontoxic and nonabsorbent; or

(c) Heat resistant glass; or

(d) Plastic, or rubber and rubber-like materials, which are relatively inert, resistant to scratching, scoring, decomposition, crazing, chipping, and distortion under normal use conditions; which are nontoxic, fat resistant, relatively nonabsorbent; which do not impart flavor or odor to the product; and which maintain their original properties under repeated use conditions, may be used for gaskets, sealing applications, and for short flexible take down jumpers or connections where flexibility is required for essential or functional reasons.

(3) Sanitary piping, fittings and connections are designed to permit easy cleaning, kept in good repair, and free of breaks or corrosion, and contain no dead ends of piping in which milk or milk products may collect.

(4) All interior surfaces of demountable piping, including valves, fittings, and connections are designed, constructed, and installed to permit inspection and drainage.

(5) All mechanically cleaned milk pipelines and return-solution lines are rigid, self-draining, and so supported to maintain uniform slope and alignment. Return solution lines shall be constructed of material meeting the specifications of (2) above. If gaskets are used, they shall be self-positioning, of material meeting the specifications outlined in (2) above, and designed, finished, and applied to form a smooth, flush interior surface. If gaskets are not used, all fittings shall have self-positioning faces designed to form a smooth, flush interior surface. All interior surfaces of welded joints in pipelines shall be smooth and free from pits, cracks, or inclusions.

(a) In the case of welded lines, all welds shall be inspected as they are made; and such welds shall be approved by DHEC.

(b) Each cleaning circuit shall have access points for inspection in addition to the entrances and exits. These may be valves, removable sections, fittings, or other means of combinations that are adequate for inspection of the interior of the line. These access points shall be located at sufficient intervals to determine the general condition of the interior surfaces of the pipeline.

(c) Detailed plans for welded pipeline systems shall be submitted to DHEC for written approval prior to installation. No alteration or addition shall be made to any welded milk pipeline system without prior written approval from DHEC.

(6) Pasteurized milk and milk products are conducted from one piece of equipment to another only through sanitary milk piping.

(7) Cottage cheese, cheese dressings, or cheese ingredients may be transported by other methods which protect the product from contamination.

(8) For milk plants that dry milk or milk products, because of the high pressure required to obtain proper dispersal of the product in the drying chamber, the pipeline between the high pressure pump and the dryer nozzle may be connected with pressure-tight threaded fittings, or may be welded.

11. Construction and Repair of Containers and Equipment

a. General - All multi-use containers and equipment with which milk or milk products come into contact shall be of smooth, impervious, corrosion-resistant, nontoxic material; shall be constructed for ease of cleaning; and shall be kept in good repair. All single-service containers, closures, gaskets, and other articles with which milk or milk products come in contact shall be nontoxic, and shall have been manufactured, packaged, transported, and handled in a sanitary manner. Articles intended for single-service use shall not be reused.

b. Administrative Procedures - This item is deemed to be satisfied when:

(1) All multi-use containers and equipment with which milk or milk products come into contact are of smooth, impervious, corrosion-resistant, and nontoxic material.

(2) All milk-contact surfaces of multi-use containers and equipment consist of:

(a) Stainless steel of the AISI (American Iron and Steel Institute) 300 series; or

(b) Equally corrosion-resistant metal which is nontoxic and nonabsorbent; or

(c) Heat resistant glass; or

(d) Plastic or rubber and rubber-like materials which are relatively inert, resistant to scratching, scoring, decomposition, crazing, chipping, and distortion under normal use conditions; which are nontoxic, fat resistant, relatively nonabsorbent, and do not impart flavor or odor to the product; and which maintain their original properties under repeated use conditions.

(3) All joints in containers, equipment, and utensils are flush and finished as smooth as adjoining surfaces, or if the surface is vitreous, it must be continuous. Tile floors are not acceptable in dryers. Joints on equipment coming in contact with dry milk or milk products only or used for hot air piping may be sealed by other acceptable means. Where a rotating shaft is inserted through a surface with which milk or milk products come into contact, the joint between the moving and stationary surfaces shall be close-fitting. Grease and oil from gears, bearings, and cables shall be kept out of the milk and milk products. Where a thermometer or temperature sensing element is inserted through a surface with which milk or milk products come into contact, a pressure-tight seal shall be provided ahead of all threads and crevices.

(4) All openings in covers of tanks, vats, separators, etc. are protected by raised edges, or otherwise to prevent the entrance of surface drainage. Condensation-diverting aprons shall be provided as close to the tank or vat as possible on all pipes, thermometer, or temperature sensing elements, and other equipment extending into a tank, bowl, vat, or similar equipment, unless a watertight joint is provided.

(5) All surfaces with which milk or milk products come into contact except pneumatic ducts and cyclonic, or air separator collectors are easily accessible or demountable for manual cleaning or are designed for mechanical cleaning. Provided that flexible plastic or rubber tanker loading and unloading hoses with screw-type hose clamps shall be considered in compliance, if an appropriate screwdriver or tool is readily available for disassembly. All product-contact surfaces shall be readily accessible for inspection and shall be self-draining. Wing nuts, bayonet locks, and similar devices shall be used whenever possible in lieu of bolts and nuts, to promote easy disassembly.

(6) There are no threads used in contact with milk or milk products except where needed for functional and safety reasons, such as in clarifiers, pumps, and separators. Such threads shall be of a sanitary type except those used on high pressure lines between the high pressure pump and the dryer nozzle.

(7) All multi-use containers and other equipment have rounded corners, are in good repair and free from breaks, crevices, and corrosion. Milk cans shall have umbrella-type covers.

(8) Strainers, if used, are of perforated metal design, and so constructed as to utilize single-service strainer media. Multiple-use woven material shall not be used for straining milk: Provided, that when required for functional reasons inherent to the production of certain milk products, such as buttermilk, whey, dry whey, and dry milk products, woven material may be used where it is impractical to use perforated metal. However woven material parts shall be mechanically cleaned by such methods that thoroughly clean the woven material and do not contaminate the product.

(9) All single service containers, closures, gaskets, and other articles, with which milk or milk products come in contact, are nontoxic.

(10) The manufacture, packing, transportation, and handling of single-service containers, closures, caps, gaskets, and similar articles comply with requirements of Appendix J, Sanitation Guidelines for the Manufacture of Single-Service Containers and Closures for Milk and Milk Products, of the PMO. Provided, that all paper, plastics, foil, adhesives, and other components of containers used in the packaging of milk or milk products that have been condensed and/or dried shall be free from deleterious substances and comply with the requirements of the FFD&C Act. Inspections and tests shall be made by DHEC or any agency authorized by them.

(11) Sifters for dry milk products are so constructed as to utilize single-service or multi-service strainer media conforming with:

(a) Plastic materials listed in (2)(d) above; or

(b) Woven stainless steel wire conforming to (2)(a) above; or

(c) Cotton, linen, silk, or synthetic fibers which are non-toxic, relatively insoluble, easily cleanable and do not impart a flavor to the product.

Tailings shall be continuously discharged from sifters through dust-tight connections to an enclosed container and shall not be used for human consumption.

NOTE: 3-A Sanitary Standards for dairy equipment are promulgated jointly by the Sanitary Standards Subcommittee of the Dairy Industry Committee, the Committee on Sanitary Procedure of the International

Association for Food Protection and the Milk Safety Branch, Center for Food Safety and Applied Nutrition, Food and Drug Administration, Public Health Service, Department of Health and Human Services. Equipment manufactured in conformity with 3-A Sanitary Standards complies with the sanitary design and construction standards of this Regulation.

12. Cleaning and Sanitizing of Containers and Equipment

a. General - The product-contact surfaces of all multi-use containers, utensils, and equipment used in the transportation, processing, condensing, drying, packaging, handling, and storage of milk or milk products shall be effectively cleaned and shall be sanitized before each use. Provided, that piping, equipment and containers used to process, conduct or package aseptically processed milk and milk products beyond the final heat treatment process shall be sterilized before any aseptically processed milk or milk product is packaged and shall be resterilized whenever any non-sterile product has contaminated it. Provided further, that cloth-collector systems used on dryers shall be cleaned and sanitized or purged at intervals and by methods recommended by the manufacturer and approved by DHEC.

b. Administrative Procedures - This item is deemed to be satisfied when:

(1) All multi-use containers and utensils are thoroughly cleaned after each use, and all equipment is thoroughly cleaned at least once each day used unless DHEC has reviewed and accepted information, in consultation with FDA, supporting the cleaning of multi-use containers and utensils at frequencies extending beyond one day or seventy-two hours in the case of storage tanks, or forty-four hours in the case of evaporators, which are continuously operated. Supporting information shall be submitted to and approved by DHEC prior to initiating the qualification period if required. Finished product produced during an extended run must meet all applicable requirements of Section VII of this Regulation. Any significant equipment or processing changes shall be communicated to DHEC.

The supporting information may include but is not limited to:
(a) Statement of proposal, including desired cleaning frequency.
(b) Product and equipment description.
(c) Intended use and consumers.
(d) Distribution and storage temperatures of product.
(e) Diagram of process of interest.
(f) Process parameters, including temperature and times.
(g) Hazard evaluation and safety assessment.
(h) Review of equipment for sanitary design.
(i) When indicated by a hazard evaluation and safety assessment, a plan for initial qualification shall be developed to address identified critical process parameters.

Otherwise, storage tanks shall be cleaned when emptied and shall be emptied at least every seventy-two hours. Records must be available to verify that milk storage in these tanks does not exceed seventy-two hours. These records shall be available for at least the previous three months or from the time of the last DHEC inspection, whichever is longer. In the case of pasteurized storage tanks, which are mechanically cleaned at intervals of less than seventy-two hours, the mechanical cleaning records required under subsection (2)(b) of this Section shall be considered adequate. Storage tanks, which are used to store raw milk or milk products or heat-treated milk products longer than twenty-four hours and silo tanks used for the storage of raw milk or milk products or heat-treated milk products shall be equipped with a seven day temperature recording device complying with the specifications of Appendix H of the PMO. Otherwise provided, evaporators shall be cleaned at the end of a continuous operation, not to exceed forty-four hours, and records must be available to verify that the operation time does not exceed forty-four hours.

Drying equipment, cloth-collector systems, packaging equipment and multi-use dry milk products and dry whey storage containers are cleaned at intervals and by methods recommended by the manufacturer and

approved by DHEC. Such methods may include cleaning without water by use of vacuum cleaners, brushes, or scrapers. After cleaning, such equipment is sanitized by a method approved by DHEC. Cloth collector systems and all dry product-contact surfaces downstream from the dryer shall be sanitized or purged at intervals and by methods recommended by the manufacturer and approved by DHEC. Storage bins used to transport dry milk or milk products shall be dry cleaned after each usage and washed and sanitized at regular intervals.

NOTE: Appendix F of the PMO contains additional information on dry cleaning of drying equipment, packaging equipment, and dry milk product and dry whey storage containers.

All milk tank trucks that transport Grade "A" milk and milk products, shall be washed and sanitized at a permitted milk plant, receiving station, transfer station, or milk tank truck cleaning facility. Whenever a milk tank truck has been cleaned and sanitized, as required by DHEC, it shall bear a tag or a record shall be made showing the date, time, place and signature or initials of the employee or contract operator doing the work, unless the milk tank truck delivers to only one receiving facility where responsibility for cleaning and sanitizing can be definitely established without tagging. The tag shall be removed at the location where the milk tank truck is next washed and sanitized and kept on file for fifteen days as directed by DHEC.

Pipelines and/or equipment designed for mechanical cleaning meet the following requirements:

(a) An effective cleaning and sanitizing regimen for each separate cleaning circuit shall be followed.

(b) A temperature recording device, complying with the specifications in Appendix H of the PMO, or a recording device which provides sufficient information to adequately evaluate the cleaning and sanitizing regimen and which is approved by DHEC, shall be installed in the return solution line or other appropriate area to record the temperature and time which the line or equipment is exposed to cleaning and sanitizing solutions. For purposes of this Section, recording devices which produce records not meeting the specifications of Appendix H. of the PMO may be acceptable if:

(i) The device provides a continuous record of the monitoring of the cleaning cycle time and temperature, cleaning solution velocity or cleaning pump operation and the presence or strength of cleaning chemicals for each cleaning cycle.

(ii) The record shows a typical pattern of each circuit cleaned, so that changes in the cleaning regimen may be readily detected.

(iii) Electronic storage of required cleaning records, with or without hard copy printouts, may be acceptable, provided, the electronically generated records are readily available. Electronic records must meet the criteria of this section and those provisions of Appendix H of the PMO, which are determined to be applicable by DHEC and FDA. Except that, electronic storage of required cleaning records, with or without hard copy, shall be acceptable, provided the computer and computer generated records are readily available and meet the criteria of this section and the 21 CFR 11.

(c) Cleaning charts and electronically stored records required by this Section shall be identified, dated and retained for three months or until the next DHEC inspection, whichever is longer.

During each official inspection, DHEC shall examine charts and records to verify the cleaning regimens.

Milk plants in which containers are washed manually are equipped with a two-compartment wash-and-rinse vat for this purpose. Such milk plants shall also provide a steam cabinet or individual steam-jet plate with hood for sanitizing of cleaned containers, or, if sanitizing is done with chemicals, a third treatment vat.

In milk plants utilizing automatic bottle washers, such washers must provide for bactericidal treatment by means of steam, hot water, or chemical treatment. In soaker-type bottle washers, in which bactericidal treatment depends upon the causticity of the washing solution, the caustic strength for a given soaking time and temperature shall be as specified in the following table listing combinations of causticity, time, and temperature of equal bactericidal value, for soaker tank of soaker-type bottle washers:

Table 2.
Combinations of Causticity, Time and Temperature, of Equal Bactericidal Value, for the Soaker Tank of Soaker-Type Bottle Washers
(Based on NSDA Specifications for beverage bottles)

Temperature, Degrees							
Celsius	77	71	66	60	54	49	43
Fahrenheit	170	160	150	140	130	120	110
Time in Minutes	Concentration of NaOH (percent)						
3	0.57	0.86	1.28	1.91	2.86	4.27	6.39
5	0.43	0.64	0.96	1.43	2.16	3.22	4.80
7	0.36	0.53	0.80	1.19	1.78	2.66	3.98

NOTE: The National Soft Drink Association (NSDA), Washington, D.C. 20036 alkali test, the NSDA caustic test, or other suitable test may be used to determine the strength of the soaker solution. The caustic strength shall be tested monthly by the Regulatory Agency.

When caustic is so used, subsequent final rinsing of the bottles shall be with water which has been treated with heat or chemicals to assure freedom from viable pathogenic or otherwise harmful organisms, to prevent recontamination of the treated bottle during the rinsing operation.

(5) All multi-use containers, equipment, and utensils are sanitized before use, employing one or a combination of the methods prescribed under Section VII.B.11. Additionally, for milk plants that condense or dry milk or milk products the following methods are acceptable, or any other method, which has been demonstrated to be equally efficient:

(a) Exposure to an enclosed jet of steam for not less than 1 minute.

(b) Exposure to hot air at a temperature of at least 83°C (180°F) for at least twenty minutes as measured by an acceptable indicating thermometer located in the coldest zone.

Assembled equipment must be sanitized prior to each day's run, unless FDA and DHEC have reviewed and accepted information supporting the sanitizing of multi-use containers, utensils and equipment at frequencies extending beyond one day. Tests to determine the efficiency of sanitization should be made by DHEC at intervals sufficient to satisfy DHEC that the sanitization process is effective. Provided, that all piping, equipment, and containers used to conduct, process or package aseptically processed milk and milk products beyond the final heat treatment process shall be sterilized by heat, chemical sterilant(s) or other appropriate treatment before use and resterilized whenever it has been contaminated by non-sterile product.

For milk plants that dry milk or milk products, higher temperatures and longer periods may be necessary for the sanitization of high-pressure lines. It has been demonstrated that alkaline cleaners at 72ºC (160ºF) for thirty minutes, followed by an acid cleaner for thirty minutes at the same temperature, produce satisfactory results. Studies have indicated that effective sanitization of the dryer may be accomplished by the following procedure:

i. Operate the spray nozzles with water at a temperature and rates at least as high as those employed during the drying operation.

ii. Adjust airflow to give at least 0.5 inch (water) pressure in the drying chamber.

iii. Continue the operation for twenty minutes while a temperature of not less than 85ºC (185ºF) is being registered at the discharge from the dryer.

Portions of the drying system not reached by this treatment or dryers in which this procedure is not practical shall be treated by one of the methods prescribed above, or by other methods of demonstrated effectiveness.

(6) (a) The residual bacteria count of multi-use containers and closures for packaging pasteurized milk and milk products shall be conducted as outlined in Appendix J of the PMO. The residual bacteria count of multi-use containers, used for packaging pasteurized milk and milk products, shall not exceed one colony per milliliter (1/mL) of capacity, when the rinse test is used, or fifty colonies per fifty square centimeters (one colony per square centimeter) of product-contact surface, when the swab test is used, in three out of four samples taken at random on a given day. Coliform organisms shall be undetectable in all multi-use containers.

(b) The residual bacteria count of single-service containers and closures, used for packaging pasteurized milk and milk products, shall not exceed fifty colonies per container, or in the case of dry product packaging, shall not exceed one colony per milliliter (1/mL) of capacity when the rinse test is used, except that in containers less than 100 mL the count shall not exceed ten colonies or fifty colonies per eight square inches (one colony per square centimeter) of product-contact surface, when the swab test is used, in three out of four samples taken at random on a given day. Coliform organisms shall be undetectable in all single-service containers.

When single-service containers or closures are fabricated in another plant which conforms to the standards of Appendix J of the PMO, and DHEC has information that they do comply, DHEC may accept the containers as being in conformance without additional tests. If there is reason to believe that containers do not conform to the bacteriological standards, additional tests may be required. If containers are fabricated in the milk plant, DHEC shall collect during any consecutive six months, at least four sample sets of containers, as defined in Appendix J. of the PMO, from each manufacturing line, as defined in Appendix J. of the PMO, in at least four separate months, except when three months show a month containing two sampling dates separated by at least twenty days, and analyze the sample sets at an Official, Commercial or Industry Laboratory, approved by DHEC specifically for the examinations required under Appendix J. of the PMO.

(7) Milk plants which utilize multi-use plastic containers for pasteurized milk and milk products shall comply with the following criteria:

(a) All containers shall be identified as to plant of manufacture, date of manufacture, and type and class of plastic material used. This information may be by code: Provided, that the code is revealed to DHEC.

(b) A device shall be installed in the filling line capable of detecting in each container before it is filled, volatile organic contaminants in amounts that are of public health significance. Such device must be constructed so that it may be sealed by DHEC to prevent the changing of its sensitivity functioning level. Models using an air injection system and with a testing device built into the detection equipment do not have to be sealed. To assure proper functioning of the system the operator needs to be able to adjust the sensitivity. However, those models utilizing an external testing device must be sealed. Any container detected by the device as being unsatisfactory must be automatically made unusable to prevent refilling. In addition, the device must be interconnected so that the system will not operate unless the detecting device is in proper operating condition. Provided, that any other system so designed and operated that will provide equal assurance of freedom from contamination and recognized by the Food and Drug Administration to be equally efficient may be accepted by DHEC.

When other systems are used in place of a device for the detection of volatile organic contaminants, the following criteria has been developed to determine what constitutes equal assurance:

i. A soaker-type washer shall be used for cleaning and sanitizing the containers and shall conform with the following criteria:

aa. If caustic is used, the caustic strength for a given washing time and temperature shall be as specified in Table 2 of this item; or

bb. If a cleaning compound, other than caustic is used, the compound shall be a mild or moderately alkaline, granular composition formulated from a blend of sodium phosphate and anionic synthetic detergents and conform to the following:

(i) The used solution shall have at least a 3 percent concentration with a pH of at least 11.9 and an alkalinity expressed as sodium oxide of at least 2.5 percent;

(ii) There shall be at least a two minute soak time in the soaker tank;

(iii) The temperature of the soaker tank shall be at least 69ºC (155ºF); and

(iv) The final rinse subsequent to the soaking tank shall be with a sanitizing solution.

ii. The soaker-type washer system shall be so designed and operated that unless the time, temperature and concentration, as specified for the soaker solutions, are met, the containers cannot be discharged from the washer. The mechanism for control of the time, temperature and concentration of the use solution shall be sealed.

iii. A thorough inspection procedure shall be in effect to remove any containers, which show stress cracks, splitting, pitting, discoloration, or cloudiness, as well as any unremoved soil. This must be carried out with adequate light and be much more thorough than the customary cursory inspection given to glass bottles.

iv. A standard must be available for use of DHEC for testing the proper sensitivity functioning levels of the detection device.

v. The containers shall comply with the applicable construction requirements of Section VII.C.11. of this Regulation. The closure for the container shall be single-service. Screw-type closures shall not be used.

vi. The container shall not impart into the product pesticide residual levels or other chemical contaminants in excess of those considered acceptable under the Federal Food, Drug and Cosmetic Act, and regulations issued thereunder.

vii. The phrase "Use only for food" shall appear on all containers.

13. Storage of Cleaned Containers and Equipment

a. General - After cleaning, all multi-use milk or milk product containers, utensils, and equipment shall be transported and stored to assure complete drainage, and shall be protected from contamination before use.

b. Administrative Procedures - This item is deemed to be satisfied when:

(1) All multi-use containers, equipment and utensils, after cleaning are transported and/or stored on racks made of food grade materials or in clean cases elevated above the floor. Containers shall be stored inverted, if practical, on racks or in cases constructed of relatively nonabsorbent, corrosion-resistant, nontoxic materials, or otherwise protected from contamination.

(2) Floors are not flushed or washed when crates of clean bottles are stacked on them.

14. Storage Of Single-Service Containers, Utensils And Materials

a. General - Single-service caps, cap stock, parchment paper, containers, gaskets, liners, bags, and other single-service articles for use in contact with milk and milk products shall be purchased and stored in sanitary tubes, wrappings, or cartons; shall be kept therein in a clean, dry place until used; and shall be handled in a sanitary manner.

b. Administrative Procedures - This item is deemed to be satisfied when:

(1) Single-service caps, cap stock, parchment paper, containers, gaskets, liners, bags, and other single-service articles for use in contact with milk and milk products are purchased and stored in sanitary tubes, wrappings, or cartons; are kept in a clean, dry place until used; and are handled in a sanitary manner.

(2) Paperboard shipping containers used to enclose plastic bags or unfilled containers are used only once unless other methods are employed to protect the containers from contamination.

(3) Tubes or cartons are not refilled with spilled caps, gaskets, or parchment papers.

(4) Cartons or boxes from which contents have been partially removed are kept closed.

(5) Suitable cabinets are provided for storage of tubes after removal from the large outer box, and for storage of opened cartons, unless other satisfactory means are employed to protect the caps, closures, or containers.

15. Protection From Contamination

a. General - Milk plant operations, equipment, and facilities shall be located and conducted to prevent any contamination of milk or milk products, ingredients, equipment, containers, and utensils. All milk or milk products or ingredients which have been spilled, overflowed, or leaked shall be discarded. The processing or handling of products other than milk or milk products in the pasteurization plant shall be performed to preclude the contamination of such Grade "A" milk and milk products. The storage, handling, and use of poisonous or toxic materials shall be performed to preclude the contamination of milk and milk products or ingredients of such milk and milk products or the product-contact surfaces of all equipment, containers or utensils.

b. Administrative Procedures - This item is deemed to be satisfied when:

(1) Equipment and operations are so located within the plant as to prevent overcrowding and contamination of cleaned and sanitized containers, equipment, and utensils by splash, condensation, or manual contact.

(2) Packaged milk and milk products which have physically left the premises or the processing milk plant are not re-pasteurized for Grade "A" use. DHEC may, on a specific individual request, authorize reprocessing of packaged milk and milk products, provided all other aspects of this item, including proper storage temperature and container integrity are complied with. Provided, that the re-pasteurization of milk and milk products shipped in milk tank trucks which have been pasteurized at another Grade "A" milk plant and have been handled in a sanitary manner and maintained at 7ºC (45ºF) or less is permitted. Equipment, designated

areas or rooms utilized for storage, processing, and handling of returned packaged milk and milk products are maintained, operated, cleaned, and sanitized so as to preclude contamination of Grade "A" products and equipment and the Grade "A" operations.

(3) All product-contact surfaces of containers, equipment, and utensils are covered or otherwise protected to prevent the access of insects, dust, condensation, and other contamination. All openings, including valves and piping attached to milk and milk product storage tanks and milk tank trucks, pumps, or vats, etc., shall be capped or otherwise properly protected. While unloading at a receiving station, transfer station, or milk plant, one of the following conditions shall be met:

(a) If the area is completely enclosed (walls and ceiling, with doors closed) during the unloading process and the dust-cover or dome and the manhole cover is opened slightly and held in this position by the metal clamps used to close the cover, then a filter is not required. However, if the dust-cover and/or manhole cover(s) are opened in excess of that provided by the metal clamps or the covers have been removed, then a suitable filter is required for the manhole.

(b) If the area is not completely enclosed or doors of the unloading area are open during unloading, a suitable filter is required for the manhole or air inlet vent and suitable protection must be provided over the filter material either by design of the filter holding apparatus or a roof or ceiling over the area. When weather and environmental conditions permit, manhole openings and covers of milk tank trucks may be opened outdoors for the short period of time necessary for the collection of samples for animal drug residue screening. Direct connections from milk tank truck to milk tank truck must be made from valve to valve or through the manhole lid: Provided, that all connections are made ferrule to ferrule and adequate protection is provided for the air vent.

Receiving and dump vats shall be completely covered, except during washing and sanitizing, and when milk is being dumped. Where strainers are used, the cover for the vat opening shall be designed to cover the opening with the strainer in place.

(4) Whenever air under pressure is used for the agitation or movement of milk, or is directed at a milk or milk product contact surface, it is free of oil, dust, rust, excessive moisture, extraneous materials, and odor, and shall otherwise comply with the applicable standards of Appendix H of the PMO. Air intakes for drying equipment shall be located so as to minimize the amount of atmospheric contamination and shall be equipped with suitable single-service filters, multi-use filters, or continuous air filter systems. (Refer to Appendix H. of the PMO). The use of steam containing toxic substances is expressly prohibited. Whenever steam is used in contact with milk or milk products, it shall be of culinary quality and shall comply with the applicable standards of Appendix H. of the PMO.

(5) Standardization is done before the pasteurization process is started, unless pasteurized milk or milk products are used for standardization. Such pasteurized milk products shall be protected against contamination. In no case shall pasteurized milk or milk products be standardized with unpasteurized milk unless the standardized product is subsequently pasteurized. Reconstituted or recombined milk and milk products shall be pasteurized after reconstitution or recombining of all ingredients. Standardization of Grade A milk and milk products with other than Grade A milk and milk products is prohibited. This Regulation permits standardization as a process of adjusting the milkfat of milk in a milk plant by the addition or removal of cream or non-fat (skim) milk.

(6) All multi-use cases used to encase packaged milk and milk product containers are cleaned prior to their use.

(7) All ingredients and non-product-contact materials used in the preparation or packaging of milk and milk products are stored in a clean place and are so handled as to prevent their contamination.

(8) Pasteurized milk and milk products are not strained or filtered except through a perforated metal strainer.

(9) Only those poisonous or toxic materials, including but not limited to insecticides, rodenticides, detergents, sanitizers, caustics, acids, and related cleaning compounds, and medicinal agents necessary for the maintenance of the milk plant are present in the milk plant.

(10) Those poisonous or toxic materials that are necessary are not stored in any room where milk or milk products are received, processed, pasteurized, condensed, dried, or stored, or where equipment, containers or utensils are washed or where single-service containers, closures, bags, or caps are stored.

(11) Those poisonous or toxic materials that are necessary are stored in a separate area of the plant in prominently and distinctly labeled containers: Provided, that this does not preclude the convenient availability of detergents or sanitizers to areas where equipment, containers, and utensils are washed and sanitized.

(12) Only insecticides and rodenticides approved by DHEC and/or registered with the U.S. Environmental Protection Agency shall be used for insect and rodent control. Such insecticides and rodenticides shall be used only in accordance with the manufacturer's label directions and shall be prevented from contaminating milk, containers, equipment, and utensils.

(13) Air exhausts from dryer systems are covered when dryers are not in operation.

(14) In the case of separating non-Grade “A” and Grade “A” milk or milk products, a water rinse after processing non-Grade “A” and prior to Grade “A” is adequate separation, provided both are processed as Grade “A”, and raw and pasteurized milk or milk products are kept physically separated.

(15) Grade "A" raw milk or milk products and non-Grade “A” raw products, dairy or non-dairy, shall be separated by one valve.

(16) Grade “A” pasteurized milk or milk products and non-Grade "A" pasteurized products, dairy or non-dairy, shall be separated by one valve.

(17) Provided, that during the actual flushing of raw milk or milk product lines and vessels with water, there shall be a sufficient separation between water piping and unpasteurized milk or milk products, or lines used to conduct unpasteurized milk or milk products, to prevent the accidental addition of water.

(18) Two grades of milk or milk products are received in the same milk plant in dual receiving equipment, a swing type dump grill is not permitted. When two grades of milk or milk products are received in the milk plant by milk tank trucks, separate receiving equipment and unloading pumps shall be provided.

(19) During processing, pipelines and equipment used to contain or conduct milk and milk products shall be effectively separated from tanks or circuits containing cleaning and/or sanitizing solutions. This can be accomplished by:

(a) Physically disconnecting all connection points between tanks or circuits containing cleaning and/or sanitizing solutions from pipelines and equipment used to contain or conduct milk or milk products; or

(b) Separation of all connection points between such circuits by at least two automatically controlled valves with a drainable opening to the atmosphere between the valves; or by a single-bodied double seat valve, with a drainable opening to the atmosphere between the seats, if:

i. The opening to the atmosphere (vent) is equal to the largest pipeline feeding the valve(s).

ii. Both valves, and valve seats in the case of single-bodied double seat valves, are position detectable and capable of providing an electronic signal when not properly seated in the blocked position.

iii. These valves, or valve seats in the case of single-bodied double seat valves, are part of an automatic fail-safe system that will prevent contamination of product with cleaning or sanitizing solutions. Automatic fail-safe systems will be unique to each particular installation but are normally based on the premise that both blocking valve seats are properly seated in the blocked position before the mechanical cleaning system can be activated for the cleaning circuit containing this valve arrangement.

iv. The system does not have any manual overrides.

v. Controls for the fail-safe system are secured as directed by DHEC in order to prevent unauthorized changes.

vi. The vent is not cleaned until milk and milk products have been removed or isolated.

vii. Variations from the above specifications may be individually evaluated and found to also be acceptable if the level of protection is not compromised.

FOR EXAMPLE: In low pressure, gravity drain applications where the product line is the same size or larger than the cleaning or sanitizing solution line, the vent may be the size of the solution line and the valves or valve seats need not be position detectable. If a common drain line is used to connect vent lines from more than one block-and-bleed vent, such as in the case of drain lines from a series of cheese vats with a common drain for the block-and-bleed vent lines, the cross sectional area of the common drain line must be at least equal to the total cross sectional area of the lines connected to the header. Or, a common drain line of the same size as the vent may be used, if provisions are included in a fail-safe control system to sequence the use and cleaning of the vats to assure that no more than one vat attached to that drain can be washed at the same time. All other criteria still apply. In order to accept this variation, the valve(s) must fail to the blocked position upon loss of air or power, and there must be no pumps capable of pushing milk or milk product, cleaning solutions, or sanitizing solutions into this valve arrangement.

(c) In the case of aseptically processed and higher-heat-shorter-time (HHST) pasteurized milk and milk products that are processed and the equipment cleaned and/or chemically sanitized above the atmospheric boiling point of the milk or milk product or cleaning and/or sanitizing solutions, the required separation between pipe lines and equipment, used to contain or conduct milk and milk products, and tanks or circuits containing cleaning and/or chemical sanitizing solutions, may be accomplished using an alarmed steam block(s), located between the milk and milk product and cleaning and/or chemical sanitizing solutions if:

i. The steam block is equipped with a visible steam trace that exits at the bottom of the steam block;

ii. The steam trace is equipped with a temperature sensor that is capable of differentiating between those temperatures that indicate steam exiting the steam trace has not been exposed to liquid in the steam block and temperatures that will occur when liquid is present in the steam block;

iii. This steam trace shall be physically isolated from other steam lines or traces such that the temperature sensor measures the steam temperature only from that single trace;

iv. The temperature sensor is integrated with automatic controls, such that when there is milk or milk products on one side of the steam block and cleaning and/or chemical sanitizing solutions on the other side of the steam block, and the temperature sensor in the steam trace detects a temperature that indicates that liquid, rather than steam, is present in the steam trace, the cleaning pump will be de-energized, and when

needed to prevent solution pressure on the steam block, the cleaning and/or chemical sanitizing solution are automatically drained away from the steam block. Except that:

aa. In systems where the cleaning and/or sanitizing solution is circulated by the timing pump, that pump may continue to operate during an alarmed condition, provided a legal flow-diversion device (FDD) is used to divert the cleaning and/or chemical sanitizing solution flow away from the steam block.

bb. In aseptic processing systems that are not equipped with a legal FDD and where the cleaning and/or sanitizing solution is circulated by the timing pump of the aseptic processing system, that pump may continue to operate during an alarmed condition, provided there are at least two instrumented steam blocks between the milk and milk product and the cleaning and/or chemical sanitizing solutions and at least one of the blocks remains uncompromised.

v. During times when a steam block(s) is used as described in this Section to provide separation between pipelines and equipment, used to contain or conduct milk and milk products, and tanks or circuits containing cleaning and/or chemical sanitizing solutions, there shall be no time delays or other means that delay an immediate automatic response to liquid exiting the steam trace; and

vi. Although the automatic control system is not required to comply with Appendix H. V., Criteria for the Evaluation of Computerized Systems for Grade "A" Public Health Controls of the PMO, there shall be means provided to test and verify the accuracy of the sensor and the operation of the control system.

In order to facilitate testing, the temperature set point that will activate the automatic controls, described in this Section, will be identified for each steam block used for this purpose. Means shall be provided to verify that lowering the temperature below this set point will activate the control system when a steam block(s) is used, as described in this Section, to provide separation between pipelines and equipment, used to contain or conduct milk and milk products, and tanks or circuits containing cleaning and/or chemical sanitizing solutions.

NOTE: The valve arrangement(s) described in this Section shall not be used to separate raw products, dairy, non-dairy or water, from pasteurized milk or milk products. Provided that, nothing in this Section shall be construed as barring any other means to separate milk and milk product from cleaning/sanitizing solution in HHST and Aseptic Processing Systems, which have been recognized by FDA and in the case of aseptic processing equipment, by the Processing Authority, to be equally effective and which are approved by DHEC.

(20) Except as permitted in Section VII.C.16, there shall be no physical connection between unpasteurized products, dairy, non-dairy, or water, and pasteurized milk or milk products. Pasteurized non-dairy products or water not completely separated from pasteurized milk and milk products, shall be pasteurized at times and temperatures which meet at least the minimum times and temperatures provided for in Section I, Definition 48 or in the case of water have undergone an equivalent process found acceptable by FDA and DHEC or has undergone a hazard evaluation and safety assessment of the specific water supply and application involved and has been treated, as necessary, following a protocol acceptable to DHEC, in consultation with FDA, to ensure the water will not compromise the safety of the milk or milk product.

NOTE: This section does not require separate raw and pasteurized mechanical cleaning systems.

(21) Pasteurized re-circulation lines, divert lines, and leak-detect lines connecting to the constant-level tank shall be designed so that there is an air gap between the termination of these pipelines and the raw milk or milk product overflow level. This air gap must be equivalent to at least two times the diameter of the largest of these pipelines. For purposes of this Section, an overflow is defined as the flood rim of the constant-level tank or any unrestricted opening below the flood rim of the constant-level tank which is large enough that it is at least equivalent to two times the diameter of the largest of these pipelines.

(22) All milk and milk products which have overflowed, leaked, been spilled, or improperly handled are discarded. Milk and milk products drained from processing equipment at the end of a run, collected from a defoamer system, and milk and milk product solids rinsed from equipment, containers, or pipelines shall be re-pasteurized only if such milk and milk products are handled in a sanitary manner and maintained at 7ºC (45ºF) or less. When the handling and/or cooling of such milk and milk products are not in compliance with this requirement, they shall be discarded. Milk and milk products from damaged, punctured, or otherwise contaminated containers or product from out of code containers shall not be re-pasteurized for Grade "A" use.

(23) Means are provided to prevent contamination of milk and milk product containers, utensils, and equipment by drippings, spillage, and splash from overhead piping, platforms, or mezzanines.

(24) The processing of foods and/or drinks other than Grade "A" milk and milk products are performed to preclude the contamination of such milk and milk products.

(25) No product is handled in the milk plant that may create a public health hazard. Permission to handle products other than those defined in Section I. or to conduct operations in equipment or rooms, other than those for which they are designated, should be provisional and subject to revocation if found objectionable.

(26) In no case shall pasteurized milk or milk products, be standardized with unpasteurized milk or milk products, unless the standardized milk or milk product is subsequently pasteurized.

(27) Reconstituted or recombined milk and milk products shall be pasteurized after reconstitution or recombining of all ingredients.

16. Pasteurization - Aseptic Processing

a. General - Pasteurization shall be performed as defined in Section I, of this Regulation. Aseptic processing shall be performed in accordance with 21 CFR 113 and 21 CFR 108 and the Administrative Procedures of Section VII.C.16.e.,16.f., and 16.g.

In all cases, except for the specific exemptions provided for in b.(2) ADMINISTRATIVE PROCEDURES, pasteurization of raw milk or milk product shall be performed before the raw milk or milk product enters the reverse osmosis (RO), ultra-filtration (UF), evaporator or condensing equipment and shall be performed in the milk plant where the processing is done. All condensed milk and milk products transported to a milk plant for drying shall be re-pasteurized at the milk plant at which it is dried. If condensed whey containing at least forty percent total solids, has been partially crystallized by cooling, it may be transported to a separate milk plant for drying without re-pasteurization, provided the following conditions are complied with:

(1) The condensed, partially crystallized whey is cooled and maintained at 7^{o}C (45^{o}F) or less.

(2) Milk tank trucks, dedicated to hauling pasteurized product, shall be used to transport the condensed, partially crystallized whey and shall be washed and sanitized immediately prior to filling and then sealed after filling until unloading.

(3) Separate unloading pumps and pipelines shall be provided and used only for the unloading of the condensed, partially crystallized whey. Such pumps and pipelines shall be cleaned and sanitized as a separate cleaning circuit.

b. Administrative Procedures - The pasteurization portion of this item is deemed to be satisfied when:

(1) Every particle of milk or milk product is heated in properly designed and operated equipment that meets the requirements of this item and Appendix H of the PMO to one of the temperatures specified in the following table and held continuously at or above that temperature for at least the time specified:

Table 3. Pasteurization Temperature vs. Time	
Temperature	Time
63°C (145°F)*	30 minutes
72°C (161°F)*	15 seconds
89°C (191°F)	1.0 seconds
90°C (194°F)	0.5 seconds
94°C (201°F)	0.1 seconds
96°C (204°F)	0.05 seconds
100°C (212°F)	0.01 seconds

*If the fat content of the milk product is 10 percent or more, or if it contains added sweeteners, or is concentrated (condensed), the specific temperature shall be increased by 3°C (5°F). Provided, that eggnog shall be heated to at least the following temperature and time specifications:

69ºC (155ºF)	30 minutes
80ºC (175ºF)	25 seconds
83ºC (180ºF)	15 seconds

Provided further, that nothing shall be construed as barring any other pasteurization process which has been recognized by the Food and Drug Administration to be equally efficient and which is approved by DHEC.

(2) All milk and milk products shall be pasteurized, prior to the entrance into Reverse Osmosis (RO), Ultra-Filtration (UF), evaporator or condensing equipment, and shall be performed in the milk plant where the processing is done, except that:

(a) If the product is whey, pasteurization is not required, provided:

i. The product is acid whey (pH less than 4.7); or

ii. It is processed in RO or UF equipment at temperatures at or below 7^{o}C (45^{o}F).

(b) If the product is raw milk for pasteurization, the product may be concentrated by the use of RO or UF membrane filtration without pasteurization, prior to entrance into the equipment, provided the following sampling, testing, design, installation and operational criteria are met:

i. Prior to processing, all raw milk supplies are sampled and tested for antibiotic residues in accordance with the provisions of Appendix N. of the PMO;

ii. The RO or UF filtration system is designed and operated to assure that milk or milk product temperature is maintained at or below 7°C (45°F) throughout the process;

iii. The RO or UF system must be equipped with temperature monitoring and recording devices that comply with the applicable specifications outlined in Appendix H. of the PMO. At a minimum, milk or milk product temperature shall be monitored and recorded prior to entering the system, prior to entering each stage of the modules in series that contains cooling, and prior to any final cooler; and

iv. If the RO or UF system is not designed, installed and operated in accordance with the above noted criteria, the raw milk or milk product must be pasteurized prior to entering the RO or UF system.

(3) All condensed milk and milk products transported to a milk plant for drying shall be re-pasteurized at the milk plant where it is dried.

(4) If condensed whey containing at least forty percent total solids, has been partially crystallized by cooling, it may be transported to a separate milk plant for drying without re-pasteurization, provided the following conditions are complied with:

(a) The condensed, partially crystallized whey is cooled and maintained at 7^{o}C (45^{o}F) or less.

(b) Milk tank trucks used to transport the condensed, partially crystallized whey, shall be washed and sanitized immediately prior to filling and are sealed after filling until unloading.

(c) Separate unloading pumps and pipelines shall be provided and used only for the unloading of the condensed, partially crystallized whey. Such pumps and pipelines shall be cleaned and sanitized as a separate cleaning circuit.

(5) The design and the operation of pasteurization equipment and all appurtenances thereto comply with the applicable specifications and operational procedures of subsections c., d., f. and g.

c. Batch Pasteurization

(1). General - All indicating and recording thermometer used in connection with the batch pasteurization of milk or milk products shall comply with the applicable specifications set forth in Appendix H. of the PMO. Specifications for test thermometers and other test equipment appear in Appendix I of the PMO.

(2). Administrative Procedures

(a) Time And Temperature Controls For Batch Pasteurizers

i. Temperature Difference - The pasteurizer shall be so designed that the simultaneous temperature difference between the milk or milk product at the center of the coldest milk or milk product in the vat will not exceed 0.5°C (1°F) at any time during the holding period. The vat shall be provided with adequate agitation, operating throughout the holding period. No batch of milk or milk product shall be pasteurized unless it covers a sufficient area of the agitator to insure adequate agitation.

ii. Location and Required Readings of Indicating and Recording Thermometers - Each batch pasteurizer shall be equipped with both an indicating and a recording thermometer. The thermometer shall read not less than the required pasteurization temperature throughout the required holding period. The milk plant operator shall check the temperature shown by the recording thermometer against the temperature shown by the indicating thermometer at the start of the holding period; this comparison shall be noted on the recording

thermometer chart. The recording thermometer shall not read higher than the indicating thermometer. No batch of milk or milk products shall be pasteurized unless it is sufficient to cover the bulbs of both the indicating and the recording thermometer.

iii. Assurance of Minimum Holding Periods - Batch pasteurizers shall be so operated that every particle of milk or milk product will be held at not less than the minimum pasteurization temperature continuously for at least thirty minutes. When milk or milk products are raised to pasteurization temperature in the vat, and cooling is begun in the vat, simultaneously with or before the opening of the outlet valve, the recorder chart shall show at least thirty minutes at not less than minimum pasteurization temperature. When milk or milk products are preheated to pasteurization temperature before entering the vat, the recorder chart shall show a holding period of at least thirty minutes at not less than the minimum pasteurization temperature plus the time of filling from the level of the recorder thermometer bulb. When cooling is begun in the batch pasteurizer after the opening of the outlet valve, or is done entirely outside the batch pasteurizer, the recording chart shall show at least thirty minutes at not less than the minimum pasteurization temperature plus the time of emptying to the level of the recording-thermometer bulb.

When the recorder time interval on the recorder chart at the pasteurization temperature includes filling and/or emptying time, such intervals shall be indicated on the recorder chart by the operator, by removing the recording-thermometer bulb from the milk or milk product for a sufficient time to depress the pen, or by turning cold water into the vat jacket at the end of the holding period, or by inscribing the holding time on the chart. The filling time and the emptying time for each holder so operated shall be determined by DHEC, initially and after any change which may affect these times.

No milk shall be added to the batch pasteurizer after the start of the holding period.

(b) Airspace Heating

i. Means shall be provided and used in batch pasteurizers to keep the atmosphere above the milk and milk products at a temperature not less than 3°C (5°F) higher than the minimum required temperature of pasteurization during the holding period (Refer to Appendix H. of the PMO),

ii. Each batch pasteurizer shall be equipped with an airspace thermometer. The surface of the milk or milk product shall be at least twenty-five millimeters (one inch) below the bottom of the thermometer bulb when the vat is in operation.

iii. The temperature shown by the airspace thermometer shall be recorded on the recording thermometer chart at the start of the holding period and at the end of the holding period, at a given time or reference point as indicated on the recording chart.

(c) Inlet and Outlet Valves and Connections: - The following definitions shall apply to inlet and outlet valves and connections:

i. "Valve stop" shall mean a guide which permits turning the valve plug to, but not beyond, the fully closed position.

ii. "Valve with an irreversible plug" shall mean one in which the plug cannot be reversed in the shell.

iii. "The fully open position" shall mean that position of the valve seat which permits the maximum flow into or out of the pasteurizer.

iv. "The closed position" shall mean any position of the valve seat which stops the flow of milk or milk product into or out of the pasteurizer.

v. "The fully closed position" shall mean that closed position of the valve seat which requires the maximum movement of the valve to reach the fully open position.

vi. "The just-closed position" shall mean that closed position of a plug-type valve in which the flow into or out of the holder is barely stopped, or any position within two millimeters (0.078 inch) thereof as measured along the maximum circumference of the valve seat.

vii. "Leakage" shall mean the entrance of unpasteurized milk or milk product into a batch pasteurizer during the holding or emptying period, or the entrance of unpasteurized milk into any pasteurized milk or milk product line at any time.

viii. "Leak-protector valve" shall mean a valve provided with a leak-diverting device, which, when the valve is in any closed position, will prevent leakage of milk past the valve or, in the case of batch pasteurizers filled or emptied by suction or compressed air, will prevent leakage of milk past the valve or, the leakage of milk due to the leakage of air past the suction valve or the compressed air valve, as the case may be.

ix. "Closed-coupled valve" shall mean a valve, the seat of which is either flush with the inner wall of the pasteurizer or so closely coupled that no milk in the valve inlet is more than 0.5°C (1°F) colder than the milk or milk product at the center of the pasteurizer at any time during the holding period. A closed-coupled valve which is not truly flush, shall be considered as satisfying this requirement when:

aa. The vat outlet is so flared that the smallest diameter of the large end of the flare is not less than the diameter of the outlet line, plus the depth of the flare; and

bb. The greatest distance from the valve seat to the small end of the flare is not greater than the diameter of the outlet line; and

cc. In the case of batch pasteurizers, the outlet and the agitator are so placed as to insure that milk or milk product currents will be swept into the outlet.

(d) Design and Installation Of Valves and Connections: All valves and connections shall comply with the following requirements:

i. Valves and pipeline connections shall meet the requirements of Section VII.C.10.

ii. All pipelines and fittings shall be so constructed and so located that leakage will not occur. Dependence shall not be placed on soldered joints to prevent leakage.

iii. To prevent clogging, and to promote drainage, all leak-protection grooves shall be at least five millimeters (0.187 inch wide), and at least 2.3 millimeters (0.094 inch) deep at the center. Mating grooves shall provide these dimensions throughout their combined length whenever the valve is in, or approximately in, the fully closed position. All single-leak grooves, and all mating leak grooves when mated, shall extend throughout the entire depth of the seat, so as to divert leakage occurring at all points throughout the depth of the seat, and so as to prevent air binding. Washers or other parts shall not obstruct leak-protector grooves.

iv. A stop shall be provided on all plug-type outlet valves s in order to guide the operator in closing the valve so that unpasteurized milk or milk product may not inadvertently be permitted to enter the outlet line. The stop shall be so designed that the plug will be irreversible when the plug is provided with any grooves or their equivalent, unless duplicate, diametrically opposite grooves are also provided. Stops shall be so designed that the operator cannot turn the valve beyond the stop position, either by raising the plug or by any other means.

v. Outlet valves, in addition to the requirements listed above, shall be so designed as to prevent the accumulation of unpasteurized milk or milk product in the milk or milk product passages of the valve when the valve is in any closed position.

vi. All outlets from vat pasteurizers shall be equipped with close-coupled leak-protector valves or be otherwise similarly protected during the filling, holding and emptying periods.

vii. All leak-protector grooved outlet valves shall be installed in the proper position to insure the function of the leak protector grooves and the drainage of the leak-detector valve.

viii. All outlet valves shall be kept fully closed during filling, heating, and holding periods.

ix. Close-coupled vat pasteurizer outlet valve bodies and plugs shall be made of stainless steel or of other materials that have heat transfer properties at least equal to stainless steel.

x. All inlet pipelines are disconnected during the holding and emptying periods.

(e) Recording Charts - All recording thermometer charts shall comply with all the applicable requirements of Section VII.C.16.g.

d. High Temperature-Short-Time (HTST) Continuous-Flow Pasteurization

(1) Administrative Procedures

(a) Indicating Thermometer and Recorder/Controller Instruments - All indicating thermometer and recorder/controller instruments and devices used in connection with the high-temperature-short-time continuous-flow pasteurization of milk or milk products shall comply with the applicable specifications set forth in Appendix H. of the PMO.

(b) Automatic Milk Controller - Each high-temperature-short-time continuous-flow pasteurization system shall be equipped with an automatic milk-flow control of the diversion type, which complies with the following definition, specifications, and performance requirements:

i. "Automatic Milk or Milk Product-flow Controls - "The term "automatic milk or milk product-flow controls" shall mean those safety devices which control the flow of milk or milk products in relation to the temperature of the milk or milk products, or heating medium and/or pressure, vacuum, or other auxiliary equipment. Milk or milk product-flow controls shall not be considered as part of the temperature control equipment. Milk or milk product-flow controls shall be of the flow-diversion type which automatically cause the diversion of the milk in response to a sub-legal pasteurization temperature. At sublegal temperatures, flow-diversion devices return the milk to the raw milk side of the heating system continuously until legal pasteurization temperatures are obtained; at which time, the device restores forward flow through the pasteurizer.

ii. Flow-Diversion Devices - All flow-diversion devices used in continuous pasteurizers shall comply with the following or equally satisfactory specifications:

aa. The forward-flow of milk or milk product below the minimum pasteurization temperature shall be prevented by requiring the timing pump to be de-energized when the milk or milk product is below the pasteurization temperature and the valve is not in the fully diverted position; or by any other equally satisfactory means.

bb. When a packing gland is used to prevent leakage around the actuating stem, it shall be impossible to tighten the stem-packing nut to such an extent as to prevent the valve from assuming the fully-diverted position.

cc. A leak escape shall be installed on the forward-flow side of the valve seat. However, when back pressure is exerted on the forward-flow side of the valve seat, while the milk or milk product-flow is being diverted, the leak escape should lie between two valve seats, or between two portions of the same seat, one upstream and the other downstream from the leak escape. The leak escape shall be designed and installed to discharge all leakage to the outside, or to the constant-level tank through a line separate from the diversion line: Provided, that when leakage is discharged to the constant-level tank, a sight glass shall be installed in the leak escape line to provide a visual means of leak detection.

dd. The closure of the forward-flow seat shall be sufficiently tight so that leakage past it will not exceed the capacity of the leak escape device, as evidenced when the forward-flow line is disconnected; and, in order that proper seating may not be disturbed, the length of the connecting rod shall not be adjustable by the user.

ee. The flow-diversion device shall be so designed and installed that failure of the primary motivating power shall automatically divert the flow of milk or milk product.

ff. The flow-diversion device shall be located downstream from the holder. The flow-control sensor shall be located in the milk or milk product line not more than forty-six centimeters (eighteen inches) upstream from the flow-diversion device.

gg. The flow-diversion device may be located downstream from the regenerator and/or cooler section, provided, that when the flow-diversion device is located downstream from the regenerator and/or cooler section, the flow-diversion device shall be automatically prevented from assuming the forward-flow position until all product-contact surfaces between the holding tube and flow-diversion device have been held at or above the required pasteurization temperature continuously and simultaneously for at least the required pasteurization time as defined in Section I, Definition 48, of this Regulation.

hh. The pipeline from the diversion port of the flow-diversion device shall be self-draining, and shall be free of restrictions or valves, unless such restrictions or valves are so designed that stoppage of the diversion line cannot occur. In the case of HHST systems, which have the flow-diversion device located downstream from the regenerator and/or cooler and are inter-wired or are computer controlled to thoroughly clean the system, including the divert pipeline before the re-starting of production, a cooling section, which is not self-draining, may be present in the divert pipeline.

ii. When it is used, the pipeline from the leak detector port of the flow-diversion device shall be self-draining, and shall be free of restrictions or valves.

jj. For the timing pump, a one second maximum "off" time delay is allowed to maintain the flow-promoting device in the "on" position through the travel time of the flow-diversion device.

kk. If the area between the divert and leak-detect valve seats is not self-draining when the flow-diversion device is in the diverted position, a delay of at least one second and not more than five seconds is required between the movement of the divert and leak-detect valves when the flow-diversion device assumes the forward-flow position. Except that, the delay may be longer than five seconds if: the timing system is a magnetic flow meter based timing system; or if the holding time in diverted-flow through an unrestricted divert valve line is longer than the required pasteurization time as specified in Section I, Definition 48 of this Regulation; and except that, no time delay is required in pasteurization systems in which the flow-diversion device is located downstream from the pasteurized regenerator and in which all forward-flow product-contact surfaces of the flow-diversion device are sanitized, or sterilized during the normal start-up process.

ll. In the case of HHST pasteurizing systems utilizing temperatures and holding times to meet the ultra-pasteurization definition of this Regulation, the flow-diversion device may be located downstream of the regenerator and/or cooler section. Said flow-diversion device may alternatively be a system of the "Steam-Block Type" as described in Appendix H of the PMO. This flow-diversion device system shall allow for the flow of water and/or milk or milk product to the constant-level tank through appropriate valves and coolers during sterilization and when diverted.

iii. Milk or Milk Product-Flow Controller Instrumentation - The following requirements shall be met with respect to the instrumentation of the milk or milk product-flow controller:

aa. The thermal limit controller shall be set and sealed so that forward flow of milk or milk product cannot start unless the temperature at the controller sensor is above the required pasteurization temperature as defined in Section I, Definition 48 of this Regulation for the milk or milk product and the process used, nor continue during descending temperatures when the temperature is below the required pasteurization temperature. The seal shall be applied by DHEC after testing, and shall not be removed without immediately notifying DHEC. The system shall be so designed that no milk or milk product can be bypassed around the controller sensor which shall not be removed from its proper position during the pasteurization process. The cut-in and cut-out milk temperatures, as shown by the indicating thermometer, shall be determined at the beginning of each day's operation and entered upon the recorder chart daily by the plant operator.

bb. In the case of pasteurization systems, with the flow-diversion device located downstream from the regenerator and/or cooler section, additional temperature controllers and timers shall be inter-wired with the thermal limit controller, and the control system shall be set and sealed so that forward flow of milk or milk product cannot start until all product-contact surfaces between the holding tube and flow-diversion device have been held at or above the required pasteurization temperature, continuously and simultaneously for at least the required pasteurization time as defined in Section I, Definition 48 of this Regulation. The control system shall also be set and sealed so that forward flow cannot continue when the temperature of the milk or milk product in the holding tube is below the required pasteurization temperature. Provided, that for systems used for the processing of milk or milk products labeled as UP, it is not necessary to set and seal the thermal-limit-controller at or above 138ºC (280ºF). Also, provided that these systems shall meet all the public health control requirements for HHST systems, and that the recorder-controller chart shows that the UP milk or milk product has been processed at a minimum temperature of 138ºC (280ºF), and has been verified by DHEC to have a calculated holding time of at least two seconds. The seal, if required, shall be applied by DHEC after the equipment has been tested, and shall not be removed without immediately notifying DHEC. The system shall be so designed that no product can be bypassed around the control sensors, which shall not be removed from their proper position during the pasteurization process. For these HHST systems, daily measurement by the operator of the cut-in and cut-out temperatures is not required.

cc. Manual switches for the control of pumps, homogenizers, or other devices which produce flow through the holder, shall be wired so that the circuit is completed only when the milk or milk product is above the required pasteurization temperature as defined in Section I, Definition 48 of this Regulation for the milk or milk product and the process used, or when the flow-diversion device is in the fully-diverted position.

iv. Holding Tube

aa. Holding tubes shall be designed to provide for the holding of every particle of milk or milk product for at least the time required in Section I, Definition 48 of this Regulation for the milk or milk product and the process used.

bb. The holding tube shall be so designed that the simultaneous temperature difference between the hottest and coldest milk or milk product in any cross section of flow at any time during the holding period will not be greater than 0.5°C (l°F). This requirement may be assumed to have been satisfied without test in tubular

holders of 17.8 centimeters (seven inches) or smaller diameter which are free of any fittings through which the milk or milk product may not be thoroughly swept.

cc. No device shall be permitted for short circuiting a portion of the holding tube to compensate for changes in rate of milk or milk product-flow. Holding tubes shall be installed so that sections of pipe cannot be left out, resulting in a shortened holding time.

dd. The holding tube shall be arranged to have a continuously upward slope in the direction of flow of not less than 2.1 centimeters per meter (one-fourth inch per foot).

ee. Supports for tubes shall be provided to maintain all parts of holding tubes in a fixed position, free from any lateral or vertical movement.

ff. The holding tube shall be so designed that no portion between the inlet and the recorder-controller temperature sensor is heated.

The following items apply to HHST systems:

gg. The holding time for the HHST processes must be determined from the pumping rate rather than by salt conductivity test because of the short holding tube. The holding tube length must be such that the fastest flowing particle of any milk or milk product will not traverse the holding tube in less than required holding time. Since laminar flow (the fastest flowing particle travels twice as fast as the average flowing particle) can occur in the holding tube during pasteurization of high-viscosity milk or milk products, holding tube lengths are calculated as twice the length required to hold the average flow for the time standard.

hh. With the direct steam heating processes, the holding time is reduced because the milk or milk product volume increases as the steam condenses to water during heating in the injector. This surplus water is evaporated as the pasteurized milk or milk product is cooled in the vacuum chamber. For example, with a 66°C (120°F) increase by steam injection which is probably the maximum temperature rise that will be used, a volume increase of twelve percent will occur in the holding tube. The measurement of the average flow rate at the discharge of the pasteurizer does not reflect this volume increase in the holding tube. However, this volume increase, i.e., holding time decrease, must be considered in the calculations.

ii. For those HHST systems capable of operating with less that 518 kPa (75 psig) pressure in the holding tube, a pressure limit indicator/pressure switch must be interwired so that the FDD will move to the divert position if the milk or milk product pressure falls below a prescribed value. For operating temperatures between 89°C (191ºF) and 100ºC (212ºF) the instrument must be set at 69 kPa (10 psi). To prevent vaporization in the holding tube, which may substantially reduce residence times, HHST systems operating above 100°C (212ºF), the instrument must be set at 69 kPa (10 psi) above the boiling pressure of the product, at its maximum temperature in the holding tube.

jj. With the steam injection process a differential pressure limit indicator across the injector is needed to keep the heated milk or milk product in the liquid phase and to ensure adequate isolation of the injection chamber. The instrument must have a differential pressure switch so that the flow-diversion device will move to the divert position if the pressure drop across the injector falls below 69 kPa (ten psi).

v. Indicating and Recording Thermometer

aa. An indicating thermometer shall be located as near as practicable to the temperature sensor of the recorder/controller, but may be located a short distance upstream from the latter where milk or milk product between the two thermometers does not differ significantly in temperature.

bb. The temperature shown by the recorder/controller shall be checked daily by the plant operator against the temperature shown by the indicating thermometer. Readings shall be recorded on the chart. The recorder/controller shall be adjusted to read no higher than the indicating thermometer.

cc. The recorder/controller charts shall comply with the applicable provisions of Section VII.C.16.g.

vi. Flow-Promoting Devices

aa. The pump, or pumps, and other equipment which may produce flow through the holding tube shall be located upstream from the holding tube, provided that pumps and other flow-promoting devices may be located downstream from the holding tube if means are provided to eliminate negative pressure between the holding tube and the inlet to such equipment. When vacuum equipment is located downstream from the holding tube, an effective vacuum breaker, plus an automatic means of preventing a negative pressure in the line between the flow-diversion device and the vacuum chamber, shall be acceptable.

bb. The speed of pumps or other flow-promoting devices governing the rate of flow through the holding tube shall be so controlled as to insure the holding of every particle of milk for at least the time required as defined in Section I, Definition 48 of this Regulation for the milk or milk product and the process used. In all cases, the motor shall be connected to the timing pump by means of a common drive shaft, or by means of gears, pulleys, or a variable-speed drive, with the gear box, the pulley box, or the setting of the variable speed protected in such a manner that the holding time cannot be shortened without detection by DHEC. This shall be accomplished by the application of a suitable seal(s) after tests by DHEC and such seal shall not be broken without immediately notifying DHEC. This provision shall apply to all homogenizers used as timing pumps. Variable speed drives used in connection with the timing pump shall be so constructed that wearing or stretching of the belt results in a slowdown, rather than a speedup, of the pump. The metering or timing pump shall be of the positive displacement type or shall comply with the specifications for magnetic flow meter systems as outlined in Appendix H. of the PMO. Timing pumps and homogenizers, when used as a timing pump, shall not have by-pass lines connected from their outlet pipelines to their inlet pipelines during processing if an additional flow-promoting or vacuum producing device is located within the system. When a homogenizer is used in conjunction with a timing pump it shall be either:

(i) Of larger capacity than the timing pump: In which case an unrestricted, open, recirculation line shall be used to connect the outlet pipeline from the homogenizer to its inlet line. The recirculation line must be of at least the same or larger diameter than the inlet pipeline feeding milk or milk product to the homogenizer. A check valve, allowing flow from the outlet line to the inlet line, may be used in the recirculating line provided it is of the type which provides a cross-sectional area at least as large as the recirculating line.

(ii) Of smaller capacity than the timing pump: In which case a relief line and valve shall be used. Such relief line shall be located after the timing pump and before the inlet to the homogenizer and shall return milk or milk product to the constant-level tank or to the outlet of the constant-level tank upstream of any booster pump or other flow-promoting device.

For those systems which do not homogenize all products and wish to utilize a by-pass line to by-pass the homogenizer while processing such milk or milk product; the by-pass line must be connected with valves which are so designed that both lines cannot be open at the same time. This may be accomplished with three-way plug valves with properly designed and operating pins or other automatic, fail-safe valves which accomplish the same objective.

(iii) The holding time shall be taken to mean the flow time of the fastest particle of milk or milk product, at or above the required pasteurization temperature as defined in Section I, Definition 48 of this Regulation for the milk or milk product and the process used, throughout the holding tube section; i.e., that portion of the system that is outside of the influence of the heating medium, and slopes continuously upward in the downstream direction, and is located upstream from the flow-diversion device. Tests for holding time shall

be made when all equipment and devices are operated and adjusted to provide for maximum flow. When a homogenizer is located upstream from the holding tube, the holding time shall be determined with the homogenizer in operation with no pressure on the homogenizer valves. For those systems which do not homogenize all products and utilize by-pass lines as outlined in vi.bb.(i). above, the holding time shall be tested in both flow patterns and the fastest time used. The holding time shall be tested during both forward and diverted flow. If it is necessary to lengthen the holding time during diverted flow, an identifiable restriction may be placed in the vertical portion of the diversion pipeline. When vacuum equipment is located downstream from the holding tube, the holding time shall be tested with the timing pump operating at maximum flow, and the vacuum equipment adjusted to provide for the maximum vacuum. The holding time shall be tested in both forward and diverted flow by DHEC initially; semiannually thereafter; after any alteration or replacement that may affect the holding time; and whenever the seal of the speed setting has been broken.

vii. Heating by Direct Addition of Steam - Steam injection is an inherently unstable process; accordingly, when steam is injected into a fluid, condensation of the steam may not be completed inside the injector unless the proper design criteria are used. Lack of complete condensation inside the injector would cause temperature variations in the holding tube that could lead to some milk or milk product particles being processed below pasteurization temperature. When culinary steam is introduced directly into milk or milk products, as the means of terminal heating to achieve pasteurization temperature, the steam injector shall be designed, installed and operated to comply with the following or equally satisfactory specifications:

aa. The milk or milk product and steam flows must be isolated from pressure fluctuations inside the injection chamber. One method of isolation is to insert supplementary orifices on the milk or milk product inlet and the heated product outlet of each injector. The two supplementary orifices must be sized for at least a 69 kPa (ten psi) milk or milk product pressure drop across the injector during a simulation of normal operations. Excessive vibrations, pressure fluctuations, or erratic noise levels indicate an unstable steam injection system and a need to check the isolation of the injection chamber.

bb. The process should be as free as possible of non-condensable gases that may evolve from the product or be carried in the steam supply. Any two-phase flow caused by the noncondensable gases would displace the product in the holding tube, resulting in reduced residence times. In addition, these gases in the steam supply may also markedly alter the condensation mechanism at the point of injection. Accordingly, the steam boiler shall be supplied with a de-aerator. The de-aerator will aid in keeping the product in the holding tube as free as possible of non-condensable gases.

viii. Prevention of Milk and Milk Product Adulteration with Added Water

aa. When culinary steam is introduced directly into the milk or milk product downstream from the flow-diversion device, means shall be provided to preclude the addition of steam to the milk or milk product, unless the flow-diversion device is in the forward-flow position. This provision may be satisfied by the use of an automatic steam control valve with temperature sensor located downstream from the steam inlet, or by the use of an automatic solenoid valve installed in the steam line and so wired through the flow-diversion device controls that steam cannot flow unless the flow-diversion device is in the forward-flow position.

bb. When culinary steam is introduced directly into the milk or milk product, automatic means, i.e., stand-alone and/or PLC-based ratio control system shall be provided to maintain a proper temperature differential between incoming and outgoing milk or milk products to preclude dilution with water.

cc. Where a water feed line is connected to a vacuum condenser and the vacuum condenser is not separated from the vacuum chamber by a physical barrier, means shall be provided to preclude the backup and overflow of water from the vacuum condenser to the vacuum chamber. This provision may be satisfied by the use of a safety shutoff valve, located on the water feed line to the vacuum condenser, automatically actuated by a control which will shut off the in-flowing water, if for example, the condensate pump stops and the water level rises above a predetermined point in the vacuum condenser. This valve may be actuated by water, air, or

electricity, and shall be so designed that failure of the primary motivating power will automatically stop the flow of water into the vacuum condenser.

e. Aseptic Processing Systems

(1) Administrative Procedures - Aseptic Processing Systems - The aseptic processing portion of this item is deemed to be satisfied when the design and operation of aseptic processing systems comply with the applicable specifications and operational procedures of subitems e., f. and g. as follows: Provided, that nothing shall be construed as barring any other aseptic processing system which have been recognized by the Food and Drug Administration to be equally effective and which is approved by DHEC .

(a) Indicating Thermometers and Recorder/Controller Instruments - All indicating thermometers, recorder/controller instruments and devices used in connection with aseptic processing systems used for the aseptic processing of milk or milk products shall comply with the applicable specifications set forth in Appendix H. of the PMO

(b) Aseptic Processing Equipment

i. Temperature Indicating Device - Each aseptic processing system shall be equipped with at least one mercury-in-glass thermometer or an equivalent temperature-indicating device.

ii. Temperature Recorder-Controller - An accurate temperature recorder-controller shall be installed in the milk or milk product at the holding-tube outlet and before the inlet to the cooler or regenerator. The following requirements shall be met with respect to the instrumentation of the temperature recorder/controller:

aa. The temperature recorder/controller shall be set and sealed so that during milk or milk product processing the forward flow of product cannot start unless the temperature at the controller sensor is above the required temperature for the milk or milk product and the process used, nor continue during descending temperatures when the temperature is below the required temperature. The seal shall be applied by DHEC after testing, and shall not be removed without immediately notifying DHEC. The system shall be so designed that no milk or milk product can be bypassed around the controller sensor which shall not be removed from its proper position during the processing of aseptic milk and milk products.

bb. Additional temperature controllers and timers shall be interwired with the thermal limit controller, and the control system shall be set and sealed so that forward flow of milk or milk product cannot start until all product-contact surfaces between the holding tube and flow-diversion device have been held at or above the required sterilization temperature, continuously and simultaneously for at least the required sterilization time. The control system shall also be set and sealed so that forward flow cannot continue when the temperature of the milk or milk product in the holding tube is below the required temperature. The seal shall be applied by DHEC after test, and shall not be removed without immediately notifying DHEC. The system shall be so designed that no milk or milk product can be bypassed around the control sensors, which shall not be removed from their proper position during the processing of aseptic milk and milk products.

cc. Manual switches for the control of pumps, homogenizers, or other devices which produce flow through the holding tube, shall be wired so that the circuit is completed only when the milk or milk product is above the required temperature for the milk or milk product and the process used, or when the diversion device is in the fully-diverted position.

iii. Timing Pump

aa. A timing pump shall be located upstream from the holding tube and shall be operated to maintain the required rate of milk or milk product flow. The motor shall be connected to the timing pump by means of a common drive shaft, or by means of gears, pulleys, or a variable-speed drive, with the gear box, the pulley box, or the setting of the variable speed protected in such a manner that the hold time cannot be shortened without detection by DHEC. This shall be accomplished by the application of a suitable seal(s) after tests by DHEC and such seal shall not be broken without immediately notifying DHEC. The provision shall apply to all homogenizers used as timing pumps. Variable speed drives used in connection with the timing pump shall be so constructed that wearing or stretching of the belt results in a slowdown, rather than a speedup, of the pump. The metering or timing pump shall be of the positive displacement type or shall comply with the specifications for magnetic flow meter systems.

bb. The holding time shall be taken to mean the flow time of the fastest particle of milk or milk product throughout the holding tube section; i.e., that portion of the system that is outside of the influence of the heating medium, and slopes continuously upward in the down-stream direction, and is located upstream from the flow-diversion device.

iv. Milk or Milk Product Holding Tube

aa. The milk or milk product holding tube shall be designed to give continuous holding of every particle of milk or milk product for at least the minimum holding time specified in the scheduled process. The holding tube shall be designed so that no portion of the tube between the milk or milk product inlet and the milk or milk product outlet can be heated, and it must be sloped upward at least 2.1 centimeters per meter (one-fourth inch) per foot. Supports for holding tubes shall be provided to maintain all parts of holding tubes in a fixed position, free from any lateral or vertical movement.

bb. No device shall be permitted for short circuiting a portion of the holding tube to compensate for changes in rate of milk or milk product flow. Holding tubes shall be installed so that sections of pipe cannot be left out, resulting in a shortened holding time. The holding time for the processes must be determined from the pumping rate rather than by the salt conductivity test.

cc. The holding tube length must be such that the fastest flowing particle of any milk or milk product will not traverse the holding tube in less than the required holding time.

NOTE: Since laminar flow (the fastest flowing particle travels twice as fast as the average flowing particle) can occur in the holding tube during aseptic processing of high-viscosity products, holding tube lengths are calculated as twice the length required to hold the average flow for the time standard. With the steam injection process, the holding time is reduced because the milk or milk product volume increases as the steam condenses to water during heating in the injector. This surplus water is evaporated as the aseptically processed milk or milk product is cooled in the vacuum chamber. For example, with a 66°C (120°F) increase by steam injection which is probably the maximum temperature rise that will be used, a volume increase of twelve percent will occur in the holding tube. The measurement of the average flow rate at the discharge of the aseptic processor does not reflect this volume increase in the holding tube. However, this volume increase, i.e., holding time decrease, must be considered in the calculations.

dd. An aseptic processing system which can operate with milk or milk product in forward-flow mode, with less than 518 kPa (seventy-five psig) pressure in the holding tube shall be equipped with a pressure

limit indicator/pressure switch in the holding tube to assure that the heated milk or milk product remains in the liquid phase. In systems that do not have a vacuum chamber between the holding tube and the aseptic milk or milk product side of the regenerator, this can be established by verifying that the aseptic processing equipment cannot operate in forward-flow with less than 518 kPa (seventy-five psig) pressure on the aseptically processed side of the regenerator. (Refer to Appendix I. of the PMO). The pressure limit indicator/pressure switch must be interwired so that the flow-diversion device, milk or milk product divert system, milk or milk product divert valve or other acceptable control system will move to the divert position, if the milk or milk product pressure falls below a prescribed value. The instrument must be set at a pressure 69 kPa (ten psi) above the boiling pressure of the milk or milk product at its maximum temperature in the holding tube. If this pressure is too low, the resultant vaporization in the holding tube will substantially reduce residence times.

ee. With the steam injection process a differential pressure limit indicator across the injector is needed to ensure adequate isolation of the injection chamber. The instrument must have a differential pressure switch so that the flow-diversion device will move to the divert position if the pressure drop across the injector falls below 69 kPa (ten psi).

v. Heating by Direct Addition of Steam - Steam injection is an inherently unstable process; accordingly, when steam is injected into a fluid, condensation of the steam may not be completed inside the injector unless the proper design criteria are used. Lack of complete condensation inside the injector would cause temperature variations in the holding tube that could lead to some milk or milk product particles being processed below filed process temperature. When culinary steam is injected directly into milk or milk products as the means of terminal heating to achieve aseptic processing temperature, the steam injector shall be designed, installed and operated to comply with the following or equally satisfactory specifications:

aa. The milk or milk product and steam flows must be isolated from pressure fluctuations inside the injection chamber. One method of isolation is to insert supplementary orifices on the milk or milk product inlet and the heated milk or milk product outlet of each injector. The two supplementary orifices must be sized for at least a 69 kPa (ten psi) product pressure drop across the injector during a simulation of normal operations. Excessive vibrations, pressure fluctuations, or erratic noise levels indicate an unstable steam injection system and a need to check the isolation of the injection chamber.

bb. The process should be as free as possible of noncondensable gases that may evolve from the milk or milk product or be carried in the steam supply. Any two-phase flow caused by the noncondensable gases would displace the product in the holding tube, resulting in reduced residence times. In addition, these gases in the steam supply may also markedly alter the condensation mechanism at the point of injection. Accordingly, the steam boiler shall be supplied with a de-aerator. The de-aerator will aid in keeping the milk or milk product in the holding tube as free as possible of noncondensable gases.

vi. Prevention of Milk or Milk Product Adulteration with Added Water

aa. When culinary steam is introduced directly into the milk or milk product, automatic means, i.e., stand-alone and/or PLC-based ratio control system, shall be provided to maintain a proper temperature differential between incoming and outgoing milk or milk product to preclude dilution with water.

bb. Where a water feed line is connected to a vacuum condenser and the vacuum condenser is not separated from the vacuum chamber by a physical barrier, means shall be provided to preclude the back-up and overflow of water from the vacuum condenser to the vacuum chamber. This provision may be satisfied by the use of a safety shutoff valve, located on the water feed line to the vacuum condenser, automatically actuated by a control which will shut off the in-flowing water. This valve may be actuated by water, air, or electricity, and shall be so designed that failure of the primary motivating power will automatically stop the flow of water into the vacuum condenser.

vii. Flow-Diversion Device - All flow-diversion devices used in continuous aseptic process systems shall comply with 16.d.(1)(b)ii. or equally satisfactory specifications.

f. Pasteurizers and Aseptic Processing Systems Employing Regenerative Heating

(1) Administrative Procedures - Milk or Milk Product-to-Milk or Milk Product Regenerative Heating. Pasteurizers and aseptic processing systems employing milk or milk product-to-milk or milk product regenerative heating with both sides closed to the atmosphere shall comply with the following or equally satisfactory specifications:

(a) Regenerators shall be constructed, installed, and operated so that pasteurized or aseptic milk or milk product in the regenerator will automatically be under greater pressure than raw milk in the regenerator at all times.

(b) The pasteurized or aseptic milk or milk product, between its outlet from the regenerator and the nearest point downstream open to the atmosphere, shall rise to a vertical elevation of 30.50 centimeters (twelve inches) above the highest raw milk or milk product level downstream from the constant-level tank and shall be open to the atmosphere at this or a higher elevation.

(c) The overflow of the top rim of the constant level raw milk tank shall always be lower than the lowest milk or milk product level in the regenerator.

(d) No pump or flow-promoting device which can affect the proper pressure relationships within the regenerator shall be located between the pasteurized or aseptic milk or milk product outlet from the regenerator and the nearest downstream point open to the atmosphere.

(e) No pump shall be located between the raw milk or milk product inlet to the regenerator and the constant-level tank, unless it is designed and installed to operate only when milk or milk product is flowing through the pasteurized or aseptic milk or milk product side of the regenerator, and when the pressure of the pasteurized or aseptic milk or milk product is higher than the maximum pressure produced by the pump. This may be accomplished by wiring the booster pump so that it cannot operate unless:

i. The timing pump is in operation;

ii. The flow-diversion device is in forward-flow position; and

iii. The pasteurized or aseptic milk or milk product pressure exceeds, by at least 6.9 kPa (one psi), the maximum pressure developed by the booster pump. Pressure gauges shall be installed at the raw milk or milk product inlet to the regenerator and the pasteurized or aseptic product outlet of the regenerator or the outlet of the cooler. The accuracy of required pressure gauges shall be checked by DHEC on installation, quarterly thereafter, and following repair or adjustment.

(f) The motor, casing, and impeller of the booster pump shall be identified for those systems that rely on a pressure switch, located on the pasteurized side, and such records thereof maintained as directed by DHEC.

(g) All electric wiring interconnections should be in permanent conduit (except that rubber covered cable may be used for final connections), with no electrical connections to defeat the purpose of any provisions of this Regulation.

(h) All raw milk or milk product in the regenerator will drain freely back into the constant-level raw milk tank when the raw milk or milk product pump(s) are shut down and the raw milk or milk product outlet from the regenerator is disconnected.

(i) When vacuum equipment is located downstream from the flow-diversion device, means shall be provided to prevent the lowering of the pasteurized or aseptic milk or milk product level in the regenerator during periods of diverted flow or shutdown. An effective vacuum breaker, plus an automatic means of preventing a negative pressure, shall be installed in the line between the vacuum chamber and the pasteurized or aseptic milk or milk product inlet to the regenerator.

(j) In the case of pasteurization systems with the flow-diversion device located downstream from the regenerator and/or cooler section, the requirements of subsections (b), (c), and (i) of this section may be eliminated: Provided, that a differential pressure controller is used to monitor the highest pressure in the raw milk or milk product side of the regenerator and the lowest pressure in the pasteurized side of the regenerator, and the controller is interlocked with the flow-diversion device and is set and sealed so that whenever improper pressures occur in the regenerator, forward flow of product is automatically prevented and will not start again until all milk or milk product-contact surfaces between the holding tube and flow-diversion device have been held at or above the required pasteurization temperature, continuously and simultaneously for at least the required pasteurization time as defined in Section I, Definition 48 of this Regulation.

In the case of aseptic processing systems used for producing aseptic milk and milk products, there shall be an accurate differential pressure recorder-controller installed on the regenerator. The scale divisions shall not exceed 13.8 kPa (two pounds per square inch) on the working scale of not more than 138 kPa (twenty pounds per square inch) per 2.54 centimeters (inch). The controller shall be tested for accuracy against a known accurate standard pressure indicator upon installation and at least once every three months of operation thereafter, or more frequently if necessary, to ensure its accuracy. One pressure sensor shall be installed at the aseptic milk or milk product regenerator outlet and the other pressure sensor shall be installed at the raw milk or milk product regenerator inlet.

(k) When culinary steam is introduced directly into milk or milk products, to achieve pasteurization or aseptic processing temperature, and vacuum equipment is located downstream from the holding tube, the requirement that a vacuum breaker be installed at the inlet to the pasteurized or aseptic side of the regenerator may be eliminated: Provided, that the differential pressure controller is installed and wired to control the flow-diversion device as described in paragraph (j) of this section.

(l) When the differential pressure controller is installed and wired to control the flow-diversion device as described in paragraph (j) of this section, the raw product booster pump may be permitted to run at all times: Provided, that the timing pump is in operation.

(2) Administrative Procedures

(a) (Option 1) - Milk or Milk Product-to-Water-to-Milk or Milk Product Regenerative Heating. Milk or milk product-to-water-to-milk or milk product regenerators with both the milk or milk product and the heat-transfer water in the raw milk or milk product section closed to the atmosphere shall comply with the following or equally satisfactory specifications:

i. Regenerators of this type shall be so designed, installed, and operated that the heat-transfer-medium side of the regenerator in the raw milk or milk product section will, automatically, be under greater pressure than the raw milk or milk product side at all times.

ii. The heat-transfer water shall be a safe water and the heat-transfer water shall be in a covered tank which is open to the atmosphere at an elevation higher, by at least 30.5 centimeters (twelve inches), than any raw milk or milk product level downstream from the constant-level tank. The heat-transfer water between its outlet from the regenerator and the nearest point downstream open to the atmosphere shall rise to a vertical elevation of at least 30.5 centimeters (twelve inches) above any raw milk or milk product in the system and shall be open to the atmosphere at this or a higher elevation.

iii. The heat-transfer water circuit shall be full of water at the beginning of the run, and all loss of water from the circuit shall be automatically and immediately replenished whenever raw milk or milk product is present in the regenerator.

iv. The overflow of the top rim of the constant level raw milk tank shall always be lower than the lowest milk or milk product level in the raw milk or milk product section of the regenerator. The regenerator shall be designed and installed so that all raw milk or milk product shall drain freely back to the upstream supply tank when the raw milk or milk product pumps are shut down and the raw milk or milk product line is disconnected from the regenerator outlet.

v. No pump shall be located between the raw milk or milk product inlet to the regenerator and the constant level tank, unless it is designed and installed to operate only when water is flowing through the heat-transfer section of the regenerator, and when the pressure of the heat-transfer water is higher than the pressure of the raw milk or milk product. This may be accomplished by wiring the booster pump so that it cannot operate unless:

aa. The heat-transfer water pump is in operation;

bb. The heat-transfer water pressure exceeds, by at least 6.9 kPa (one psi), the raw milk or milk product pressure in the regenerator. A differential pressure controller shall be installed at the raw milk or milk product inlet and the heat-transfer water outlet of the regenerator. The raw milk or milk product booster pump must be wired so that it cannot operate unless the differential pressure is met. The accuracy of the required differential pressure controller shall be checked by DHEC on installation, quarterly thereafter, and following repair or replacement.

(b) (Option 2) - Milk or milk product-to-water-to-milk or milk product regenerators may also be constructed, installed and operated such that the pasteurized or aseptic milk or milk product in the regenerator will be under greater pressure than the heat-transfer-medium in the pasteurized or aseptic milk or milk product side of the regenerator:

i. A differential pressure controller shall be used to monitor pressures of the pasteurized milk or milk product and the heat-transfer medium.

ii. In the case of aseptic processing systems, a differential pressure-recorder shall be used to monitor pressures of the aseptic milk or milk product and the heat-transfer-medium.

iii. In either case, one pressure sensor shall be installed at the pasteurized or aseptic milk or milk product outlet of the regenerator and the other pressure sensor shall be installed at the heat-transfer-medium inlet of the pasteurized or aseptic milk or milk product side of the regenerator. This controller or recorder-controller shall divert the flow diversion device whenever the lowest pressure of pasteurized or aseptic milk or milk product in the regenerator fails to exceed the highest pressure of the heat-transfer-medium in the pasteurized or aseptic milk or milk product side of the regenerator by at least 6.9 kPa (one psi). Forward-flow of milk or milk product shall be automatically prevented until all milk or milk product-contact surfaces between the holding tube and the flow diversion device have been held at or above the required pasteurization or sterilization temperature continuously and simultaneously for at least the pasteurization or sterilization time.

iv. The heat-transfer-medium pump shall be wired so that it cannot operate unless the timing pump is in operation.

NOTE: Refer to Appendix H of the PMO for further discussion concerning methods of achieving the required pressure relationships within the regenerator.

g. Pasteurization and Aseptic Processing Records, Equipment Tests, and Examinations

(1) Pasteurization and Aseptic Processing Records - All temperature and flow rate pasteurization recording charts or alternative records, acceptable to FDA, in place of charts, shall be preserved for a period of three months. Provided, that all records and recording charts for aseptic milk and milk product systems shall be retained for a period of three years. The use of such charts shall not exceed the time limit for which they are designed. Overlapping of recorded data shall be a violation of this item. The following information shall be entered on the charts or other records acceptable to FDA in place of charts as applicable:

(a) Batch Pasteurizers:

i. Date.

ii. Number or location of recording thermometer when more than one is used.

iii. A continuous record of the product temperature.

iv. Extent of holding period, including filling and emptying times when required (Section VII.C.16 c.).

v. Reading of airspace thermometer at the start of the holding period and at the end of the holding period at a given time or reference point as indicated on the chart (Section VII.C.16.c.).

vi. Reading of indicating thermometer at the start of the holding period, at a given time or reference point as indicated on the chart (Section VII.C.16.c.).

vii. Quarterly, the initials of DHEC, or in the case of milk plants regulated under the NCIMS HACCP Program, a qualified industry person acceptable to DHEC, opposite the required readings of the indicating thermometer and airspace thermometer (Section VII.C.16.c.).

viii. Quarterly, the time accuracy of the recording thermometer, as determined by DHEC (Appendix I, Test 3 of the PMO), or in the case of milk plants regulated under the NCIMS HACCP Program, a qualified industry person acceptable to DHEC.

ix. Amount and name of pasteurized milk or milk product represented by each batch or run on the chart.

x. Record of unusual occurrences.

xi. Signature or initials of operator.

xii. Name of milk plant.

(b) High-Temperature, Short-Time (HTST) and Higher-Heat, Shorter-Time (HHST) Pasteurizers - Recording thermometer charts shall contain all the information specified in (a) above, except iv., v., and reference to airspace thermometer in vii., and in addition, shall include the following:

i. A record of the time during which the flow diversion device is in the forward-flow position.

ii. The cut-in and cut-out milk or milk product temperatures recorded daily by the operator at the beginning of the run (HTST only), and initialed quarterly by DHEC, or in the case of plants regulated under the NCIMS HACCP Program, a qualified industry person acceptable to DHEC; and

iii. Section vi. from above shall also be recorded immediately after a chart has been changed.

NOTE: The temperature shown on the recording thermometer chart shall be used to determine that the required temperature for milk or milk products containing higher fat and/or sweeteners has been achieved.

(c) Continuous-Flow Pasteurizers or Aseptic Processing Equipment with Magnetic Flow Meter Based Timing Systems: Flow rate recording charts shall be capable of continuously recording flow at the flow alarm set point and at least 19 liters (five gallons) per minute higher than the high flow alarm setting. Flow rate recording charts shall contain all the information specified in (a) above, except (iii), (iv), (v), (vi), and (vii), and in addition, shall include the following:

i. A continuous record of the status of the high and low-flow/loss of signal alarms;
and

ii. A continuous record of the flow rate.

(d) Aseptic Processing Systems - Recording thermometer charts shall contain all the information specified in (a) above, except (iv), (v), and reference to airspace thermometers in (vii), and in addition shall include the following:

i. A continuous record of the time during which the flow diversion device valve or system is in the forward-flow position.

ii. A continuous record of applicable regenerator pressures.

iii. Not later than one working day after the actual process, and before shipment or release for distribution, a representative of plant management who is qualified by suitable training or experience shall review all processing and production records for completeness and to ensure that the milk or milk product received the schedule process. The records, including the recording thermometer chart(s), shall be signed or initialed and dated by the reviewer.

iv. Number (a)vi. from above shall also be recorded immediately after a chart has been changed.

(2) Equipment Tests and Examinations - DHEC shall perform the indicated tests on the following instruments and devices initially on installation, and at least once each three months thereafter, including the remaining days of the month in which the equipment tests are due; and whenever any alteration or replacement is made which may affect the proper operation of the instrument or device: Provided, that the holding time test shall be conducted at least every six months, including the remaining days of the month in which the equipment check is due. On an emergency basis, pasteurization equipment may be tested and temporarily sealed by a milk plant employee provided the following conditions are met:

(a) The individual applying the seal(s) is employed by the milk plant in which the seal was removed;

(b) The individual has satisfactorily completed training, acceptable to DHEC, on test controls for pasteurization equipment;

(c) The individual has demonstrated the ability to satisfactorily conduct all pasteurization control tests, in the presence of a DHEC official, within the past year;

(d) The individual is in possession of authorization from DHEC to perform these tests;

(e) The individual will immediately notify DHEC of the time of the shutdown that would necessitate the removal of the regulatory seal(s). Permission to test and seal the equipment must be obtained for each specific incident. The individual will also notify DHEC of the identity of the controls affected, the cause, if known, of

the equipment failure, the repairs made and the results of testing. The individual will provide the identity and volume of milk and milk products processed during the period that temporary seals were applied to DHEC;

(f) If regulatory tests reveal that equipment or controls are not in compliance with the provisions of this Regulation, all milk and milk products that were processed during that period may be recalled;

(g) DHEC or a properly trained regulatory official commissioned by DHEC will remove the temporary seal(s), retest the equipment and apply the regulatory seal(s) within ten (10) working days of notification by industry; and

(h) No Grade "A" milk or milk products will be processed after ten (10) working days without the affected equipment being tested and sealed by DHEC or a properly trained regulatory official commissioned by DHEC.

(i) In the case of milk plants with HACCP Plans regulated under the NCIMS HACCP Program, pasteurization and aseptic processing equipment may be tested and sealed by industry personnel acceptable to DHEC, if the following conditions are met:

i. Test results for Pasteurization and Aseptic Processing Equipment Testing shall be recorded on a similar document for all milk plants. (Refer to the reference in Appendix M of the PMO for an example.)

ii. Industry personnel conducting the Pasteurization and Aseptic Processing Equipment Testing must be adequately trained and must be able to demonstrate an acceptable understanding and ability to conduct these tests to DHEC.

aa. Industry must physically demonstrate to DHEC that they understand and can perform the required equipment tests according to the requirements of this Regulation.

bb. DHEC shall accept a field practical exercise, a written exam, formal classroom training, on-the-job training or any combination of these except that, if industry personnel do not physically demonstrate the appropriate capability to perform the tests to the satisfaction of DHEC, they are not acceptable for conducting such tests.

cc. Continued training such as, but not limited to, on-the-job training with supervision or an acceptable pasteurizer training course should be completed before they reapply for pasteurizer equipment testing approval.

iii. Pasteurization and Aseptic Processing Equipment Tests shall be conducted at a frequency not less than the requirements of this Regulation. Industry shall have responsibility for the performance of all required tests. At least each six months DHEC shall physically supervise these tests. DHEC supervised tests shall include the semi-annual HTST and HHST tests. These six month tests should be performed at a time that is mutually convenient to all parties. Because these tests are required to support a CCP, the industry is responsible for conducting these tests even in the absence of the DHEC official.

iv. Upon initial installation or extensive modification of any pasteurization and aseptic processing equipment, tests shall be physically supervised or conducted by DHEC.

v. Sealing guidance for pasteurization equipment by industry is as follows:

aa. All equipment that is required to be sealed within this Regulation shall also be sealed under the HACCP System. The sealing shall be done by a trained, qualified individual who is acceptable to the milk plant and DHEC; and

bb. DHEC may verify any equipment sealing and evaluate (accept or reject) the skills and knowledge of the individual performing the sealing.

vi. During an audit, the auditor may conduct any or all of the Pasteurization or Aseptic Processing Equipment Tests. The auditor should, through a combination of physical examination of the equipment and a records review, satisfy themselves that the equipment is properly installed and operated.

Table 4. Equipment Tests - Batch, HTST, HHST and Aseptic Processing Systems (Refer to Appendix I of the PMO)		
1.	Vat, HTST, HHST, Aseptic indicating and airspace thermometers	Temperature accuracy
2.	Vat, HTST, HHST, Aseptic recording thermometer	Temperature accuracy
3.	Vat, HTST, HHST, Aseptic recording thermometer	Time accuracy
4.	Vat, HTST, HHST, Aseptic indicating and recording thermometer	Recording vs. Indicating thermometer
5.1	HTST, HHST FDD	Leakage pass FDD
5.2	HTST, HHST FDD	FDD freedom of movement
5.3	HTST, HHST FDD	Device assembly (single stem)
5.4	HTST, HHST FDD	Device assembly (dual stem)
5.5	HTST FDD	Manual diversion
5.6	HTST, HHST FDD	Response time
5.7	HTST, HHST FDD	Time delay (inspect)
5.8	HTST, HHST FDD	Time delay (CIP)
5.9	HTST FDD	Time delay (leak-detect flush)
6.	Vat leak-protector valve(s)	Leakage
7.	HTST indicating thermometers	Response time
8.	HTST recording thermometers	Response time
9.1	HTST pressure switches	Regenerator pressures
9.2.1	HTST, HHST, Aseptic differential pressure controllers	Calibration
9.2.2	HTST differential pressure controllers	Regenerator pressure
9.2.3	HHST and Aseptic differential pressure controllers	Regenerator pressure
9.3.1	HTST booster pump/FDD	Inter-wiring check
9.3.2	HTST booster pump/metering pump	Inter-wiring check
10.1	HTST FDD	Temperature cut-in/cut-out
10.2	HHST FDD, Aseptic divert system (indirect heat)	Temperature cut-in/cut-out
10.3	HHST FDD, Aseptic divert system (direct heat)	Temperature cut-in/cut-out
11.1	HTST holding tubes/timing pumps (except magnetic flow meter based timing systems)	Holding time
11.2.a	HTST holding tubes/magnetic flow meter based timing systems	Holding time
11.2.b	HTST, HHST, Aseptic magnetic flow meter based timing systems	Flow alarm
11.2.c	HTST, HHST, Aseptic magnetic flow meter based timing systems	Loss of signal/low flow
11.2.d	HTST magnetic flow meter based timing systems	Flow rate cut-in/cut-out
11.2.e	HTST magnetic flow meter based timing systems	Time delay
11.3	HHST holding tubes indirect heat	Holding time
11.4	HHST holding tubes direct injection heat	Holding time
11.5	HHST holding tubes direct infusion heat	Holding time
12.1	HHST, Aseptic systems indirect heating	Sequence logic
12.2	HHST, Aseptic systems direct heating	Sequence logic
13.	HHST, Aseptic systems	Pressure in the holding tube

14.	HHST, Aseptic systems using direct injection heating	Pressure differential across injector
15.	Vat, HTST, HHST, Aseptic (all electronic controls)	Electro-Magnetic Interference

17. Cooling of Milk

General - All raw milk and milk products shall be maintained at 7°C (45°F) or less until processed. All whey and whey products for condensing shall be maintained at a temperature of 7°C (45°F) or less; or 63°C (145°F) or greater until processed, except that acid-type whey with a titratable acidity of 0.40% or above, or a pH of 4.6 or below, is exempted from these temperature requirements. All pasteurized milk and milk products, except those to be cultured, shall be cooled immediately prior to filling or packaging in approved equipment to a temperature of 7°C (45°F) or less, unless drying is commenced immediately after condensing. All condensed whey and whey products shall be cooled during the crystallization process to 7°C (45°F) or less within 48 hours of condensing, including the filling and emptying time, unless filling occurs above 57°C (135°F), in which case, the 48 hour time period begins when cooling is started. All pasteurized milk and milk products shall be stored at a temperature of 7°C (45°F) or less and maintained thereat until further processed. On delivery vehicles, the temperature of milk and milk products shall not exceed 7°C (45°F). Every refrigerated room or tank in which milk or milk products, whey and whey products, and condensed milk and milk products are stored shall be equipped with an accurate indicating thermometer. Provided, that aseptically processed milk and milk products to be packaged in hermetically sealed containers shall be exempt from the cooling requirements of this item.

b. Administrative Procedures - This item is deemed to be satisfied when:

(1) All raw milk and milk products are maintained at 7°C (45°F) or less until processed except that acid-type whey with a titratable acidity of 0.40% or above, or a pH of 4.6 or below, is exempt from these temperature requirements.

(2) All whey and whey products for condensing are maintained at a temperature of 7°C (45°F) or less; or 63°C (145°F) or greater until processed, unless surge tanks are used and emptied, cleaned and sanitized after each 4 hours of use or less.

(3) All pasteurized milk and milk products, except those to be cultured, are cooled immediately in approved equipment prior to filling and packaging to a temperature of 7°C (45°F) or less unless drying is commenced immediately after condensing. On delivery vehicles the temperature of milk and milk products shall not exceed 7°C (45°F).

(4) All pasteurized milk and milk products shall be stored at a temperature of 7°C (45°F) or less and be maintained thereat until further processed. If surge tanks or balance tanks are used between the evaporator and the drier, such tanks shall hold the product at a temperature of 66°C (150°F) or more, or shall be completely emptied and cleaned after each four hours of operation or less.

(5) All condensed whey and whey products are cooled during the crystallization process to 7°C (45°F) or less, within 48 hours of condensing including the filling and emptying time, unless filling occurs above 57°C (135°F), in which case, the 48 hour time period begins when cooling is started.

(6) Each refrigerator room in which milk or milk products are stored, except aseptically processed milk and milk products, is equipped with an indicating thermometer which complies with the applicable specifications of Appendix H of the PMO. Such thermometer shall be located in the warmest zone of the refrigerator room.

(7) Each storage tank shall be equipped with an indicating thermometer the sensor of which shall be located to permit the registering of the temperature of the contents when the tank contains no more than twenty percent of its calibrated capacity. Such thermometer shall comply with the applicable specifications of Appendix H of the PMO.

(8) All surface coolers comply with the following specifications:

(a) The sections of open-surface coolers shall be so installed as to leave a gap of at least 6.4 millimeters (0.25 inch) between the header sections to permit easy cleaning.

(b) Where header ends are not completely enclosed within the cooler covers, condensation or leakage from the headers shall be prevented from entering the milk or milk products by so shaping the exposed header faces, above and below all gaps, that condensation is directed away from the tubes, and by using deflectors at the bottom of the headers, or by shortening the bottom of the headers, or by shortening the bottom trough, or by some other approved method.

(c) The location of supports of cooler sections shall prevent condensing and leakage from entering the milk or milk products.

(d) All open-surface coolers shall be provided with tight-fitting shields which protect the milk and milk products from contamination by insects, dust, drip, splash, or manual contact.

(9) Recirculated cold water which is used in coolers and heat exchangers, including those systems in which a freezing point depressant is used, is from a safe source and protected from contamination. Such water shall be tested semiannually and shall comply with the bacteriological standards of Appendix G of the PMO. Samples shall be taken by DHEC and examination shall be conducted in an official laboratory. Recirculated cooling water systems which become contaminated through repair work or otherwise shall be properly treated and tested before being returned to use. Freezing point depressants and other chemical additives, when used in recirculating systems, shall be nontoxic under conditions of use. Recirculated cooling water contained in corrosion resistant, continuous piping, with no joints or welds, which fail to meet applicable ASME or equivalent standards in the non-potable water contact areas, may be considered to be protected from contamination, as required above, when cooled by non-potable water flowing over the exterior of the piping, within open evaporative type cooling tower. In these systems, the recirculated cooling water piping shall be properly maintained and shall be installed so that it is at least two pipe diameters above the flood rim of the cooling tower.

18. Bottling and Packaging

a. General - Bottling, packaging, and container filling of milk and milk products shall be done at the place of pasteurization in a sanitary manner by approved mechanical equipment. For milk plants that dry milk products, these dry milk products shall be packaged in new containers, which protect the contents from contamination, and after packaging, shall be stored in a sanitary manner. For milk plants that condense and/or dry milk or milk products, these condensed and dry milk products may be transported in sealed containers in a sanitary manner from one milk plant to another for further processing and/or packaging. Condensed and dry milk product packaging containers shall be stored in a sanitary manner.

b. Administrative Procedures - This item is deemed to be satisfied when:

(1) All milk and milk products, including concentrated (condensed) milk and milk products are bottled and packaged at the plant where final pasteurization is performed. Such bottling and packaging shall be done without undue delay following final pasteurization.

(2) All bottling or packaging is done on approved mechanical equipment. The term "approved mechanical equipment" shall not be interpreted to exclude manually operated machinery but is interpreted to exclude methods in which the bottling and capping devices are not integral in one system.

(3) Bottling or packaging machines are designed to minimize the need for adjustment during operation. All pipes, connections, defoaming devices, and similar appurtenances shall comply with Section VII.C.10. and 11. Milk and milk products from continuous defoamers are not returned directly to the filler bowl.

(4) Bottling or packaging machine supply tanks and bowls have covers which are constructed to prevent any contamination from reaching the inside of the filler tank or bowl. All covers shall be in place during operation.

(5) A drip deflector is installed on each filler valve. Such drip deflector shall be designed and adjusted to divert condensation away from the open container.

(6) Container in-feed conveyors to automatic bottling or packaging machines have overhead shields to protect the bottles or packages from contamination. Such shields shall extend from the bottle washer discharge to the bottle feed star or, in the case of single-service packaging machines, from the forming unit discharge to the filling unit and from the filling unit to the closure unit. Overhead shields shall be required on can in-feed conveyors when the cans are fed to the filler with covers off.

(7) Container coding/dating devices are designed, installed and operated such that the coding/dating operations are performed in such a manner that open containers are not subjected to contamination. Shielding shall be properly designed and installed to preclude contamination of open containers.

(8) Container fabricating materials, such as paper stock, foil, wax, plastic, etc., are handled in a sanitary manner and protected against undue exposure during the package assembly operation.

(9) Bottling and packaging machine floats are designed to be adjustable without removing the cover.

(10) The filler pipe of all bottling and packaging machines have a diversion apron or other approved device as close to the filler bowl as possible to prevent condensation or drip from reaching the inside of the filler bowl.

(11) Filling cylinders on packaging machines are protected from contamination by the use of overhead shields. When any lubricant is applied to the filler pistons, cylinders, or other milk or milk product contact surfaces, the lubricant shall be food grade and applied in a sanitary manner.

(12) In the case of aseptic processing systems used for producing aseptic milk and milk products, the aseptic product shall be aseptically filled into sterilized containers and hermetically sealed in conformance with the applicable requirements of 21 CFR 113.

(13) Cottage cheese products are protected in a sanitary manner; they may be transported in sealed containers from one plant to another for creaming and/or packaging.

(14) For milk plants that condense and/or dry milk or milk products, the following shall apply:

(a) The filling of condensed and dry milk product containers is done by mechanical equipment. The term "mechanical equipment" shall not be interpreted to exclude manually operated equipment.

(b) All pipes, connections and similar appurtenances comply with Section VII.C.10. and 11.

(c) Filling devices are constructed so as to prevent any contamination from reaching the product. Covers of filling devices, if used, shall be in place during operation.

(d) Packaged dry milk and milk products are stored and arranged so as to be easily accessible for inspection and to permit cleaning of the storage room.

(e) All condensed and dry milk product containers are filled in a sanitary manner by methods which:

i. Protect the product from airborne contamination;

ii. Prevent manual contact with condensed and dry milk product-contact surfaces; and

iii. Minimize manual contact with the product.

(f) All final containers for dry milk products shall be new and of the single-service type and sufficiently substantial to protect the contents from impairment of quality with respect to sanitation, contamination and moisture, under customary conditions of handling, transportation, and storage.

(g) If portable storage bins are used, they comply with the applicable provisions of Section VII.C.10. and 11.

(h) Containers are closed immediately after being filled.

19. Capping, Container Closure and Sealing, and Dry Milk Product Storage

a. General - Capping, closing or sealing of milk and milk product containers shall be done in a sanitary manner by approved mechanical capping, closing, and/or sealing equipment. The cap or closure shall be designed and applied in such a manner that the pouring lip is protected to at least its largest diameter and, with regard to fluid product containers, removal cannot be made without detection.

b. Administrative Procedures - This item is deemed to be satisfied when:

(1) The capping or closing of milk and milk product containers is done in a sanitary manner on approved mechanical capping, closing and/or sealing equipment. The term "approved mechanical capping, closing, and/or sealing equipment" shall not exclude manually operated machinery. Hand-capping shall be prohibited: Provided, that if suitable mechanical equipment for the capping or closing of specific container(s) of 12.8 liters (three gallons) or more is not available, other methods which eliminate all possibility of contamination may be approved by DHEC. Provided further, that if suitable equipment is not available for capping cottage cheese products, other methods of capping which eliminate possible chance of contamination may be approved by DHEC.

(2) All mechanical capping, closing and/or sealing mechanisms are designed to minimize the need for adjustment during operation.

(3) Bottles and packages which have been imperfectly capped or closed are emptied immediately into approved sanitary containers. Such milk or milk products shall be protected from contamination, maintained at 7°C (45°F) or less, except dry milk products and subsequently repasteurized or discarded.

(4) All caps and closures are designed and applied in such a manner that the pouring lip is protected to at least its largest diameter and, with respect to fluid product containers, removal cannot be made without detection. Single-service containers are so constructed that the product and the pouring and opening areas are protected from contamination during handling, storage and when the containers are initially opened. Closures for cottage cheese product containers shall extend over the top edges of the container so as to protect the product from contamination during subsequent handling.

(5) Caps and closures are handled in a sanitary manner. The first cap from each tube, the first lap(s) from each roll of cap or cover stock, and the first sheet of parchment or cover paper shall be discarded. The subsequent use of loose caps which are left in the cappers at the end of an operating period after removal from the cap tubes shall be a violation of this item, provided, that loose plastic caps and closures supplied by the manufacturer in plastic bags may be returned to storage in a protective wrap if removed from a hopper/descrambler immediately after a production run. Plastic caps and closures remaining in the chute between the hopper and the capping device shall be discarded. Provided further, that this requirement shall not apply to cottage cheese product container closures, when such closures are supplied in a totally enclosed package, or wrapped so as to protect the closures.

(6) All dry milk products are stored in a sanitary manner.

20. Personnel Cleanliness

a. General - Hands shall be thoroughly washed before commencing plant functions and as often as may be required to remove soil and contamination. No employee shall resume work after visiting the toilet room without thoroughly washing his/her hands. All persons, while engaged in the processing, pasteurization, handling, storage, or transportation or packaging of milk, milk products, containers, equipment, and utensils shall wear clean outer garments. All persons, while engaged in the processing of milk or milk products shall wear adequate hair coverings and shall not use tobacco.

b. Administrative Procedures - This item is deemed to be satisfied when:

(1) Hands are thoroughly washed before commencing milk plant functions and as often as may be required to remove soil and contamination.

(2) Each employee washes his/her hands following a visit to the toilet room and prior to resuming work.

(3) All persons while engaged in the processing, pasteurization, handling, storage, packaging, or transportation of milk, milk products, containers, equipment, and utensils wear clean outer garments.

(4) The use of tobacco products is prohibited in all rooms in which milk and milk products are handled, processed or stored, or in which milk or milk product containers, utensils and/or equipment are washed. These rooms shall include, but are not limited to, the receiving, processing, packaging, milk and milk product storage, cooling and dry storage ingredients, single-service article storage and container/utensil wash-up areas. Any person engaged in the processing of milk or milk products wears adequate hair coverings.

(5) Specially provided clean rubbers or boot covers, clean coveralls, and white cap, clean cloth or paper, are worn whenever it is necessary to enter the drying chambers. Such articles of clothing are stored in such a manner as to be protected from contamination. Boot covers, which have come into contact with areas other than those within the dryer, are not considered clean.

21. Vehicles

a. General - All vehicles used for transportation of pasteurized milk and milk products shall be constructed and operated so that the milk and milk products are maintained at 7°C (45°F) or less, and are protected from

contamination. Milk tank cars, milk trucks, and portable shipping bins shall not be used to transport or contain any substances that may be toxic or harmful to humans.

b. Administrative Procedures - This item is deemed to be satisfied when:

(1) All vehicles are kept clean.

(2) Material which is capable of contaminating milk or milk products is not transported with milk or milk products.

(3) Vehicles have fully enclosed bodies with well-fitted solid doors.

(4) Milk and milk products, except dry milk products, are maintained at 7°C (45°F) or less.

(5) The operation of milk tank cars and shipping bins comply with the following provisions:

(a) Milk and milk products shall be conducted to and from tank cars or shipping bins only through sanitary conveying equipment. Such equipment shall be capped or otherwise protected when not in use.

(b) Inlets and outlets of shipping bins shall be provided with tight-fitting dust caps or covers.

(c) Facilities shall be provided for the adequate washing and sanitizing of shipping bins, piping, and accessories at all milk plants receiving or shipping milk or milk products in shipping bins.

(d) Shipping bins shall be cleaned at the receiving milk plant immediately after being emptied. The clean shipping bins shall be sanitized at the shipping milk plant before loading. Milk tank trucks, which must make more than one trip while unloading a tank car, need not be cleaned and sanitized after each time they are emptied.

(e) Piping connections and pumps used with shipping bins shall be cleaned and sanitized after each use.

(6) The doors of tank cars and covers of shipping bins are sealed with a metal seal immediately after loading. The seal shall remain unbroken until the contents are delivered to the consignee. Contents of the tank car or shipping bin shall be labeled as prescribed in Section IV by means of a tag attached to the tank car or shipping bin.

22. Surroundings

a. General - Milk plant surroundings shall be kept neat, clean, and free from conditions which might attract or harbor flies, other insects and rodents, or which otherwise constitute a nuisance.

b. Administrative Procedures - This item is deemed to be satisfied when:

(1) There is no accumulation of trash, garbage, or similar waste in areas adjacent to the milk plant. Waste material stored in suitable covered containers shall be considered in compliance.

(2) Driveways, lanes, and areas serving milk plant vehicular traffic are graded, drained, and free from pools of standing water.

(3) Outdoor areas for milk tank truck unloading are constructed of smooth concrete or equally impervious material, properly sloped to drain, and equipped with trapped drains of sufficient size.

(4) Only insecticides and rodenticides approved for use by DHEC and/or registered with the U.S. Environmental Protection Agency shall be used for insect and rodent control.

(5) Rooftops are kept clean of dry milk or milk products, which may accumulate and contribute to unsanitary conditions.

SECTION VIII. ANIMAL HEALTH

A. General - All milk for pasteurization must be from healthy animals.

B. Administrative Procedures - This item is deemed to be satisfied when:

1. All milk for pasteurization shall be from herds in Areas which have a Modified Accredited Tuberculosis status or greater as determined by the U.S. Department of Agriculture: Provided, that in an Area that fails to maintain such status, any herd shall have been accredited by said Department as tuberculosis free, or shall have passed an annual tuberculosis test, or the Area shall have established a tuberculosis testing protocol for livestock that assures tuberculosis protection and surveillance of the dairy industry within the Area and that it is approved by FDA, USDA and DHEC.

2. All milk for pasteurization shall be from herds under a brucellosis eradication program which meets one of the following conditions:

a. Located in a Certified Brucellosis-free Area as defined by the U.S. Department of Agriculture and enrolled in the testing program for such areas; or

b. Meet U.S. Department of Agriculture requirements for an individually certified herd; or

c. Participating in a milk ring testing program at least two times per year at approximately one hundred eighty day intervals, and all herds with positive milk ring results shall have the entire herd blood tested within thirty days from the date of the laboratory ring tests; or

d. Have an individual blood agglutination test annually with an allowable maximum grace period not to exceed two months.

3. Goat, sheep, water buffalo, or any other hooved mammal milk for pasteurization, ultra-pasteurization or aseptic processing, defined under this Regulation shall be from a herd or flock that:

a. Has passed an annual whole herd or flock brucellosis test as recommended by the State Veterinarian or USDA Area Veterinarian in Charge (AVIC); or

b. Has passed an initial whole herd brucellosis test, followed only by testing replacement animals or any animals entering the milking group or sold as dairy animals; or

c. Has passed an annual random blood-testing program sufficient to provide a confidence level of 99% with a P value of 0.05. Any herd or flock with one or more confirmed positive animals shall go to 100% testing until the whole herd tests show no positive animals are found; or

d. Has passed a USDA approved bulk milk test, at USDA recommended frequency, with an implementation date based on availability of the test.

The following table will provide the random sampling size needed to achieve 99% confidence with a P value of 0.05:

Herd/Flock Size	Sampling Size	Herd/Flock Size	Sampling Size
20	20	500	82
50	41	600	83
100	59	700	84
150	67	800	85
200	72	1000	86
250	75	1400	87
300	77	1800	88
350	79	4000	89
400	80	10000	89
450	81	100000	90

4. For diseases other than brucellosis and tuberculosis, DHEC shall require such physical, chemical, or bacteriological tests as it deems necessary. The diagnosis of other diseases in dairy animals shall be based upon the findings of a licensed and accredited veterinarian or an accredited veterinarian in the employ of an official agency. Any diseased animal disclosed by such test(s) shall be disposed of as DHEC directs.

5. Records supporting the tests required in this Section shall be available to DHEC and be validated with the signature of a licensed and accredited veterinarian or an accredited veterinarian in the employ of an official Agency.

6. Specific criteria for Bovine Tuberculosis and Brucellosis Testing is as follows:

a. Bovine Tuberculosis - All tuberculin tests and retests shall be made, and any reactors disposed of, in accordance with the current edition of Uniform Methods and Rules; Bovine Tuberculosis Eradication, Uniform Methods and rules for Establishment and Maintenance of Tuberculosis-Free Accredited Herds of Cattle, Modified Accredited Areas and Areas Accredited Free of Bovine Tuberculosis in the Domestic Bovine, as published by the U.S. Department of Agriculture. For tuberculosis test purposes, the herd is defined as all adult cattle twenty-four months of age and over, including any commingled beef animals. Dairy cattle less than two years of age and already milking, shall be included in the herd test. A letter or other official correspondence attesting to the accreditation status of the locality in which the herd is located, including the date of accreditation, or a certificate identifying the animals tested, the date of injection, the date of reading of the test, and the results of the test signed by a U.S. Department of Agriculture accredited veterinarian, shall be evidence of compliance with the above requirements and shall be filed with DHEC. (Refer to Appendix A of the PMO.)

b. Bovine Brucellosis - All brucellosis tests, retests, disposal of reactors, vaccination of calves and certification of herds and areas shall be in accordance with the current edition of Brucellosis Eradication "Recommended Uniform Methods and Rules," as approved by the U.S. Department of Agriculture. All reactors disclosed on blood agglutination tests shall be separated immediately from the milking herd; the milk of these reactors shall not be used for human consumption.

A certificate identifying each animal, signed by the veterinarian and the director of the laboratory making the test, shall be filed as directed by DHEC: Provided, that in the event the herd is subject to the milk ring test, the record shall be required to show only the date and results of such test. Within thirty days following the expiration of an official milk ring testing program, or in the case of a herd subject to annual blood tests, thirteen months following the last annual blood tests, DHEC shall notify the herd owner or operator of the necessity to comply with the brucellosis requirements. The failure of the herd owner or operator to comply with the brucellosis requirements within thirty days of written notice shall result in immediate suspension of the permit. (Refer to Appendix A of the PMO.)

SECTION IX. MILK AND MILK PRODUCTS WHICH MAY BE SOLD

Upon adoption of this Regulation, only Grade A milk and milk products shall be offered for sale to the final consumer: Provided, only Grade "A" milk and milk products shall be sold to milk plants for use in the commercial preparation of Grade "A" milk and milk products. Provided further, that in an emergency, the sale of pasteurized milk and milk products which have not been graded, or the grade of which is unknown, may be authorized by DHEC, in which case such milk and milk products shall be labeled "ungraded."

SECTION X. TRANSFERRING, DELIVERY CONTAINERS, COOLING

A. General

1. Except as permitted in this section, no milk producer, milk hauler/sampler or distributor shall transfer milk or milk products from one container or milk tank truck to another on the street, in any vehicle, store, or in any place except a milk plant, receiving station, transfer station, or milkhouse especially used for that purpose. The dipping or ladling of milk or fluid milk products is prohibited.

2. It shall be unlawful to sell or serve any pasteurized milk or milk product which has not been maintained at the temperature set forth in Section VII of this Regulation. If containers of pasteurized milk or milk products are stored in ice, the storage container shall be properly drained.

B. Administrative Procedures

1. Transferring - The dipping or ladling of milk and fluid milk products is expressly prohibited, except for immediate cooking purposes. Milk and milk product containers which have been filled and sealed at a milk plant shall be used for the delivery of milk or milk products. Caps, closures, or labels shall not be removed or replaced during transportation.

2. Bulk Dispensers - Bulk dispensers, approved by the DHEC, shall satisfy the following sanitary design, construction, and operation requirements:

a. All dispensers shall comply with the applicable requirements of Section VII of this Regulation.

b. Product-contact surfaces shall be inaccessible to manual contact, droplet infection, dust, or flies; but the delivery orifice may be exempted from this requirement.

c. All parts of the dispensing device with which milk or milk products come into contact, including any measuring device, shall be thoroughly cleaned and sanitized at the milk plant: Provided, that dispensing valves which are applied to the dispenser subsequent to its delivery to the retail vendor may be cleaned and sanitized at such establishments.

d. The dispensing container shall be filled at the milk plant and shall be so sealed that it is impossible to withdraw any part of its contents, or to introduce any substance without breaking the seal(s).

e. The milk or milk products shall be thoroughly and automatically mixed with each dispensing operation, except for milk or milk products which remain homogeneous.

f. All cans shall be thoroughly cleaned and sanitized. Milk and milk products shall be kept at or below 7°C (45°F) at all times. The dispenser tube shall be integral with the dispensing container, shall be protected, and shall be under adequate refrigeration during transportation and storage.

SECTION XI. MILK AND MILK PRODUCTS FROM POINTS BEYOND THE LIMITS OF ROUTINE INSPECTION

A. General

1. Milk and milk products from points beyond the limits of routine inspection by DHEC or its police jurisdiction, may be sold in South Carolina, or its police jurisdiction, provided they are produced and pasteurized, ultra-pasteurized or aseptically processed, concentrated (condensed) or dried under regulations which are substantially equivalent to this Regulation and are under routine official supervision; and have been awarded by the State milk sanitation rating officer certified by the Food and Drug Administration, a milk sanitation compliance and enforcement rating made on the basis of procedures outlined in Methods of Making Sanitation Ratings of Milk Supplies recommended by the Food and Drug Administration, or have been awarded a satisfactory HACCP listing, under the NCIMS Program as specified in Appendix K of the PMO.

2. Upon arrival, each periodic shipment of raw milk for pasteurization shall comply with the bacteriological, chemical, somatic cell, and temperature standards of Section VII. Routine shipments of raw milk for pasteurization shall comply with the bacteriological, chemical, somatic cell, and temperature standards of Section VII as determined in accordance with Section VI.

3. After receipt, pasteurized milk and milk products shall comply with chemical, bacteriological, and temperature standards for Grade A milk and milk products under Section VII as determined in accordance with Section VI, and not be adulterated.

B. Administrative Procedures

DHEC should accept, without their actual physical inspection, supplies of milk and milk products from an area or an individual shipper not under their routine inspection, provided, that:

1. Milk and milk products upon arrival shall comply with bacteriological, physical, chemical and temperature standards of Section VII. Provided, that direct shipped producer milk that is under the supervision of more than one Regulatory Agency may be exempt from the bacteriological requirement for commingled samples. However, DHEC shall have the right to use the individual producer samples to determine compliance with the bacteriological standards.

2. After receipt, pasteurized, ultra-pasteurized, aseptically processed, concentrated (condensed) or dried milk and milk products shall comply with Sections II, IV, and X.

NOTE: Raw and pasteurized milk and milk products beyond the limits of routine inspection shall be sampled as DHEC requires.

3. The milk or milk products are produced and processed under regulations substantially equivalent to those of this Regulation.

4. The supplies are under routine official supervision;

5. The supplies have been awarded, by a Milk Sanitation Rating Officer (SRO), certified by FDA, Milk Sanitation Compliance and Enforcement Ratings equal to that of the local supply or equal to ninety percent (90%) or higher; and

6. All ratings are made on the basis of procedures outlined in the *Methods of Making Sanitation Ratings of Milk Supplies* (MMSR).

NOTE: Names of interstate milk shippers and their ratings, as reported by State Rating Agencies, are contained in the *IMS List-Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers* (IMS List), issued semi-annually by FDA. Copies of this list may be obtained from the State Milk Rating/Regulatory Agency or from the Food and Drug Administration, HFS-626, 5100 Paint Branch Parkway, College Park, MD 20740-3835.

7. The supplies have been awarded, by a State Rating Officer, certified by FDA, a satisfactory listing under the NCIMS HACCP Program as specified in Appendix K of the PMO.

SECTION XII. FUTURE DAIRY FARMS AND MILK PLANTS

Properly prepared plans for all milk houses, milking barns, stables and parlors, milk tank truck cleaning facilities, transfer stations, receiving stations, and milk plants regulated under this Regulation which are hereafter constructed, reconstructed, or extensively altered shall be submitted to DHEC for written approval before work is begun.

SECTION XIII. PERSONNEL HEALTH

A. General - No persons affected with any disease capable of being transmitted to others through the contamination of food shall work at a milk plant in any capacity which brings them into direct contact with finished products such as pasteurized or aseptically processed milk or milk products or which brings them into direct contact with associated pasteurized or aseptically processed milk product contact surfaces. In the case of milk plants, receiving stations, or transfer stations that have HACCP Systems, which are regulated under the NCIMS HACCP Program, the HACCP System shall address the public health concerns described in this Section in a manner that provides protection equivalent to the requirements in this Section.

B. Administrative Procedures

Milk plant operators who have received reports, under this Section, from employees who have handled pasteurized milk or milk products or associated milk or milk product-contact surfaces shall immediately report these facts to DHEC.

Milk plant employees, or applicants to whom a conditional offer of employment has been made, shall be instructed by the milk plant that the employee or applicant or applicants to whom a conditional offer of employment has been made is responsible to report to the milk plant management, in a manner that allows the milk plant to prevent the likelihood of the transmission of diseases that are transmissible through foods, if the employee or applicant to whom a conditional offer of employment has been made:

1. Is diagnosed with an illness due to Hepatitis A virus, *Salmonella typhi, Shigella* species, Norwalk and Norwalk-like Viruses, *Staphylococcus aureus, Streptococcus pyogenes, Escherichia coli* 0157:H7*,* enterohemorrhagic *Escherichia coli, enterotoxigenic Escherichia coli, Campylobacter jejuni, Entamoeba histolytica, Giardia lamblia,* Non-typhoidal *Salmonella, Rotovirus, Taenia solium, Yersinia enterocolitica, Vibrio cholerae O1* or other infectious or communicable disease that has been declared by the Secretary of Health and Human Services (HHS) to be transmissible to others through the handling of food, or has been clearly shown to be so based upon verifiable epidemiological data; or

2. Is exposed to, or suspected of causing, a confirmed foodborne disease outbreak of one of the diseases specified in section 1 above, including an outbreak at an event such as a family meal, church supper or ethnic festival because the employee or applicant to whom a conditional offer of employment has been made:

a. Prepared food implicated in the outbreak; or

b. Consumed food implicated in the outbreak; or

c. Consumed food at the event prepared by a person who is infected or ill.

3. Lives in the same household as a person who attends or works in a day care center or school, similar institution experiencing a confirmed outbreak of one of the diseases specified in section 1 above. Similarly, milk plant employees shall be instructed by the milk plant management to report to the milk plant management if the employee, or applicant to whom a conditional offer of employment has been made.

4. Has a symptom associated with acute gastrointestinal illness such as: Abdominal cramps or discomfort, diarrhea, fever, loss of appetite for three or more days, vomiting, jaundice; or

5. Has a pustular lesion such as a boil or infected wound that is:

a. On the hands, wrists or exposed portions of the arms, unless the lesion is covered by a durable, moisture proof, tight-fitting barrier; or

b. On other parts of the body if the lesion is open or draining, unless the lesion is covered by a durable, moisture proof, tight-fitting barrier.

SECTION XIV. PROCEDURE WHEN INFECTION OR HIGH RISK OF INFECTION IS DISCOVERED

When a person who may have handled pasteurized or aseptically processed milk or milk products or pasteurized or aseptically processed milk product contact surfaces meets one or more of the conditions specified in the administrative procedures of Section XIII, DHEC is authorized to require any or all of the following measures:

A. The immediate restricting of that person from duties that require handling pasteurized milk or milk products, or the handling of related milk or milk product-contact surfaces. This restriction may be lifted after an appropriate medical clearance or cessation of symptoms or both, according to the following Table:

Removal of Restrictions when Infection or High Risk of Infection is Discovered	
Health Status	**Removing Restrictions**
a. Is diagnosed with an illness due to Hepatitis A virus, *Salmonella typhi, Shigella* species, Norwalk and Norwalk-like Viruses, *Staphylococcus aureus, Streptococcus pyogenes, Escherichia coli* 0157:H7, enterohemorrhagic *Escherichia coli, enterotoxigenic Escherichia coli, Campylobactor jejuni, Entamoeba histolytica, Giardia lamblia,* Non-typhoidal *Salmonella,* Rotovirus, *Taenia solium, Yersinia enterocolitica, Vibrio cholerae* O1 or other infectious or communicable disease that has been declared by the Secretary of HHS to be transmissible to others through the handling of food or has been clearly shown to be so based upon verifiable epidemiological	Restrictions lifted by medical clearance.

data.	
b. Meeting a high-risk scenario as specified in Section XIII. (2 or 3) and/or experiencing symptoms in Section XIII. (4 or 5).	Restrictions lifted when symptoms cease or medical documentation is provided that infection does not exist.
c. Asymptomatic, but stools positive for *Salmonella typhi, Shigella* or *Escherichia coli* 0157:H7.	Restrictions lifted by medical clearance.
d. Past illness from *Salmonella typhi, Shigella, Escherichia coli* 0157:H7 or other human pathogens for which humans have been determined to be carriers.	Restrictions lifted by medical clearance.
e. In the case of diagnosed or suspected Hepatitis A, onset of jaundice within the last seven days.	Restrictions lifted by medical clearance.
f. In the case of diagnosed or suspected Hepatitis A, onset of jaundice occurred more than seven days ago.	Restrictions lifted by medical clearance or jaundice ceases.

B. The immediate exclusion of the affected milk or milk products from distribution and use when medically appropriate, i.e., a medical evaluation of the sequence of events indicates that contamination of milk or milk product may have occurred.

C. The immediate requesting of medical and bacteriological examination of the person at risk.

NOTE: Persons at risk who decline to be examined may be reassigned to duties where they will not be required to handle pasteurized, ultra-pasteurized or aseptically processed milk or milk products and associated milk or milk product-contact surfaces.

In the case of milk plants, receiving stations, or transfer stations that have HACCP Systems, which are regulated under the NCIMS HACCP Program, the HACCP System shall address the public health concerns described in this Section in a manner that provides protection equivalent to the requirements in this Section.

SECTION XV. ENFORCEMENT

This Regulation is issued and shall be enforced under the authority of Section 44-1-140, 1976 Code of Laws of South Carolina, as amended.

SECTION XVI. PENALTY

Violations of this Regulation shall be punishable in accordance with Section 44-1-150, 1976 Code of Laws of South Carolina, as amended. Each day of continued violation shall be a separate offense.

SECTION XVII. IMPLEMENTATION

Those portions of Regulation 61-34, as they deal with pasteurized milk, pasteurized milk products and milk for pasteurization are hereby superseded by this Regulation. These requirements shall be in full force and effect upon approval by the General Assembly.

SECTION XVIII. PERMIT FEES

A. If a fee system is hereafter established by the Department of Health and Environmental Control, proof of payment of the fee shall accompany each initial application and shall be furnished to DHEC within thirty days after the renewal date. If such proof is not presented, the permit shall be suspended immediately until such proof is received, notwithstanding the sanitary conditions of the establishment.

B. Upon receipt of an application for a permit to operate an establishment governed by this Regulation, accompanied by the required fee receipt, a permit shall be issued if the establishment meets the requirements of this Regulation.

SECTION XIX. UNCONSTITUTIONALITY CLAUSE

Should any section, paragraph, sentence, clause, or phrase, of this Regulation be declared unconstitutional or invalid for any reason, the remainder of said Regulation shall not be affected thereby.

Fiscal Impact Statement:

The Department estimates there will be no new costs imposed on the State or its political subdivisions by this regulation.

Statement of Need and Reasonableness and Rationale:

The Statement of Need and Reasonableness was determined by staff analysis pursuant to S.C. Code Section 1-23-115(C)(1)-(3) and (9)-(11):

DESCRIPTION OF REGULATION:

Purpose: R.61-34.1 ensures that consumers are receiving safe, high quality Grade "A" milk and milk products. The Regulation was amended last in 1993. These amendments will bring the Regulation into compliance with the latest guidelines of the Interstate Milk Shipments Conference Pasteurized Milk Ordinance and assure consumers that the latest sanitation requirements are being met by the dairy industry. Also, the United States Public Health Service, Food and Drug Administration (FDA) requires that South Carolina's dairy regulation be at least as stringent as the Pasteurized Milk Ordinance in order for South Carolina milk producers to ship their products in interstate commerce and market their product as Grade "A" milk products; the FDA has previously cited the South Carolina program for not meeting this requirement. Amendments will also insure that the regulation complies with the requirements of the federal Nutrition Labeling and Education Act, the federal Food, Drug and Cosmetic Act, and the South Carolina Administrative Procedures Act, and is compatible with R.61-36, *Frozen Desserts*. Other related editorial and stylistic changes were included to improve the overall quality of the regulation.

Legal Authority: The legal authority for R.61-34.1 is Section 44-1-140 et seq., S.C. Code of Laws.

Plan for Implementation: These amendments will take effect upon approval by the General Assembly and publication in the *State Register*. The majority of these latest requirements have already been implemented by the Department under the authority of the FDA and the need for the regulated community to meet minimum PMO requirements for interstate milk shipments. The regulated community will be provided copies of the regulation.

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

These regulations will ensure that consumers are receiving safe, high quality Grade "A" milk and milk products, and will bring the regulation into compliance with the latest requirements and guidelines set forth by the United States Food and Drug Administration (FDA) Pasteurized Milk Ordinance requirements. Also, the proposed regulation will update requirements of the Administrative Procedures Act, incorporate the federal Dry Milk Ordinance into this document and allow for a Hazard Analysis Critical Control Point Regulatory Program. The incorporated changes update the South Carolina regulation to meet FDA's minimum Pasteurized Milk Ordinance requirements.

DETERMINATION OF COSTS AND BENEFITS: There are no anticipated new costs associated with the implementation of this regulation. There will be a benefit to South Carolina's environment and the health of its citizens by ensuring that consumers are receiving safe, high quality Grade "A" milk and milk products.

UNCERTAINTIES OF ESTIMATES: None.

EFFECT ON ENVIRONMENT AND PUBLIC HEALTH: These regulations will ensure that consumers are receiving safe, high quality Grade "A" milk and milk products.

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATION IS NOT IMPLEMENTED: Not implementing the regulation will cause a decrease in the sanitary standards in Grade "A" milk and milk product manufacturing and processing facilities; this decrease in sanitary standards could have a detrimental effect on the health of South Carolina's citizens and visitors. Further delays in revising South Carolina's regulation governing pasteurized milk and milk products will also likely result in penalties imposed on the program by FDA and the National Conference on Interstate Milk Shipments.

Statement of Rationale:

The determination to revise this regulation was in response to an FDA evaluation of the South Carolina Dairy Program in 2002 (reported June 12, 2003) in which it was recommended that South Carolina should adopt into law or by reference the most current edition of the Pasteurized Milk Ordinance and related guidance documents. Due to legal difficulties involved in adopting this Ordinance into law or by reference, it was determined that the regulation should be rewritten to include all minimum Ordinance requirements. Another FDA state program survey is currently underway and it is anticipated that failure to have this regulation updated could result in increased criticism and possible FDA and IMS Conference penalties.

Document No. 2963
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61
Statutory Authority: 1976 Code Section 13-7-40, as amended

R.61-63. Radioactive Materials (Title A)

Synopsis:

The Nuclear Regulatory Commission continually updates regulations, and state regulations are amended regularly to incorporate federal updates. Section 274 of the Atomic Energy Act of 1954, as amended, requires that the states adopt federal regulations for compatibility. This amendment adopts into regulation the Nuclear Regulatory Commission updates as an item of compatibility. The action revises the skin dose limit (Part III), and amends the regulations regarding the medical use of radioactive materials (Parts II, III and IV). This

amendment will comply with 10 CFR Parts 20, 32 and 35, Final Rules, published in the Federal Register on April 5, 2002, and April 24, 2002 (Volume 67). Legislative review will not be required.

This amendment was approved by the Board of Health and Environmental Control on April 14, 2005. The revision was promulgated to comply with federal law; neither a fiscal impact statement nor preliminary assessment report is required. See discussion of revisions below and a statement of need and reasonableness provided herein.

Discussion of Revisions:

Insert 1

(1) Clarifying revisions to Part II due to the total revision to Part IV of Regulation 61-63.

SECTION REVISION

61-63.2.7.5.2.1 Revises reference sections.

61-63.2.7.5.2.2.2 Revises reference sections. Also allows a two year "grandfathering" term for meeting the new requirements.

61-63.2.7.5.2.4 Revises date reference.

61-63.2.7.7.1 Revises reference sections.

61.63.2.7.7.1.3 Revises reference sections. Also deletes archaic "pending application" reference.

(2) Revision of the Skin Dose Limit

SECTION REVISION

61-63.3.2.83 Revises definition for "shallow-dose equivalent."

61-63.3.5.1.2 Revises method of calculating "shallow-dose equivalent."

61-63.3.5.1.2.2 Revises method of calculating "shallow-dose equivalent."
61-63.3.5.3 Revises method of calculating "shallow-dose equivalent."

(3) Clarification of dose limits for individual members of the public

SECTION REVISION

61-63.3.1 Omits redundant first paragraph and clarifies that the dose to individual members of the public from a licensed operation does not include doses received by individuals exposed to patients who were released by the licensee under the provisions of RHA 4.32, Title A.

61-63.3.2.66 Corresponding change made to definition for "occupational dose" to clarify that these doses do not include doses received by individuals exposed to patients who were released by the licensee under the provisions of RHA 4.32, Title A.

61-63.3.2.73 Corresponding change made to "public dose" as outlined in 61-63.3.2.66, above.

61-63.3.13.1.1 Clarification of the factors considered when determining the total effective dose equivalent to individual members of the public.

61-63.3.13.3 New section added to designate criteria for determining stay-time for visitors of through 3.13.3.2 patients not released under RHA 4.32.

61-63.3.13.3 Renumbered to 3.13.4 through 3.13.6.
through 3.13.5

(4) Complete revision to Part IV, Medical Use

SECTION REVISION

61-63.4.1 Delete current Part IV due to complete revision.
through 4.17.2.2

61-63.4.1 Replace Part IV in its entirety with new regulations for medical use. Revision is made through 4.119 in order to focus the regulations on those medical procedures that pose the highest risk to workers, patients, and the public.

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

Text:

Revise R.61-63.2.7.5.2.1 to read:

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.

Revise R.61-63.2.7.5.2.2.2 to read:

2.7.5.2.2.2 This individual meets the requirements specified in RHA 4.22.2 (or, for a period of two years following the effective date of these regulations, RHA 4.86.2) and 4.24 and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist, or

Revise R.61-63.2.7.5.2.2.3 to read:

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.

Revise R.61-63.2.7.5.2.4 to read:

2.7.5.2.4 May designate a pharmacist (as defined in RHA 4.2) as an authorized nuclear pharmacist if the individual is identified as of December 2, 1994, as an "authorized user" on a nuclear pharmacy license issued by the Department under this part.

Revise R.61-63.2.7.7.1 to read:

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 uses as a calibration or reference source or for the uses listed in RHA 4.46, 4.56, and 4.58 of Part IV of these regulations will be approved if:

Revise R.61-63.2.7.7.1.3 to read:

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.

Revise R.61-63.3.1 to read:

RHA 3.1 PURPOSE AND SCOPE

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.

Revise R.61-63.3.2.66 to read:

3.2.66 "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.

Revise R.61-63.3.2.73 to read:

3.2.73 "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.

Revise R.61-63.3.2.83 to read:

3.2.83 "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).

Revise R.61-63.3.5.1.2 to read:

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:

Revise R.61-63.3.5.1.2.2 to read:

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.

Revise R.61-63.3.5.3 to read:

3.5.3 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.

Revise R.61-63.3.13.1.1 to read:

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

Revise R.61-63.3.13.3 through 3.13.3.2 to read:

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.

Renumber existing R.61-63.3.13.3 to 3.13.4:

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:

Renumber existing R.61-63.3.13.3.1 to 3.13.4.1:

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;

Renumber existing R.61-63.3.13.3.2 to 3.13.4.2:

3.13.4.2 The licensee's program to assess and control dose within the 0.5 rem (5 mSv) annual limit; and

Renumber existing R.61-63.3.13.3.3 to 3.13.4.3:

3.13.4.3 The procedures to be followed to maintain the dose as low as is reasonably achievable.

Renumber existing R.61-63.3.13.4 to 3.13.5:

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.

Renumber existing R.61-63.3.13.5 to 3.13.6:

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.

Replace entire R.61-63. Part IV (R.61-63.4.1 through 4.17.2.2) to read:

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 "Authorized medical physicist" means an individual who--

4.2.4.1 Meets the requirements in RHA 4.21.1 and RHA 4.24; or

4.2.4.2 Is identified as an authorized medical physicist or teletherapy physicist on--

4.2.4.2.1 A specific medical use license issued by the NRC or an Agreement state;

4.2.4.2.2 A medical use permit issued by an NRC master material licensee;

4.2.4.2.3 A permit issued by an NRC or Agreement State broad scope medical use licensee; or

4.2.4.2.4 A permit issued by an NRC master material license broad scope medical use permittee.

4.2.5 "Authorized nuclear pharmacist" means a pharmacist who--

4.2.5.1 Meets the requirements in RHA 4.22.1 and RHA 4.24; or

4.2.5.2 Is identified as an authorized nuclear pharmacist on--

4.2.5.2.1 A specific license issued by the NRC or Agreement State that authorizes medical use or the practice of nuclear pharmacy; or

4.2.5.2.2 A permit issued by an NRC master material licensee that authorizes medical use or the practice of nuclear pharmacy; or

4.2.5.2.3 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

4.2.5.2.4 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

4.2.5.3 Is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or

4.2.5.4 Is designated as an authorized nuclear pharmacist in accordance with RHA 2.7.5.2.4.

4.2.6 "Authorized user" means a physician, dentist, or podiatrist who--

4.2.6.1 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

4.2.6.2 Is identified as an authorized user on--

4.2.6.2.1 An NRC or Agreement State license that authorizes the medical use of radioactive material;

4.2.6.2.2 A permit issued by an NRC master material licensee that is authorized to permit the medical use of radioactive material;

4.2.6.2.3 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

4.2.6.2.4 A permit issued by an NRC master material license broad scope permittee that is authorized to permit the medical use of radioactive material.

4.2.7 "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.

4.2.8 "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.

4.2.9 "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.

4.2.10 "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.

4.2.11 "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.

4.2.12 "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.

4.2.13 "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.

4.2.14 "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.

4.2.15 "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.

4.2.16 "Medical event" means an event that meets the criteria in RHA 4.117.1.

4.2.17 "Medical institution" means an organization in which more than one medical discipline is practiced.

4.2.18 "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.

4.2.19 "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.

4.2.20 "Mobile medical service" means the transportation of radioactive material to and its medical use at the client's address.

4.2.21 "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.

4.2.22 "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.

4.2.23 "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.

4.2.24 "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.

4.2.25 "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.

4.2.26 "Preceptor" means an individual who provides or directs 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.

4.2.27 "Prescribed dosage" means the specified activity or range of activity of unsealed radioactive material as documented--

4.2.27.1 In a written directive; or

4.2.27.2 In accordance with the directions of the authorized user for procedures performed pursuant to RHA 4.35 and 4.37.

4.2.28 "Prescribed dose" means--

4.2.28.1 For gamma stereotactic radiosurgery, the total dose as documented in the written directive;

4.2.28.2 For teletherapy, the total dose and dose per fraction as documented in the written directive;

4.2.28.3 For manual brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or

4.2.28.4 For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

4.2.29 "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--

4.2.29.1 Is approximately one-tenth of the activity of typical high dose-rate remote afterloader sources; and

4.2.29.2 Is used to simulate the radiobiology of a low dose-rate treatment by inserting the source for a given fraction of each hour.

4.2.30 "Radiation Safety Officer" means an individual who--

4.2.30.1 Meets the requirements in RHA 4.20.1 and RHA 4.24; or

4.2.30.2 Is identified as a Radiation Safety Officer on--

4.2.30.2.1 A specific medical use license issued by the NRC or Agreement State; or

4.2.30.2.2 A medical use permit issued by an NRC master material licensee.

4.2.31 "Sealed source" means any radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.

4.2.32 "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.

4.2.33 "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.

4.2.34 "Structured educational program" means an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.

4.2.35 "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.

4.2.36 "Temporary job" means a location where mobile medical services are conducted other than those location(s) of use authorized on the license.

4.2.37 "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.

4.2.38 "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.

4.2.39 "Treatment site" means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

4.2.40 "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.

4.2.41 "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.

4.2.42 "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.

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 radioactive 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, authorized user(s), authorized medical 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 requesting the amendment or renewal; 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 information regarding any radiation safety aspects of the medical use of the material that is not addressed in Subparts A through C of this part.

4.7.4.1 The applicant shall also provide specific information on:

4.7.4.1.1 Radiation safety precautions and instructions;

4.7.4.1.2 Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and

4.7.4.1.3 Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety.

4.7.4.2 The applicant or licensee shall also provide 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.

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 nuclear pharmacist, or authorized medical physicist under the license, except--

4.8.2.1 For an authorized user, an individual who meets the requirements in RHA 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, 4.74.1.1, 4.76, 4.77, 4.78, 4.79, 4.80, 4.81, 4.82, 4.83 or 4.84 and RHA 4.24;

4.8.2.2 For an authorized nuclear pharmacist, an individual who meets the requirements in RHA 4.22.1 or 4.86 and RHA 4.24;

4.8.2.3 For an authorized medical physicist, an individual who meets the requirements in RHA 4.21.1 or 4.85 and RHA 4.24

4.8.2.4 An individual who is identified as an authorized user, an authorized nuclear pharmacist, or authorized medical 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 receives radioactive material in excess of the amount or in a different form, or receives a different radionuclide than is authorized on the license;

4.8.5 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;

4.8.6 Before it changes the address(es) of use identified in the application or on the license; and

4.8.7 Before it revises procedures required by RHA 4.61, 4.67, 4.68 and 4.69, as applicable, where such revision reduces radiation safety.

RHA 4.9 NOTIFICATIONS

4.9.1 A licensee shall provide the Department a copy of the board certification, the NRC or Agreement State license, the permit issued by an NRC master material licensee, the permit issued by an NRC or Agreement State licensee of broad scope, or the permit issued by an NRC master material license broad scope permittee for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user, an authorized nuclear pharmacist, or an authorized medical physicist, under RHA 4.8.2.1 through 4.8.2.4.

4.9.2 A licensee shall notify the Department by letter no later than 30 days after:

4.9.2.1 An authorized user, an authorized nuclear pharmacist, a Radiation Safety Officer, or an authorized medical physicist permanently discontinues performance of duties under the license or has a name change;

4.9.2.2 The licensee's mailing address changes;

4.9.2.3 The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in RHA 2.15; or

4.9.2.4 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 4.37.

4.9.3 The licensee shall mail the documents required in this section to the appropriate address identified in RHA 1.13.

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 4.8.5 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 for an authorized user, an authorized nuclear pharmacist, or an authorized medical 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.

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 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.

4.13.3 For up to 60 days each year, a licensee may permit an authorized user or 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 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.

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 4.16 (RESERVED)

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; or

4.17.2.6 For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders:

4.17.2.6.1 Before implantation: treatment site, the radionuclide, and dose; and

4.17.2.6.2 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).

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.

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; and

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.

4.18.3 A licensee shall retain a copy of the procedures required under RHA 4.18.1 in accordance with RHA 4.92.

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

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

Except as provided in RHA 4.23, the licensee shall require an individual fulfilling the responsibilities of the 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 includes all of the requirements in RHA 4.20.2 and whose certification has been recognized by the NRC or an Agreement State; or

4.20.2 Has completed a structured educational program consisting of both:

4.20.2.1 200 hours of didactic 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 NRC or Agreement State license or on a permit issued by an NRC master material licensee that authorizes similar type(s) of use(s) of radioactive material involving 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

4.20.3 Has obtained written certification, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in RHA 4.20.2 and has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee; or

4.20.4 Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual has Radiation Safety Officer responsibilities.

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 includes all of the training and experience requirements in RHA 4.21.2 and whose certification has been recognized by the NRC or an Agreement State; or

4.21.2 Holds a master's or doctor's degree in physics, biophysics, radiological physics, medical physics, or health physics and has completed 1 year of full-time training in therapeutic radiological 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 at a medical institution that includes the tasks listed in RHA 4.29, 4.52, 4.64, 4.65, 4.66, 4.67, 4.68, 4.69 and 4.71 as applicable; and

4.21.3 Has obtained written certification that the individual has satisfactorily completed the requirements in RHA 4.21.2 and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written certification must be signed by a preceptor authorized medical physicist who meets the requirements in RHA 4.21 or equivalent NRC requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status.

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 as a nuclear pharmacist by a specialty board whose certification process includes all of the requirements in RHA 4.22.2 and whose certification has been recognized by the NRC or an Agreement State; or

4.22.2 Has completed 700 hours in a structured educational program consisting of both:

4.22.2.1 Didactic 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 certification, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in RHA 4.22.2 of this section and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

RHA 4.23 TRAINING FOR EXPERIENCED RADIATION SAFETY OFFICER, TELETHERAPY OR MEDICAL PHYSICIST, AUTHORIZED USER, AND NUCLEAR PHARMACIST

4.23.1 An individual identified as a Radiation Safety Officer, a teletherapy or medical physicist, or a nuclear pharmacist on an NRC or Agreement State license or a permit issued by an NRC or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope before the effective date of these regulations need not comply with the training requirements of RHA 4.20, 4.21 or 4.22, respectively.

4.23.2 Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material on a license issued by the NRC or Agreement State, a permit issued by an NRC master material licensee, a permit issued by an NRC or Agreement State broad scope licensee, or a permit issued by an NRC master material license broad scope permittee before the effective date of these regulations who perform only those medical uses for which they were authorized on that date need not comply with the training requirements of Subparts D-H of this part.

RHA 4.24 RECENTNESS OF TRAINING

The training and experience specified in Subparts B, D, E, F, G, H, and J 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 RADIOACTIVE 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; or

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.

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 a manufacturer or preparer licensed under RHA 2.7.5 or equivalent NRC 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 or equivalent NRC 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, 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.

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]

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[1]Department Regulatory Guide "Release of Patients Administered Radioactive Materials" describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 5 mSv (0.5 rem).

4.32.2 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.

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 120 days for decay-in-storage before disposal without regard to its radioactivity if it--

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 radioactive material prepared for medical use for uptake, dilution, or excretion studies that is--

4.35.1 Obtained from a manufacturer or preparer licensed under RHA 2.7.5 or equivalent NRC requirements;

4.35.2 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

4.35.3 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.

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 includes all of the requirements in RHA 4.36.3 and whose certification has been recognized by the NRC or an Agreement State; or

4.36.2 Is an authorized user under RHA 4.39 or 4.43 or equivalent NRC requirements; or
Has completed 60 hours of training and experience 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 4.36, 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 Calibrating 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

4.36.4 Has obtained written certification, signed by a preceptor authorized user who meets the requirements in RHA 4.36, 4.39 or 4.43 or equivalent NRC requirements, that the individual has satisfactorily completed the requirements in RHA 4.36.3 and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under RHA 4.35.

RHA 4.37 USE OF UNSEALED RADIOACTIVE 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 radioactive material prepared for medical use for imaging and localization studies that is--

4.37.1 Obtained from a manufacturer or preparer licensed under RHA 2.7.5 or equivalent NRC requirements;

4.37.2 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;

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 CONCENTRATION

4.38.1 A licensee may not administer to humans a radiopharmaceutical that contains more than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m).

4.38.2 A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration of the first eluate after receipt of a generator to demonstrate compliance with RHA 4.38.1.

4.38.3 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.

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 includes all of the requirements in RHA 4.39.3 and whose certification has been recognized by the NRC or an Agreement State; or

4.39.2 Is an authorized user under RHA 4.43 or equivalent NRC requirements; or

4.39.3 Has completed 700 hours of training and experience 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 4.39 or 4.43 or equivalent NRC requirements, involving--

4.39.3.2.1 Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

4.39.3.2.2 Calibrating 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

4.39.4 Has obtained written certification, signed by a preceptor authorized user who meets the requirements in RHA 4.39 or 4.43 or equivalent NRC requirements, that the individual has satisfactorily completed the requirements in RHA 4.39.3 and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under RHA 4.35 and 4.37.

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 prepared for medical use and for which a written directive is required that is--

4.40.1 Obtained from a manufacturer or preparer licensed under RHA 2.7.5 or equivalent NRC requirements; or

4.40.2 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.

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 includes all of the requirements in RHA 4.43.2 and whose certification has been recognized by the NRC or an Agreement State; or

4.43.2 Has completed 700 hours of training and experience 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 4.43.1, 4.43.2, or equivalent NRC requirements. A supervising authorized user, who meets the requirements in RHA 4.43.2, must have experience in administering dosages in the same dosage category or categories (i.e., RHA 4.43.2.2.7.1, 4.43.2.2.7.2, 4.43.2.2.7.3 or 4.43.2.2.7.4) 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 Calibrating 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 Eluting generator systems, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

4.43.2.2.7 Administering dosages of radioactive drugs to patients or human research subjects involving 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;

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 beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV; and/or

4.43.2.2.7.4 Parenteral administration of any other radionuclide; and

4.43.3 Has obtained written certification that the individual has satisfactorily completed the requirements in RHA 4.43.2 and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under RHA 4.40. The written certification must be signed by a preceptor authorized user who meets the requirements in RHA 4.43.1, 4.43.2, or equivalent NRC requirements. The preceptor authorized user, who meets the requirements in RHA 4.43.2, must have experience in administering dosages in the same dosage category or categories (i.e., RHA 4.43.2.2.7.1, 4.43.2.2.7.2, 4.43.2.2.7.3, or 4.43.2.2.7.4) as the individual requesting authorized user status.

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)

4.44.1 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--

4.44.1.1 Is certified by a medical specialty board whose certification process includes all of the requirements in RHA 4.44.1.3 and whose certification has been recognized by the NRC or an Agreement State; or

4.44.1.2 Is an authorized user under RHA 4.43.1, 4.43.2, 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

4.44.1.3 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--

4.44.1.3.1 Radiation physics and instrumentation;

4.44.1.3.2 Radiation protection;

4.44.1.3.3 Mathematics pertaining to the use and measurement of radioactivity;

4.44.1.3.4 Chemistry of radioactive material for medical use; and

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[2]Experience with at least 3 cases in RHA 4.43.2.2.7.2 also satisfies the requirement in RHA 4.43.2.2.7.1.

4.44.1.3.5 Radiation biology; and

4.44.1.4 Has work experience, under the supervision of an authorized user who meets the requirements in RHA 4.43.1, RHA 4.43.2, 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--

4.44.1.4.1 Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

4.44.1.4.2 Calibrating instruments used to determine the activity of dosages and performing checks for proper operation for survey meters;

4.44.1.4.3 Calculating, measuring, and safely preparing patient or human research subject dosages;

4.44.1.4.4 Using administrative controls to prevent a medical event involving the use of radioactive material;

4.44.1.4.5 Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

4.44.1.4.6 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

4.44.1.5 Has obtained written certification that the individual has satisfactorily completed the requirements in RHA 4.44.1.3 and 4.44.1.4 and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under RHA 4.40. The written certification must be signed by a preceptor authorized user who meets the requirements in RHA 4.43.1, 4.43.2, 4.44, 4.45 or equivalent NRC requirements. A preceptor authorized user, who meets the requirement 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.

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)

4.45.1 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--

4.45.1.1 Is certified by a medical specialty board whose certification process includes all of the requirements in RHA 4.45.1.3 and whose certification has been recognized by the NRC or an Agreement State; or

4.45.1.2 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

4.45.1.3 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--

4.45.1.3.1 Radiation physics and instrumentation;

4.45.1.3.2 Radiation protection;

4.45.1.3.3 Mathematics pertaining to the use and measurement of radioactivity;

4.45.1.3.4 Chemistry of radioactive material for medical use; and

4.45.1.3.5 Radiation biology; and

4.45.1.4 Has work experience, under the supervision of an authorized user who meets the requirements in RHA 4.43.1, 4.43.2, 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 4.43.2.2.7.2. The work experience must involve--

4.45.1.4.1 Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

4.45.1.4.2 Calibrating instruments used to determine the activity of dosages and performing checks for proper operation for survey meters;

4.45.1.4.3 Calculating, measuring, and safely preparing patient or human research subject dosages;

4.45.1.4.4 Using administrative controls to prevent a medical event involving the use of radioactive material;

4.45.1.4.5 Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

4.45.1.4.6 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

4.45.1.5 Has obtained written certification that the individual has satisfactorily completed the requirements in RHA 4.45.1.3 and 4.45.1.4 and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under RHA 4.40. The written certification must be signed by a preceptor authorized user who meets the requirements in RHA 4.43.1, RHA 4.43.2, RHA 4.45 or equivalent NRC requirements. A preceptor authorized user, who meets the requirements in RHA 4.43.2, must have experience in administering dosages as specified in RHA 4.43.2.2.7.2.

SUBPART F--MANUAL BRACHYTHERAPY

RHA 4.46 USE OF SOURCES FOR MANUAL BRACHYTHERAPY

4.46.1 A licensee shall use only brachytherapy sources for therapeutic medical uses:

4.46.1.1 As approved in the Sealed Source and Device Registry; or

4.46.1.2 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.

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 DECAY OF STRONTIUM-90 SOURCES FOR OPHTHALMIC TREATMENTS

4.52.1 Only an authorized medical physicist shall 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.

4.52.2 A licensee shall retain a record of the activity of each strontium-90 source in accordance with RHA 4.106.

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

4.54.1 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--

4.54.1.1 Is certified by a medical specialty board whose certification process includes all of the requirements in RHA 4.54.1.2 and whose certification has been recognized by the NRC or an Agreement State; or

4.54.1.2 Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes--

4.54.1.2.1 200 hours of classroom and laboratory training in the following areas:

4.54.1.2.1.1 Radiation physics and instrumentation;

4.54.1.2.1.2 Radiation protection;

4.54.1.2.1.3 Mathematics pertaining to the use and measurement of radioactivity; and

4.54.1.2.1.4 Radiation biology; and

4.54.1.2.2 500 hours of work experience, under the supervision of an authorized user who meets the requirements in RHA 4.54 or equivalent NRC requirements at a medical institution, involving--

4.54.1.2.2.1 Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

4.54.1.2.2.2 Checking survey meters for proper operation;

4.54.1.2.2.3 Preparing, implanting, and removing brachytherapy sources;

4.54.1.2.2.4 Maintaining running inventories of material on hand;

4.54.1.2.2.5 Using administrative controls to prevent a medical event involving the use of radioactive material;

4.54.1.2.2.6 Using emergency procedures to control radioactive material; and

4.54.1.3 Has obtained 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in RHA 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 Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by RHA 4.54.1.2.2; and

4.54.1.4 Has obtained written certification, signed by a preceptor authorized user who meets the requirements in RHA 4.54 or equivalent NRC requirements, that the individual has satisfactorily completed the requirements in RHA 4.54.1.2 and RHA 4.54.1.3 and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under RHA 4.46.

RHA 4.55 TRAINING FOR OPHTHALMIC USE OF STRONTIUM-90

4.55.1 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--

4.55.1.1 Is an authorized user under RHA 4.54 or equivalent NRC requirements; or

4.55.1.2 Has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training must include--

4.55.1.2.1 Radiation physics and instrumentation;

4.55.1.2.2 Radiation protection;

4.55.1.2.3 Mathematics pertaining to the use and measurement of radioactivity; and

4.55.1.2.4 Radiation biology; and

4.55.1.3 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--

4.55.1.3.1 Examination of each individual to be treated;

4.55.1.3.2 Calculation of the dose to be administered;

4.55.1.3.3 Administration of the dose; and

4.55.1.3.4 Follow up and review of each individual's case history; and

4.55.1.4 Has obtained written certification, signed by a preceptor authorized user who meets the requirements in RHA 4.54, 4.55, or equivalent NRC requirements, that the individual has satisfactorily completed the requirements in RHA 4.55.1.1 and 4.55.1.2 and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

SUBPART G--SEALED SOURCES FOR DIAGNOSIS

RHA 4.56 USE OF SEALED SOURCES FOR DIAGNOSIS

A licensee shall use only sealed sources for diagnostic medical uses as approved in the NRC Sealed Source and Device Registry.

RHA 4.57 TRAINING FOR USE OF SEALED SOURCES FOR DIAGNOSIS

4.57.1 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--

4.57.1.1 Is certified by a specialty board whose certification process includes all of the requirements in RHA 4.57.1.2 and whose certification has been recognized by the NRC or an Agreement State; or

4.57.1.2 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--

4.57.1.2.1 Radiation physics and instrumentation;

4.57.1.2.2 Radiation protection;

4.57.1.2.3 Mathematics pertaining to the use and measurement of radioactivity;

4.57.1.2.4 Radiation biology; and

4.57.1.2.5 Training in the use of the device for the uses requested.

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 shall use sealed sources in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units for therapeutic medical uses:

4.58.1.1 As approved in the NRC Sealed Source and Device Registry; or

4.58.1.2 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.

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 A licensee shall provide instruction, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties, in--

4.61.4.1 The procedures identified in RHA 4.61.1.4; and

4.61.4.2 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 in accordance with RHA 4.108.

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 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 FIVE-YEAR INSPECTION 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 source replacement or at intervals not to exceed 5 years, whichever comes first, to assure proper functioning of the source exposure mechanism.

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.

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

4.74.1 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--

4.74.1.1 Is certified by a medical specialty board whose certification process includes all of the requirements in RHA 4.74.1.2 and whose certification has been recognized by the NRC or an Agreement State; or

4.74.1.2 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--

4.74.1.2.1 200 hours of classroom and laboratory training in the following areas--

4.74.1.2.1.1 Radiation physics and instrumentation;

4.74.1.2.1.2 Radiation protection;

4.74.1.2.1.3 Mathematics pertaining to the use and measurement of radioactivity; and

4.74.1.2.1.4 Radiation biology; and

4.74.1.2.2 500 hours of work experience, under the supervision of an authorized user who meets the requirements in RHA 4.74 or equivalent NRC requirements at a medical institution, involving--

4.74.1.2.2.1 Reviewing full calibration measurements and periodic spot-checks;
4.74.1.2.2.2 Preparing treatment plans and calculating treatment doses and times;

4.74.1.2.2.3 Using administrative controls to prevent a medical event involving the use of radioactive material;

4.74.1.2.2.4 Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;

4.74.1.2.2.5 Checking and using survey meters; and

4.74.1.2.2.6 Selecting the proper dose and how it is to be administered; and

4.74.1.3 Has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in RHA 4.74 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 Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by RHA 4.74.1.2.2; and

4.74.1.4 Has obtained written certification that the individual has satisfactorily completed the requirements in RHA 4.74.1.2 and 4.74.1.3 and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written certification must be signed by a preceptor authorized user who meets the requirements in RHA 4.74 or equivalent NRC requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status.

SUBPART J--TRAINING AND EXPERIENCE REQUIREMENTS

RHA 4.75 RADIATION SAFETY OFFICER

Except as provided in RHA 4.23, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in RHA 4.13 to be an individual who--

4.75.1 Is certified by the--

4.75.1.1 American Board of Health Physics in Comprehensive Health Physics; or

4.75.1.2 American Board of Radiology; or

4.75.1.3 American Board of Nuclear Medicine; or

4.75.1.4 American Board of Science in Nuclear Medicine; or

4.75.1.5 Board of Pharmaceutical Specialties in Nuclear Pharmacy; or

4.75.1.6 American Board of Medical Physics in radiation oncology physics; or

4.75.1.7 Royal College of Physicians and Surgeons of Canada in nuclear medicine; or

4.75.1.8 American Osteopathic Board of Radiology; or

4.75.1.9 American Osteopathic Board of Nuclear Medicine; or

4.75.2 Has had classroom and laboratory training and experience as follows--

4.75.2.1 200 hours of classroom and laboratory training that includes--

4.75.2.1.1 Radiation physics and instrumentation;

4.75.2.1.2 Radiation protection;

4.75.2.1.3 Mathematics pertaining to the use and measurement of radioactivity;

4.75.2.1.4 Radiation biology; and

4.75.2.1.5 Radiopharmaceutical chemistry; and

4.75.2.2 One year of full time experience as a radiation safety technologist at a medical institution under the supervision of the individual identified as the Radiation Safety Officer on an NRC or Agreement State license that authorizes the medical use of radioactive material; or

4.75.3 Is an authorized user identified on the licensee's license.

RHA 4.76 TRAINING FOR UPTAKE, DILUTION, AND EXCRETION STUDIES

Except as provided in RHA 4.23, the licensee shall require the authorized user of a radiopharmaceutical in RHA 4.35.1 to be a physician who--

4.76.1 Is certified in--

4.76.1.1 Nuclear medicine by the American Board of Nuclear Medicine; or

4.76.1.2 Diagnostic radiology by the American Board of Radiology; or

4.76.1.3 Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or

4.76.1.4 Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

4.76.1.5 American Osteopathic Board of Nuclear Medicine in nuclear medicine; or

4.76.2 Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, and supervised clinical experience as follows--

4.76.2.1 40 hours of classroom and laboratory training that includes--

4.76.2.1.1 Radiation physics and instrumentation;

4.76.2.1.2 Radiation protection;

4.76.2.1.3 Mathematics pertaining to the use and measurement of radioactivity;

4.76.2.1.4 Radiation biology; and

4.76.2.1.5 Radiopharmaceutical chemistry; and

4.76.2.2 20 hours of supervised clinical experience under the supervision of an authorized user and that includes--

4.76.2.2.1 Examining patients or human research subjects and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;

4.76.2.2.2 Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

4.76.2.2.3 Administering dosages to patients or human research subjects and using syringe radiation shields;

4.76.2.2.4 Collaborating with the authorized user in the interpretation of radioisotope test results; and

4.76.2.2.5 Patient or human research subject follow up; or

4.76.3 Has successfully completed a 6-month training program in nuclear medicine as part of a training program that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in RHA 4.76.2.

RHA 4.77 TRAINING FOR IMAGING AND LOCALIZATION STUDIES

Except as provided in RHA 4.23, the licensee shall require the authorized user of a radiopharmaceutical, generator, or reagent kit in RHA 4.37.1 to be a physician who--

4.77.1 Is certified in--

4.77.1.1 Nuclear medicine by the American Board of Nuclear Medicine; or

4.77.1.2 Diagnostic radiology by the American Board of Radiology; or

4.77.1.3 Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or

4.77.1.4 Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

4.77.1.5 American Osteopathic Board of Nuclear Medicine in nuclear medicine; or

4.77.2 Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, generators, and reagent kits, supervised work experience, and supervised clinical experience as follows--

4.77.2.1 200 hours of classroom and laboratory training that includes--

4.77.2.1.1 Radiation physics and instrumentation;
4.77.2.1.2 Radiation protection;

4.77.2.1.3 Mathematics pertaining to the use and measurement of radioactivity;

4.77.2.1.4 Radiopharmaceutical chemistry; and

4.77.2.1.5 Radiation biology; and

4.77.2.2 500 hours of supervised work experience under the supervision of an authorized user that includes--

4.77.2.2.1 Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

4.77.2.2.2 Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;

4.77.2.2.3 Calculating and safely preparing patient or human research subject dosages;

4.77.2.2.4 Using administrative controls to prevent a medical event involving radioactive material;

4.77.2.2.5 Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

4.77.2.2.6 Eluting technetium-99m from generator systems, measuring and testing the eluate for molybdenum-99 and alumina contamination, and processing the eluate with reagent kits to prepare technetium-99m labeled radiopharmaceuticals; and

4.77.2.3 500 hours of supervised clinical experience under the supervision of an authorized user that includes--

4.77.2.3.1 Examining patients or human research subjects and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;

4.77.2.3.2 Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

4.77.2.3.3 Administering dosages to patients or human research subjects and using syringe radiation shields;

4.77.2.3.4 Collaborating with the authorized user in the interpretation of radioisotope test results; and

4.77.2.3.5 Patient or human research subject follow up; or

4.77.3 Has successfully completed a 6-month training program in nuclear medicine that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in RHA 4.77.2

RHA 4.78 TRAINING FOR THERAPEUTIC USE OF UNSEALED RADIOACTIVE MATERIAL

Except as provided in RHA 4.23, the licensee shall require the authorized user of radiopharmaceuticals in RHA 4.40 to be a physician who--

4.78.1 Is certified by--

4.78.1.1 The American Board of Nuclear Medicine; or

4.78.1.2 The American Board of Radiology in radiology, therapeutic radiology, or radiation oncology; or

4.78.1.3 The Royal College of Physicians and Surgeons of Canada in nuclear medicine; or

4.78.1.4 The American Osteopathic Board of Radiology after 1984; or

4.78.2 Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of therapeutic radiopharmaceuticals, and supervised clinical experience as follows--

4.78.2.1 80 hours of classroom and laboratory training that includes--

4.78.2.1.1 Radiation physics and instrumentation;

4.78.2.1.2 Radiation protection;

4.78.2.1.3 Mathematics pertaining to the use and measurement of radioactivity; and

4.78.2.1.4 Radiation biology; and

4.78.2.2 Supervised clinical experience under the supervision of an authorized user at a medical institution that includes--

4.78.2.2.1 Use of iodine-131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in 10 individuals; and

4.78.2.2.2 Use of iodine-131 for treatment of thyroid carcinoma in 3 individuals.

RHA 4.79 TRAINING FOR TREATMENT OF HYPERTHYROIDISM

Except as provided in RHA 4.23, the licensee shall require the authorized user of only iodine-131 for the treatment of hyperthyroidism to be a physician with special experience in thyroid disease who has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of iodine-131 for treating hyperthyroidism, and supervised clinical experience as follows--

4.79.1 80 hours of classroom and laboratory training that includes--

4.79.1.1 Radiation physics and instrumentation;

4.79.1.2 Radiation protection;

4.79.1.3 Mathematics pertaining to the use and measurement of radioactivity; and

4.79.1.4 Radiation biology; and

4.79.2 Supervised clinical experience under the supervision of an authorized user that includes the use of iodine-131 for diagnosis of thyroid function, and the treatment of hyperthyroidism in 10 individuals.

RHA 4.80 TRAINING FOR TREATMENT OF THYROID CARCINOMA

Except as provided in RHA 4.23, the licensee shall require the authorized user of only iodine-131 for the treatment of thyroid carcinoma to be a physician with special experience in thyroid disease who has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of iodine-131 for treating thyroid carcinoma, and supervised clinical experience as follows--

4.80.1 80 hours of classroom and laboratory training that includes--

4.80.1.1 Radiation physics and instrumentation;

4.80.1.2 Radiation protection;

4.80.1.3 Mathematics pertaining to the use and measurement of radioactivity; and

4.80.1.4 Radiation biology; and

4.80.2 Supervised clinical experience under the supervision of an authorized user that includes the use of iodine-131 for the treatment of thyroid carcinoma in 3 individuals.

RHA 4.81 TRAINING FOR USE OF BRACHYTHERAPY SOURCES

Except as provided in RHA 4.23, the licensee shall require the authorized user of a brachytherapy source listed in RHA 4.46 for therapy to be a physician who--

4.81.1 Is certified in--

4.81.1.1 Radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; or

4.81.1.2 Radiation oncology by the American Osteopathic Board of Radiology; or

4.81.1.3 Radiology, with specialization in radiotherapy, as a British “Fellow of the Faculty of Radiology” or “Fellow of the Royal College of Radiology”; or

4.81.1.4 Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

4.81.2 Is in the active practice of therapeutic radiology, has had classroom and laboratory training in radioisotope handling techniques applicable to the therapeutic use of brachytherapy sources, supervised work experience, and supervised clinical experience as follows--

4.81.2.1 200 hours of classroom and laboratory training that includes--

4.81.2.1.1 Radiation physics and instrumentation;

4.81.2.1.2 Radiation protection;

4.81.2.1.3 Mathematics pertaining to the use and measurement of radioactivity; and

4.81.2.1.4 Radiation biology; and

4.81.2.2 500 hours of supervised work experience under the supervision of an authorized user at a medical institution that includes--

4.81.2.2.1 Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

4.81.2.2.2 Checking survey meters for proper operation;

4.81.2.2.3 Preparing, implanting, and removing sealed sources;

4.81.2.2.4 Maintaining running inventories of material on hand;

4.81.2.2.5 Using administrative controls to prevent a medical event involving radioactive material; and

4.81.2.2.6 Using emergency procedures to control radioactive material; and

4.81.2.3 Three years of supervised clinical experience that includes one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association, and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution that includes--

4.81.2.3.1 Examining individuals and reviewing their case histories to determine their suitability for brachytherapy treatment, and any limitation or contraindications; and

4.81.2.3.2 Selecting the proper brachytherapy sources and dose and method of administration; and

4.81.2.3.3 Calculating the dose; and

4.81.2.3.4 Post-administration follow up and review of case histories in collaboration with the authorized user.

RHA 4.82 TRAINING FOR OPHTHALMIC USE OF STRONTIUM-90

Except as provided in RHA 4.23, the licensee shall require the authorized user of only strontium-90 for ophthalmic radiotherapy to be a physician who is in the active practice of therapeutic radiology or ophthalmology, and has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of strontium-90 for ophthalmic radiotherapy, and a period of supervised clinical training in ophthalmic radiotherapy as follows--

4.82.1 24 hours of classroom and laboratory training that includes--

4.82.1.1 Radiation physics and instrumentation;

4.82.1.2 Radiation protection;

4.82.1.3 Mathematics pertaining to the use and measurement of radioactivity; and

4.82.1.4 Radiation biology; and

4.82.2 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 that includes--

4.82.2.1 Examination of each individual to be treated;

4.82.2.2 Calculation of the dose to be administered;

4.82.2.3 Administration of the dose; and

4.82.2.4 Follow up and review of each individual's case history.

RHA 4.83 TRAINING FOR USE OF SEALED SOURCES FOR DIAGNOSIS

Except as provided in RHA 4.23, the licensee shall require the authorized user of a sealed source in a device listed in RHA 4.56 to be a physician, dentist, or podiatrist who--

4.83.1 Is certified in--

4.83.1.1 Radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; or

4.83.1.2 Nuclear medicine by the American Board of Nuclear Medicine; or

4.83.1.3 Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or

4.83.1.4 Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

4.83.2 Has had 8 hours of classroom and laboratory training in basic radioisotope handling techniques specifically applicable to the use of the device that includes--

4.83.2.1 Radiation physics, mathematics pertaining to the use and measurement of radioactivity, and instrumentation;

4.83.2.2 Radiation biology;

4.83.2.3 Radiation protection; and

4.83.2.4 Training in the use of the device for the uses requested.

RHA 4.84 TRAINING FOR USE OF THERAPEUTIC MEDICAL DEVICES

Except as provided in RHA 4.23, the licensee shall require the authorized user of a sealed source listed in RHA 4.58 to be a physician who--

4.84.1 Is certified in--

4.84.1.1 Radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; or

4.84.1.2 Radiation oncology by the American Osteopathic Board of Radiology; or

4.84.1.3 Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

4.84.1.4 Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

4.84.2 Is in the active practice of therapeutic radiology, and has had classroom and laboratory training in basic radioisotope techniques applicable to the use of a sealed source in a therapeutic medical device, supervised work experience, and supervised clinical experience as follows--

4.84.2.1 200 hours of classroom and laboratory training that includes--

4.84.2.1.1 Radiation physics and instrumentation;

4.84.2.1.2 Radiation protection;

4.84.2.1.3 Mathematics pertaining to the use and measurement of radioactivity; and

4.84.2.1.4 Radiation biology;

4.84.2.2 500 hours of supervised work experience under the supervision of an authorized user at a medical institution that includes--

4.84.2.2.1 Review of the full calibration measurements and periodic spot-checks;

4.84.2.2.2 Preparing treatment plans and calculating treatment times;

4.84.2.2.3 Using administrative controls to prevent medical events;

4.84.2.2.4 Implementing emergency procedures to be followed in the event of the abnormal operation of the medical device or console; and

4.84.2.2.5 Checking and using survey meters; and

4.84.2.3 Three years of supervised clinical experience that includes one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution that includes--

4.84.2.3.1 Examining individuals and reviewing their case histories to determine their suitability for teletherapy, remote afterloader, or gamma stereotactic radiosurgery treatment, and any limitations or contraindications;

4.84.2.3.2 Selecting the proper dose and how it is to be administered;

4.84.2.3.3 Calculating the doses and collaborating with the authorized user in the review of patients' or human research subjects' progress and consideration of the need to modify originally prescribed doses as warranted by patients' or human research subjects' reaction to radiation; and

4.84.2.3.4 Post-administration follow up and review of case histories.

RHA 4.85 TRAINING FOR AUTHORIZED MEDICAL PHYSICIST

The licensee shall require the authorized medical physicist to be an individual who--

4.85.1 Is certified by the American Board of Radiology in--

4.85.1.1 Therapeutic radiological physics; or

4.85.1.2 Roentgen ray and gamma ray physics; or

4.85.1.3 X-ray and radium physics; or

4.85.1.4 Radiological physics; or

4.85.2 Is certified by the American Board of Medical Physics in radiation oncology physics; or

4.85.3 Holds a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and has completed 1 year of full time training in therapeutic radiological physics and an additional year of full time work experience under the supervision of a medical physicist at a medical institution that includes the tasks listed in RHA 4.29, 4.64, 4.65, 4.66, 4.67, 4.68, 4.69 and 4.71, as applicable.

RHA 4.86 TRAINING FOR AN AUTHORIZED NUCLEAR PHARMACIST

The licensee shall require the authorized nuclear pharmacist to be a pharmacist who--

4.86.1 Has current board certification as a nuclear pharmacist by the Board of Pharmaceutical Specialties; or

4.86.2 Has completed 700 hours in a structured educational program consisting of both--

4.86.2.1 Didactic training in the following areas:

4.86.2.1.1 Radiation physics and instrumentation;

4.86.2.1.2 Radiation protection;

4.86.2.1.3 Mathematics pertaining to the use and measurement of radioactivity;
4.86.2.1.4 Chemistry of radioactive material for medical use; and

4.86.2.1.5 Radiation biology; and

4.86.2.2 Supervised experience in a nuclear pharmacy involving the following--

4.86.2.2.1 Shipping, receiving, and performing related radiation surveys;

4.86.2.2.2 Using and performing checks for proper operation of dose calibrators, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;

4.86.2.2.3 Calculating, assaying, and safely preparing dosages for patients or human research subjects;

4.86.2.2.4 Using administrative controls to avoid mistakes in the administration of radioactive material;

4.86.2.2.5 Using procedures to prevent or minimize contamination and using proper decontamination procedures; and

4.86.3 Has obtained written certification, signed by a preceptor authorized nuclear pharmacist, that the above training has been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

RHA 4.87 TRAINING FOR EXPERIENCED NUCLEAR PHARMACISTS

A licensee may apply for and must receive a license amendment identifying an experienced nuclear pharmacist as an authorized nuclear pharmacist before it allows this individual to work as an authorized nuclear pharmacist. A pharmacist who has completed a structured educational program as specified in RHA 4.86.2 before December 2, 1994, and who is working in a nuclear pharmacy would qualify as an experienced nuclear pharmacist. An experienced nuclear pharmacist need not comply with the requirements for a preceptor statement (RHA 4.86.3) and recentness of training (RHA 4.24) to qualify as an authorized nuclear pharmacist.

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.

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 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.

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 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 MOBIILE 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 5-YEAR INSPECTION FOR TELETHERAPY AND GAMMA STEREOTACTIC RADIOSURGERY UNITS

4.116.1 A licensee shall maintain a record of the 5-year inspections 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.

SUBPART M--REPORTS

RHA 4.117 REPORT AND NOTIFICATION OF A MEDICAL EVENT

4.117.1 A licensee shall report any event, except for an event that results from patient intervention, in which the administration of radioactive material or radiation from radioactive material results in--

4.117.1.1 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 The total dose delivered differs from the prescribed dose by 20 percent or more; or

4.117.1.1.2 The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

4.117.1.1.3 The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

4.117.1.2 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--

4.117.1.2.1 An administration of a wrong radioactive drug containing radioactive material; or

4.117.1.2.2 An administration of a radioactive drug containing radioactive material by the wrong route of administration; or

4.117.1.2.3 An administration of a dose or dosage to the wrong individual or human research subject; or

4.117.1.2.4 An administration of a dose or dosage delivered by the wrong mode of treatment; or

4.117.1.2.5 A leaking sealed source.

4.117.1.3 A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

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;

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[3]The commercial telephone number of the Bureau of Radiological Health is (803) 545-4400.

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 Social security number or other identification number, if one has been assigned, 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.

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 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 Social security number or other identification number, if one has been assigned, of the pregnant individual or the nursing child 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.

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.

Statement of Need and Reasonableness:

The statement of need and reasonableness was determined based on staff analysis pursuant to S.C. Code Section 1-23-115(c)(1)-(3) and (9)-(11):

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

Purpose: To amend Regulation 61-63 in accordance with changes to Federal Regulation 10 CFR Part 20, 32, and 35.

Legal Authority: This change to state law is authorized by S.C. Code Section 13-7-40 and required by Section 274 of the Atomic Energy Act, 40 U.S.C. Section 2021b.

Plan for Implementation: Existing staff of the Bureau of Radiological Health will implement these changes. The additional requirements are expected to require 30 man days of effort. Impact on other program areas will be slight.

DETERMINATION OF NEED AND REASONABLENESS OF THE REGULATION AND EXPECTED BENEFIT: This regulatory amendment is exempt from the requirements of a Preliminary Fiscal Impact Statement or a Preliminary Assessment Report because each change is necessary to maintain compatibility with Federal regulations. In amending the Federal regulations, the U.S. Nuclear Regulatory Commission found the following:

These regulations provide new requirements for calculating the skin dose limit.

These regulations amend in their entirety the regulations governing the medical use of radioactive material.

DETERMINATION OF COSTS AND BENEFITS: No additional cost will be incurred by the State or its political subdivisions by the implementation of this amendment. Existing staff and resources will be utilized to implement this amendment to the regulation. It is anticipated that the amendment will not create any significant additional cost to the regulated community based on the fact that requirements or changes to the regulation will be substantially consistent with the current guidelines and review guidelines utilized by the Department.

UNCERTAINTIES OF ESTIMATES: None.

EFFECT ON ENVIRONMENT AND PUBLIC HEALTH: It is necessary to update existing regulations as changes occur at the federal level in order to maintain compatibility with the federal government and other Agreement States. This will ensure an effective regulatory program for radioactive material users under state jurisdiction, and protection of the public and workers 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.

Resubmitted March 9, 2005

Document No. 2903
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61
Statutory Authority: 1976 Code Section 48-1-10 et seq.

61-110. Total Maximum Daily Loads for Pollutants in Water.

Synopsis:

Section 303(d) of the Federal Water Pollution Control Act (33 USC Section 1313(d)) requires States to establish the total loading that a water can receive without violating State water quality standards for waters that do not meet them.

This regulation defines the term "Total Maximum Daily Load" (TMDL) and defines the administrative appeal process for TMDLs. In addition, the regulation provides for public notice, public hearing, and notice of proposed decision, and addresses revisions to approved TMDLs.

Changes requested by the House Agriculture, Natural Resources and Environmental Affairs Committee:

SECTION	CHANGE
61-110.C(1)	Requirement for responsiveness summary added.
61-110.C(2)	Provision for comment period extension requests added.
61-110.D(2)	Provision for hearing at request of elected or appointed body added.
61-110.F(2)	Correction of number of days within which a TMDL may be appealed.

Discussion:

Sections A and B address the purpose and scope of the regulation, and definitions.

Sections C through F address provisions for public participation, public hearings, notices of proposed decisions, and the administrative appeals process.

Section G addresses revisions to an approved TMDL.

Instructions:

Add new regulation R.61-110, Total Maximum Daily Loads for Pollutants in Water, to Chapter 61 regulations.

Text:

R.61-110. Total Maximum Daily Loads for Pollutants in Water.

Table of Contents:

A. Purpose and Scope.
B. Definitions.
C. Public Notice.
D. Public Informational Hearing.
E. Notice of Proposed Decision.
F. Administrative Appeal Process.
G. Revisions to an Approved TMDL
H. Severability.

A. Purpose and Scope.

(1) Section 48-1-50(20), S.C. Code of Laws (1976), authorizes the Department to conduct investigations of conditions in the air or waters of the State to determine whether or not standards are being contravened and the origin of materials which are causing the polluted condition. Section 48-1-50(6) authorizes the Department to conduct studies, investigations and research with respect to pollution abatement, control or prevention.

(2) The Department establishes Total Maximum Daily Loads (TMDLs) for pollutants in waters of the state, including those listed in accordance with the Federal Water Pollution Control Act (Public Law 92 500, as amended by Pub. L. 95-217, Pub. L. 95-276, Pub. L. 96-483, Pub. L. 97-117, and Pub. L. 100-4; 33 U.S.C. 1251 et seq.) Section 303(d) (33 USC Section 1313(d)) and 40 CFR Part 130. These regulations establish the process for public participation in and administrative appeal of TMDLs developed under section 303(d) of the Act.

B. Definitions.

(1) Other than those terms defined below, any term used in this regulation shall mean the same as defined in S.C. Regulation 61-68 or Section 48-1-10 et seq. of the Code of Laws, 1976, as amended.

(2) "Total Maximum Daily Load" (TMDL) means a written quantitative analysis of water quality for a pollutant at one or more sites in a watershed. A TMDL shall include identification of the pollutant, a calculation of the maximum amount of the pollutant that a waterbody can receive and still meet state water quality standards, load allocations for nonpoint sources and natural background, individual or categorical wasteload allocations for point sources, and a margin of safety.

(3) "Margin of safety" means a consideration of any lack of knowledge concerning the relationship between load and wasteload allocations and water quality. The margin of safety may be implicit, i.e., incorporated into the TMDL through conservative assumptions in the analysis, or explicit, i.e., expressed in the TMDL as a specific loading, or both. If the margin of safety is implicit, the conservative assumptions in the analysis that

account for it shall be described. If the margin of safety is explicit, the loading set aside shall be identified. The Department shall present a detailed justification and rationale for use of the selected margin of safety.

C. Public Notice

(1) A notice will be published on the Department website or equivalent publicly available electronic media, when available, upon commencement of development of each TMDL, until such time as a draft is completed or the Department elects not to proceed with TMDL development, to solicit data and information in support of TMDL development. All data and information submitted, including characterizations of local conditions that affect attainment of water quality standards, shall be considered by the department before completing the TMDL and answered in a responsiveness summary that would be included in the TMDL.

(2) A public notice of each initial draft TMDL shall provide at least thirty (30) days from the date of notice within which interested persons may submit their views and information concerning the TMDL to the Department. The comment period shall be extended for an additional 30 days if a request is made in the initial 30 day comment period by any party, including an affected local public body. Comments will be considered in development of the final draft TMDL and addressed in a responsiveness summary, which will be provided to all commenters.

(3) Public notice of the draft TMDL shall be made by each of the following methods:

(a) publication of a notice in a daily or weekly newspaper within or near the area included in the TMDL; and

(b) notification of anyone who has specifically requested public notices. The list of such persons may be updated periodically and persons will be deleted who fail to respond to Department requests to identify continued interest; and

(c) publication on the Department website or equivalent publicly available electronic media, when available.

(4) All information supporting the TMDL, such as, but not limited to, data, models, inputs, and output, shall be available upon request from the outset of the public comment period.

D. Public Informational Hearing

(1) Any person may request a public informational hearing during the public comment period discussed in Article C.(1) above. Requests shall be in writing and shall state the nature of the issues to be raised at the informational hearing.

(2) The Department shall hold a public informational hearing upon request through an affirmative vote by an elected or appointed public body, or whenever fifteen (15) or more individual written requests are received during the public comment period and which raise issues specifically related to the development of the TMDL. An informational hearing may also be held whenever the Department staff determines that it may be beneficial. Such informational hearing will be conducted by Department staff.

(3) A notice of informational hearing shall be mailed to those persons providing comment in response to the public notice at least fifteen (15) days prior to the informational hearing.

(4) The close of the comment period shall be at the end of the informational hearing or later date if so specified by the Department.

(5) All public informational hearings shall be reported verbatim. A copy of the transcript shall be made available upon request.

E. Notice of Proposed Decision

Department staff shall issue a notice of proposed decision to submit a TMDL to the U.S. Environmental Protection Agency for approval. Such notice shall advise of availability of the final draft TMDL and related file information. Such notice shall be made available to those persons providing comment in response to the public notice and to those persons participating at an informational hearing.

F. Administrative Appeal Process

(1) The Notice of Proposed Decision may be appealed as a contested case in accordance with S.C. Regulation 61-72 and the S.C. Administrative Procedures Act.

(2) A person desiring to appeal a TMDL must submit a written request for an adjudicatory hearing to the Clerk of the Board of Health and Environmental Control within thirty (30) days after the date of the notice of proposed decision. The request must set forth the manner in which the person requesting the hearing would be injured by issuance of the TMDL. If no appeal of the proposed decision is timely received, the proposed decision of the Department shall become final.

(3) Upon timely request for a hearing, the matter shall be heard as a "contested case" under the South Carolina Administrative Procedures Act, and shall be processed according to law. Determinations of whether a person has legal standing to contest a determination shall be made in the course of the contested case proceeding.

G. Revisions to an Approved TMDL

The Department may revise an approved TMDL to accommodate new information. Revisions to load or wasteload allocations in approved TMDLs shall be subject to the same public participation and administrative appeal processes set forth herein.

H. Severability

Should any section, paragraph, sentence, word, clause or phrase of this regulation be declared unconstitutional or invalid for any reason, the remainder of this regulation shall not be affected thereby.

Fiscal Impact Statement:

The Department estimates no additional cost will be incurred to the state or its political subdivisions by the implementation of this regulation; therefore, no additional state funding is being requested. Existing staff and resources will be utilized to implement this regulation.

Statement of Need and Reasonableness:

The statement of need and reasonableness of the regulation was determined by staff analysis pursuant to S.C. Code Section 1-23-115(C)(1)-(3) and (9)-(11):

DESCRIPTION OF REGULATION: New Regulation, Total Maximum Daily Loads for Pollutants in Water.

Purpose: This regulation will define the term total maximum daily load (TMDL) and clarify the public participation and administrative appeal processes for TMDLs.

Authority: S.C. Code Sections 48-1-10 et seq. (South Carolina Pollution Control Act of 1976).

Plan for implementation: The regulation will be implemented upon approval of the General Assembly and publication in the State Register. SCDHEC Bureau of Water staff will conduct the activities set forth in the regulation in the manner presented in the regulation.

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

TMDL development is required under Section 303(d) of the Federal Water Pollution Control Act. The goal of TMDL development and implementation is to ensure that waters attain and maintain standards set forth in R.61-68, Water Classifications and Standards. Currently, there is no definition of TMDL in any South Carolina statute or regulation. This regulation will define the term and provide clarification of South Carolina public participation and administrative appeal opportunities during TMDL development.

DETERMINATION OF COSTS AND BENEFITS:

No additional cost is expected to be incurred by the State by implementation of this regulation. Existing staff and resources will be utilized to implement this regulation. This regulation is administrative in nature; costs to the regulated community for the voluntary public participation and appeal processes described in the regulation are expected to be minimal.

UNCERTAINTIES OF ESTIMATES:

Minimal.

EFFECT ON ENVIRONMENT AND PUBLIC HEALTH:

The regulation will clarify the public participation and administrative appeal processes associated with TMDL development. Upon implementation, TMDLs will result in attainment and maintenance of State water quality standards.

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

There may be an adverse effect on the environment if the regulation is not implemented. Without clarification of the public participation and administrative appeal processes, South Carolina TMDLs cannot be finalized by the Department, and delays in developing and implementing TMDLs could occur, resulting in delays in water quality improvement and possible degradation of water quality.

Statement of Rationale:

The statement of rationale was determined by staff analysis pursuant to S.C. Code Ann. Section 1-23-110(A)(3)(h) (1976, as amended).

To fulfill the requirements of the Federal Water Pollution Control Act, South Carolina must develop TMDLs. Recent litigation demonstrated the lack of a clear administrative appeal process associated with TMDL development. In addition, there was no definition of the term in any state statute or regulation. Until this regulation is promulgated, South Carolina TMDLs cannot be finalized by the Department.

This regulation is administrative in nature; therefore, no scientific studies were needed or used. The regulation provides a needed complement to existing regulations.

Document No. 2917
DEPARTMENT OF LABOR, LICENSING AND REGULATION
BUILDING CODES COUNCIL
CHAPTER 8
Statutory Authority: 1976 Code Section 6-9-40

Synopsis:

The South Carolina Building Codes Council will update the International Fuel Gas Code, 2000 Edition, to the International Fuel Gas Code, 2003 Edition, in accordance with the statutory amendments to acts governing the Building Codes Council, including proposed modifications. These provisions will be established in regulations designated under Article 3—International Fuel Gas Code.

Instructions:

Add new Article 3—International Fuel Gas Code.

Text:

Article 3—International Fuel Gas Code
Regulation 8-300. International Fuel Gas Code

NOTE-This article is identical to the International Fuel Gas Code, 2003 Edition, in accordance with the statutory amendments to acts governing the Building Codes Council, except for the modifications referenced below.

Regulation 8-301. Modifications
Section G505.1.1
Where commercial cooking appliances are vented by means of the Type I or Type II kitchen exhaust hood system that serves such appliances, the exhaust system shall be fan powered and the appliances shall be interlocked with the exhaust hood system to prevent appliance operation when the exhaust hood system is not operating. Where a solenoid valve is installed in the gas piping as part of an interlock system, gas piping shall not be installed to bypass such valve. Dampers shall not be installed in the exhaust system. Exception: An interlock between the cooking appliance and the exhaust hood system shall not be required for appliances that are of the manually operated type and are factory equipped with standing pilot burner ignition systems.

Fiscal Impact Statement:

There will be no cost incurred by the State or any of its political subdivisions.

Statement of Rationale:

There was no scientific or technical basis relied upon in the development of this regulation.

Document No. 2918
DEPARTMENT OF LABOR, LICENSING AND REGULATION
BUILDING CODES COUNCIL
CHAPTER 8
Statutory Authority: 1976 Code Section 6-9-40

Synopsis:

The South Carolina Building Codes Council will update the International Residential Code, 2000 Edition, to the International Residential Code, 2003 Edition, in accordance with the statutory amendments to acts governing the Building Codes Council, including proposed modifications. These provisions will be established in regulations designated under Article 4—International Residential Code

Instructions:

Add new Article 4—International Residential Code.

Text:

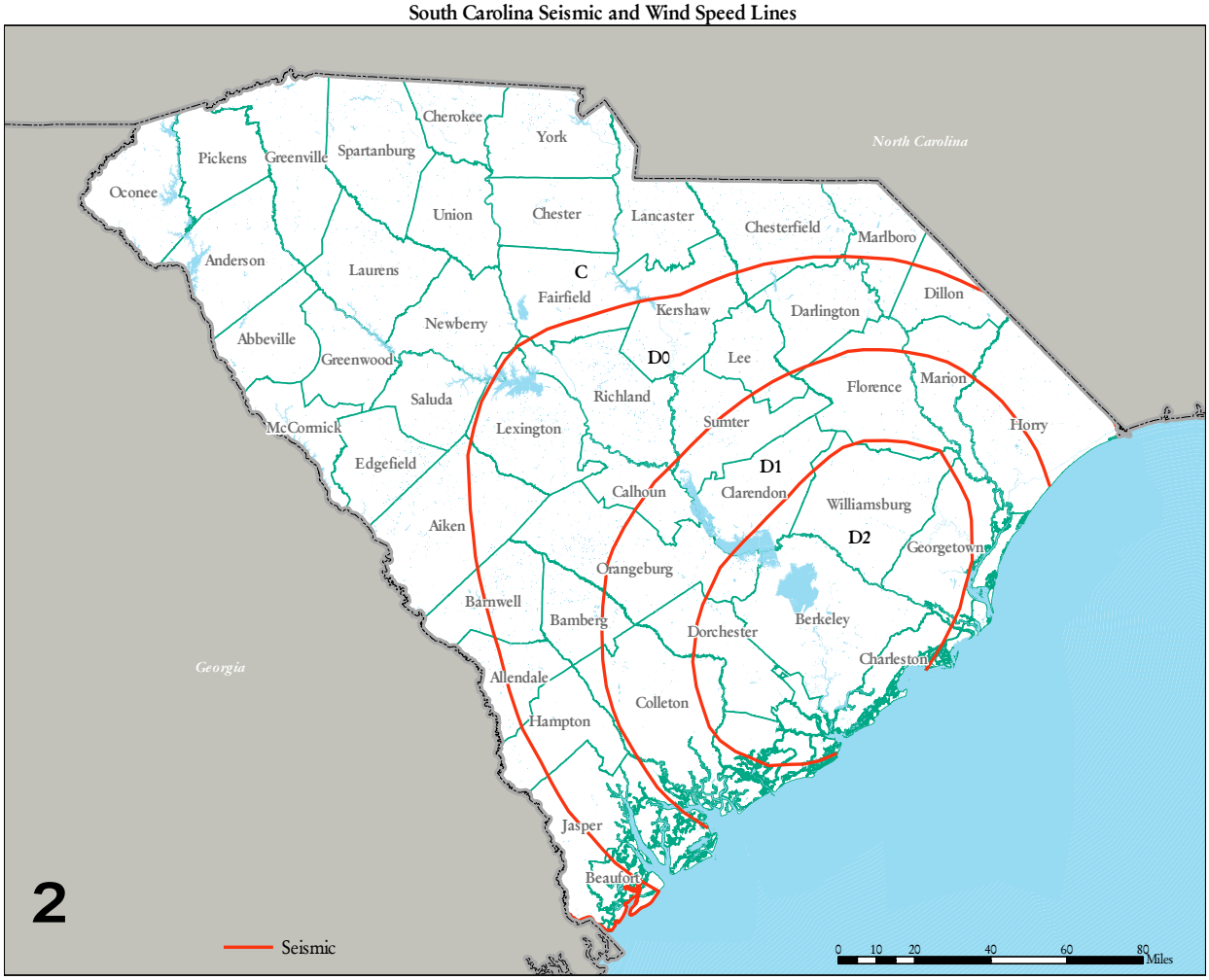
Article 4—International Residential Code.
Regulation 8-400. International Residential Code.

NOTE—This article is identical to the International Residential Code, 2003 Edition, in accordance with the statutory amendments to acts governing the Building Codes Council, except for the modifications referenced below.

Regulation 8-401. Modifications.
Section R202
Story - That portion of a building included between the upper surface of a floor and the upper surface of the floor or roof next above. For the purpose of determining the appropriate code to be used, when the first story is built in the flood plain, a 'Story' must be 'Habitable Space.'

Section R301.2(2)
The most recent seismic design map includes a new seismic zone designated as D_0 (D sub zero) that is not included in the 2003 edition of the International Residential Code, but will be included in the 2006 edition. The D_0 zone reduces the area of the existing D_1 zone in South Carolina and provides for less restrictive, and thus less costly construction requirements. The Building Codes Council determined that since the latest map is conclusive and available now, it should be used.

South Carolina Seismic and Wind Speed Lines



Section R301.2.2
Sections R301 design criteria, R403 footings, R404 foundation walls, R602 wood wall framing, R606 general masonry construction, R611 insulating concrete form wall construction, R703 exterior covering section and R1003 masonry fireplaces were revised to incorporate the design provisions for the new Seismic Design Category D_0 (D sub zero). The D_0 design category is not included in the 2003 edition of the International Residential Code, but will be included in the 2006 edition. This modification establishes the design criteria for the new D_0 seismic zone created by the modification to Section R301.2(2).

A moratorium was placed on enforcement of the D_0 (D sub zero) seismic design requirements for those areas in South Carolina designated as D_0, until adoption of the 2006 International Residential Code. The design requirements for the seismic zone C will be in effect for those areas in South Carolina designated as D_0.

Section R311.4.3
The floor or landing at the interior side of the exit door required by Section R311.4.1 shall not be more than 1.5 inches (38 mm) lower than the top of the threshold. The floor or landing at exterior doors other than the exit door required by Section R311.4.12 shall not be required to comply with this requirement but shall have a rise no greater than that permitted in Section R311.5.3.
Exception: The landing at an exterior/exit doorway shall not be more than 7 ¾ inches (196 mm) below the top of the threshold, provided the door, other than an exterior storm or screen door does not swing over the landing.

Section R311.5.3

When risers are closed, all treads may have a uniform projection not to exceed 1 ½ inches. The greatest riser height within any flight of stairs shall not exceed the smallest by more than 3/8 inch. The greatest tread run within any flight of stairs shall not exceed the smallest by more than 3/8 inch. Stairways shall not be less than 3 feet in clear width, and the headroom, rise and run shall conform to Figure R-213.1. Handrails may project from each side of a stairway a distance of 3 ½ inches into the required width.

Section R311.5.6.1
Handrail height, measured vertically from the sloped plane adjoining the tread nosing, or finished surface of ramp slope, shall be not less than 30 inches and not more than 38 inches (965 mm).

Table R402.2

MINIMUM SPECIFIED COMPRESSIVE STRENGTH OF CONCRETE

Porches, carport slabs and steps exposed to the weather 2,500 (PSI).

Section R403.1.4.2
In seismic design categories D_1 and D_2, interior footings supporting bearing or bracing walls and cast monolithically with a slab on grade shall extend to a depth of not less than 12 inches (305 mm) below the top of slab.

Section R403.1.6
When braced wall panels are supported directly on continuous foundations, the wall wood sill plate or cold-formed steel bottom track shall be anchored to the foundation in accordance with this section. The wood sole plate at exterior walls on monolithic slabs and wood sill plate shall be anchored to the foundation with anchor bolts spaced a maximum of 6 feet (1829 mm) on center. There shall be a minimum of two bolts per plate section with one bolt located not more than 12 inches (305 mm) or less than seven bolt diameters from each end of the plate section. In Seismic Design Categories D_1 and D_2, anchor bolts shall also be spaced at 6 feet (1829 mm) on center and located within 12 inches (305 mm) from the ends of each plate section at interior braced wall lines when required by Section R602.10.9 to be supported on a continuous foundation. Bolts shall be at least 1/2 inch (12.7 mm) in diameter and shall extend a minimum of 7 inches (178 mm) into masonry or concrete. Interior bearing wall sole plates on monolithic slab foundations shall be positively anchored with approved fasteners. A nut and washer shall be tightened on each bolt to the plate. Sills and sole plates shall be protected against decay and termites where required by Sections R318 and R319. Cold-formed steel framing systems shall be fastened to the wood sill plates or anchored directly to the foundation as required in Section R505.3.1 or R603.1.1.
Exception: Foundation anchor straps, spaced as required to provide equivalent anchorage to 1/2-inch-diameter (12.7 mm) anchor bolts.
Exception 2. Walls 24” total length or shorter connecting offset braced wall panels shall be anchored to the foundation with a minimum of one anchor bolt located in the center third of the plate section and shall be attached to adjacent braced wall panels per Figure R602.10.5 at corners.
Exception 3. Walls 12” total length or shorter connecting offset braced wall panels shall be permitted to be connected to the foundation without anchor bolts. The wall shall be attached to adjacent braced wall panels per Figure R602.10.5 at corners.

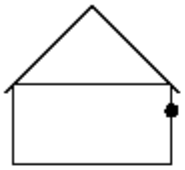
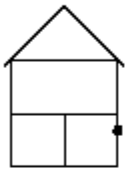
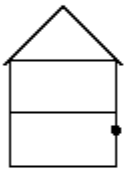
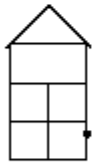
Section R403.1.7
Sections R403.1.7 (Footings on or Adjacent to Slopes); R402.1.7.1 (Building Clearances from Ascending Slopes); R403.1.7.2 (Footing Setback from Descending Slope Surfaces); R403.1.7.3 (Foundation Elevation); R403.1.7.4 (Alternate Setback and Clearances); figure R403.1.7.1 (Foundation Clearance from Slopes) were deleted. The sections referenced establish limitations for sites with varying topography that may be more appropriate in local zoning ordinances.

Table R502.5(1)

An additional table (identified as Table R502.5(1)A) was included with the existing table, which will allow for the use of standard lumber as an alternative to engineered wood for the fabrication of headers over 6 feet in length.

Alternative to IRC Table R502.5(1)

Number of Jack Studs and Maximum Spans for No. 2 SYP Girders and Headers in Exterior Bearing Walls with 10 psf Ground Snow Load

Headers Supporting	Size	Building Width (feet)							
		12		20		28		36	
		Span	NJ	Span	NJ	Span	NJ	Span	NJ
Roof and ceiling 	2-2x4	5-2	1	4-2	1	3-7	1	3-2	1
	2-2x6	7-6	1	6-0	1	5-1	1	4-7	1
	2-2x8	9-8	1	7-8	1	6-7	1	5-10	1
	2-2x10	11-7	1	9-2	1	7-10	1	7-0	1
	2-2x12	13-7	1	10-9	1	9-3	1	8-2	1
	3-2x8	12-8	1	10-2	1	8-8	1	7-8	1
	3-2x10	15-2	1	12-1	1	10-4	1	9-2	2
	3-2x12	17-9	1	14-2	1	12-2	2	10-9	2
	4-2x8	14-8	1	11-8	1	10-0	1	8-10	2
	4-2x10	17-7	1	14-0	1	12-0	2	10-8	2
	4-2x12	20-6	1	16-4	2	14-0	2	12-6	2
Roof, ceiling and one center-bearing floor 	2-2x4	---	---	3-3	1	2-9	1	2-6	1
	2-2x6	---	---	4-9	1	4-1	1	3-7	1
	2-2x8	---	---	6-2	1	5-3	1	4-8	1
	2-2x10	---	---	7-4	1	6-3	1	5-7	1
	2-2x12	---	---	8-7	1	7-4	2	6-6	2
	3-2x8	---	---	8-1	1	6-10	1	6-1	2
	3-2x10	---	---	9-8	1	8-4	2	7-3	2
	3-2x12	---	---	11-3	2	9-8	2	8-7	2
	4-2x8	---	---	9-4	1	8-0	2	7-1	2
	4-2x10	---	---	11-2	2	9-6	2	8-4	2
	4-2x12	---	---	13-1	2	11-2	2	9-10	2
Roof, ceiling and one clear span floor 	2-2x4	3-7	1	2-10	1	2-4	1	2-1	1
	2-2x6	5-2	1	4-1	1	3-6	1	3-1	1
	2-2x8	6-8	1	5-3	1	4-6	1	4-0	1
	2-2x10	8-0	1	6-3	1	5-4	2	4-8	2
	2-2x12	9-4	1	7-4	2	6-3	2	5-7	2
	3-2x8	8-9	1	6-10	1	5-10	2	5-2	2
	3-2x10	10-7	1	8-3	2	7-1	2	6-2	2
	3-2x12	12-4	2	9-8	2	8-3	2	7-3	2
	4-2x8	10-2	1	8-0	2	6-9	2	6-0	2
	4-2x10	12-2	2	9-7	2	8-1	2	7-2	2
	4-2x12	14-3	2	11-2	2	9-6	2	8-4	3
Roof, ceiling and two center-bearing floors 	2-2x4	---	---	2-10	1	2-4	1	2-1	1
	2-2x6	---	---	4-1	1	3-6	1	3-1	1
	2-2x8	---	---	5-4	1	4-6	1	4-0	1
	2-2x10	---	---	6-3	1	5-4	2	4-8	2
	2-2x12	---	---	7-4	2	6-3	2	5-7	2
	3-2x8	---	---	6-10	1	5-10	2	5-2	2
	3-2x10	---	---	8-3	2	7-1	2	6-2	2
	3-2x12	---	---	9-8	2	8-3	2	7-3	2
	4-2x8	---	---	8-0	2	6-9	2	6-0	2
	4-2x10	---	---	9-7	2	8-1	2	7-2	2
	4-2x12	---	---	11-2	2	9-6	2	8-4	3
Roof, ceiling and two clear span floors 	2-2x4	2-10	1	2-3	1	2-0	1	1-8	1
	2-2x6	4-2	1	3-3	1	2-9	1	2-6	1
	2-2x8	5-6	1	4-3	1	3-7	2	3-2	2
	2-2x10	6-6	1	5-1	2	4-3	2	3-9	2
	2-2x12	7-7	1	6-0	2	5-1	2	4-6	2
	3-2x8	7-2	1	5-7	2	4-9	2	4-2	2
	3-2x10	9-7	2	6-8	2	5-8	2	5-0	2
	3-2x12	10-0	2	7-9	2	6-8	2	5-10	3
	4-2x8	9-3	2	6-6	2	5-6	2	4-10	2
	4-2x10	9-10	2	7-8	2	6-7	2	5-9	3
	4-2x12	11-7	2	9-1	2	7-8	3	6-9	3

Building width is measured outside to outside and perpendicular to the ridge. For width between those shown, spans are permitted to be interpolated.
Table assumes 1 ft. roof overhang, 10 psf DL roof, ceiling and floors, 20 psf LL roof (construction load) and 40 psf LL floors.

SOUTH CAROLINA REGISTERED PROFESSIONAL ENGINEER GREGORY PHILLIP PARSONS No. 8942

SOUTH CAROLINA BUILDERS ENGINEERING CORP. No. COA791 CERTIFICATE OF AUTHORIZATION

BUILDERS ENGINEERING CORP. Two Hillstone Court Columbia, SC 29212	Generated By: G. Parsons PE Verified By: D. Jones PE
www.StructuralExperts.com (803) 466-2466	January 8, 2004 Note: Check website for later revision

Section R502.11.4
Truss design drawings, prepared in compliance with Section R502.11.1, shall be provided to the building official at the time of inspection. Truss design drawings shall be provided with the shipment of trusses delivered to the job site. Truss design drawings shall include at a minimum the information specified below:

Section R602.10.5
When continuous wood structural panel sheathing is provided in accordance with Method 3 of R602.10.3 on all sheathable areas of all exterior walls, and interior braced wall lines, where required, including areas above and below openings, braced wall panel lengths shall be in accordance with Table R602.10.5. Wood structural panel sheathing shall be installed at corners in accordance with Figure R602.10.5. The bracing amounts in Table R602.10.1 for Method 3 shall be permitted to be multiplied by a factor of 0.9 for walls with a maximum opening height that does not exceed 85 percent of the wall height or a factor of 0.8 for walls with a maximum opening height that does not exceed 67 percent of the wall height.
Exception: Vertical wall segments in the first of one or first of two story buildings next to garage openings shall be permitted to have a 6:1 height-to-width ratio (with height being measured from top of header to sill plate) when constructed in accordance with the following provisions. Each panel shall have a length of not less than 16 inches (406 mm) and a height of not more tan 10 feet (3048 mm). Each panel shall be sheathed on one face with a single layer of 3/8-inch minimum-thickness (9.5 mm) wood structural panel sheathing nailed with 8d common or galvanized box nails in accordance with Figure R602.10.5(2). The wood structural panel sheathing shall extend up over the solid sawn or glued-laminated header and shall be nailed in accordance with Figure R602.10.5(2). The header shall extend between the inside faces of the first full-length outer studs of each panel. The clear span of the header between the inner studs of each panel shall be not less than six feet (1829 mm) and not more than 18 feet (5486 mm) in length. A strap with an uplift capacity of not less than 1000 pounds (454 kg) shall fasten the header to the side of the inner studs opposite the sheathing. Two anchor bolts shall be installed in accordance with Section R403.1.6, and flat washers shall be a minimum of 2 inches by 2 inches by 3/1 inch (51 mm by 51 mm by 4.8 mm) thick and shall be used on each bolt. This exception is only permitted in Seismic Design Categories A-C.

Section R802.10.1
Truss design drawings, prepared in compliance with Section R802.10.1, shall be provided to the building official at the time of inspection. Truss design drawings shall be provided with the shipment of trusses delivered to the job site. Truss design drawings shall include at a minimum the information specified below:

Chapter 11
The State of South Carolina has specific energy standards in statutory form (Re: Title 6, Chapter 9, Building Codes and Title 6, Chapter 10, Building Energy Efficiency Standard Act.). To eliminate any possible conflicts concerning the insulation requirements for single and two family residential buildings between the International Residential Code and state law, Chapter 11 was deleted.

Section M1411.4
M1411.4 Insulation of refrigerant piping. Piping and fittings for refrigerant vapor (suction) lines shall be insulated with insulation have a thermal resistivity of at least R-2.5 hr. ft 2 F/Btu and having external surface permeance not exceeding 0.05 perms [2.87 ng/(s m2 Pa)] when tested in accordance with ASTM E 96.

Figure R307.2
The minimum fixture clearance for a water closet had been 12 inches from the center of the bowl to the sidewall or bathtub for many years. The dimension was changed to 15 inches in the 2000 International Residential Code without a convincing reason for doing so. The minimum clearance, therefore, was changed back to 12 inches. Figure R.307.2 is a graphic. The modification changes the dimension on the graphic from 15 inches to 12 inches.

NOTE—This article is identical to the International Residential Code, 2003 Edition, in accordance with the statutory amendments to acts governing the Building Codes Council, except for modifications.

Statement of Rationale:

There was no scientific or technical basis relied upon in the development of these regulations.

Fiscal Impact Statement:

There will be no cost incurred by the State or any of its political subdivisions.

Resubmitted February 8, 2005

Document No. 2951
DEPARTMENT OF LABOR, LICENSING AND REGULATION
BOARD OF LONG TERM HEALTH CARE ADMINISTRATORS
CHAPTER 35
Statutory Authority: 1976 Code Section 40-35-10 through 40-35-136, 40-35-230, 40-1-70

Synopsis:

The South Carolina Board of Long Term Health Care Administrators is amending Regulation 93-150 to establish guidelines for long term health care administrators with inactive or retired licensure status in this state.

Instruction:

Replace current 93-150(A) thru 93-150(E) with text 93-150(A) thru 93-150(F) as printed below.

Text:

93-150. Inactive or Retired Status Licenses.

A. The board may consider a request from a licensee to have his or her license placed in inactive or retired status.

B. To qualify for inactive or retired license status, the licensee must affirm that he or she is not employed as the administrator in a nursing home or a community residential care facility in the State.

C. An application for inactive or retired status shall be submitted to the board with the fee for inactive or retired status renewal on or before the expiration date of the license.

D. In order to qualify for retired status the applicant must have attained the age of sixty five (65) years or at least twenty (20) years of licensure and must affirm that he or she is not employed as the administrator in a nursing home or a community residential care facility in the State.

E. In order to reactivate an inactive license, an applicant must submit an application on a form approved by the board, along with the required fee, and proof of the annual continuing educational requirements for each year that the license was inactive. In order to reactivate a retired license, an applicant for reactivation must submit an application on a form approved by the board, along with the required fee, and proof of six (6) hours of continuing education during the previous twelve (12) months. The applicant must provide proof of an additional fourteen (14) hours of continuing education within 90 days of the license being reactivated or the license will automatically be replaced in the retired status and the licensee must immediately cease and desist any work in a nursing home or community residential care facility in the State.

F. If the applicant has been retired for five (5) years or more, the board may require the applicant to pass an examination approved by the board in lieu of or in addition to completing the required continuing education.

Fiscal Impact Statement:

There will be no cost incurred by the State or any of its political subdivisions.

Statement of Rationale:

There was no scientific or technical basis relied upon in the development of this regulation.

Document No. 2981
DEPARTMENT OF LABOR, LICENSING AND REGULATION
CHAPTER 71
Statutory Authority: 1976 Code Section 41-15-210
Article I, Subarticle 6 and 7
Occupational Safety and Health Standards

The South Carolina Department of Labor, Licensing and Regulation, Division of Labor, Office of Occupational Safety and Health, hereby promulgates the following changes to South Carolina Regulations:

In Subarticle 6 (General Industry and Shipyard Employment):
Minimum standard for Subarticle 6 shall be 1910.103, 1910.217, 1910.219, and 1910.268, as amended in FEDERAL REGISTER, Volume 69, Number 110, pages 31880-31882, dated June 8, 2004.

Minimum standard for Subarticle 6 shall be 1910.134, as amended in FEDERAL REGISTER, Volume 69, Number 149, pages 46986-46994, dated August 4, 2004.

Minimum standard for Subarticle 6 shall be 1910.142, 1910.268, 1910.1001, 1910.1003, 1910.1017, 1910.1018, 1910.1025, 1910.1027, 1910.1028, 1910.1029, 1910.1043, 1910.1044, 1910.1045, 1910.1047, 1910.1048, 1910.1051, and 1915.1001 as amended in FEDERAL REGISTER, Volume 70, Number 3, pages 1111-1114, dated January 5, 2005.

In Subarticle 7 (Construction):
Minimum standard for Subarticle 7 shall be 1926.307 as amended in FEDERAL REGISTER, Volume 69, Number 110, page 31880-31882, dated June 8, 2004.

Minimum standard for Subarticle 7 shall be 1926.60 as amended in FEDERAL REGISTER, Volume 69, Number 233, page 70373, dated December 6, 2004.

Minimum standard for Subarticle 7 shall be 1926.60, 1926.62, 1926.1101, and 1926.1127 as amended in FEDERAL REGISTER, Volume 70, Number 3, page 1111-1114, dated January 5, 2005.

Copies of these final regulation changes can be obtained or reviewed at the South Carolina Department of Labor, Licensing and Regulation during normal business hours by contacting the Office of Public Information at (803) 896-4380.

Document No. 2933
DEPARTMENT OF NATURAL RESOURCES
CHAPTER 123

Statutory Authority: 1976 Code Sections 50-1-200, 50-1-210, 50-3-100, 50-11-10, 50-11-65, 50-11-105, 50-11-310, 50-11-335, 50-11-350, 50-11-390, 50-11-430, 50-11-500, 50-11-520, 50-11-530, 50-11-854 and 50-11-2200.

Synopsis:

These regulations amend Chapter 123-40, 123-51 and 123-52 in order to set seasons, bag limits and methods of hunting and taking of wildlife on existing and additional Wildlife Management Areas.

Instructions:

Amend Regulations 123-40, 123-51 and 123-52 to establish changes and include additional WMA's.

123-40. Wildlife Management Area Regulations.

1.1 The following regulations amend South Carolina Department of Natural Resources regulation Numbers 123-40, 123-51 and 123-52.

1.2. The regulations governing hunting including prescribed schedules and seasons, methods of hunting and taking wildlife, and bag limits for Wildlife Management Areas are as follows:

(A) Game Zone 1

Chauga, Franklin L. Gravely, Caesar's Head and Keowee WMA's

Archery Only Hunts For Deer on WMA (No dogs)	Dec. 23 - Jan. 1	Total of 2 deer for all archery only hunts. 2 per day, either-sex.

Glassy Mountain Archery Only Area – Chestnut Ridge Heritage Preserve

Located on the southwest side of the South Pacolet River and west of the junction of the South Pacolet River and its' main tributary creek as posted.

Archery Only Hunts For Deer (No Dogs)	Oct. 1 through Oct. 16 Oct. 31- Dec. 22 Dec. 23 – Jan. 1	Total 2 deer, 2 per day, either-sex.

(D) Game Zone 4

Draper WMA

Deer	Game Zone 4 seasons.	Game Zone 4 limits.

Small Game

Quail	Sat. after Thanksgiving, 2nd Sat. and 4th Wed. in Dec., 1st Wed. in Jan. Sunrise until 4:00pm.	10 per day
Rabbit	1st Wed. after Thanksgiving, 1st and 3rd Wed. in Dec., Wednesdays and Saturdays beginning 2nd Sat. in Jan. to Mar. 1.	3 per day

(G) Francis Marion National Forest

During still gun hunts for deer there shall be no hunting or shooting from, on or across any road open to vehicle traffic. No buckshot on still gun hunts. During deer hunts when dogs are used buckshot only is permitted.		Total of 8 deer for all gun hunts on the Francis Marion.

Wambaw WMA

Dog Hunts (Shotguns only)	1st Fri. and Sat. after Aug. 15; 2nd Fri. and Sat.	2 deer per day, buck only, except either-sex the Sat. of the
Still gun hunts only East of Hwy 17 . Rifles allowed.	following the opening date on the WMA and Fri. and Sat. every 3rd week thereafter through Jan. 1.	2nd and 4th Northampton dog hunt.

Northampton

Dog Hunts (Shotguns only)	1st Fri. and Sat. following the 2nd Wambaw hunt and Fri. and Sat. every 3rd week thereafter through Jan. 1	2 deer per day, buck only, except either-sex the Sat. of the 2nd and 4th Northampton dog hunt.

Santee

Dog Drive Hunts (Shotguns only)	1st Fri. and Sat. following the 1st Northampton hunt and Fri. and Sat. every 3rd week thereafter through Jan. 1.	2 deer per day, buck only, except either-sex Sat. of the 2nd and 4th Northampton dog hunt.

(N) Bear Island WMA

All hunters must sign in and out at the Bear Island Office. Hunting in designated areas only.

Deer

Archery	1st Fri. in Oct. through 2nd Sat.	3 deer, either-sex. Hogs.

	in Oct.	
Still Gun Hunts (No dogs) Rifles only.	Last 10 days in Oct.	3 deer, either-sex, only 1 buck. Hogs.

(S) Other Small WMAs

Chesterfield, Kershaw, & Marlboro Counties

Archery Only Hunts	Sept. 1 - 30	Total of 3 deer for all archery hunts, either-sex Sept. 15 – 30, 2 per day.
Still Gun Hunts and Archery (No Dogs)	Oct. 1 - Jan 1	Total 10 deer for all gun hunts, 2 per day, buck only except on Game Zone 5 either-sex days as specified in Reg. 4.2. Limit of 10 may not include more than 5 bucks. Male deer required 2 inches of visible antler above the hairline to be legal. Male fawns (button bucks) are considered antlerless deer, legal only during either-sex hunts; however, they apply toward the buck limit. Archers are allowed to take either-sex during entire period; however, daily and season bag limits apply.

(W) Marsh Furniture WMA

Special Hog Still Gun Hunt	3rd Mon. in Nov. – following Sat. Mar. 1st – 3rd Sat. in Mar.	Hogs Only, no limit, no buckshot, no bay or catch dogs.
Small Game Seasons Open only for rabbit, squirrel, opossum, quail, and woodcock only	Thanksgiving - Mar. 1 Wed. - Sat. only Woodcock – Wed. – Sat. only during Federal season.	Game Zone 10 bag limits. Woodcock – Fed. limits

(AA) Little Pee Dee River Complex WMA

Special Hog Still Gun Hunt	Mar. 1 – 3rd Sat. in March	Hogs only, no limit, no buckshot, no bay or catch dogs.

(BB) Great Pee Dee River WMA

Special Hog Hunt Still hunt, no dogs	1st Mon. in Dec. – the following Sat. 2nd Mon. in Dec. – the following Sat. 3rd Mon. in Dec. – the following Sat. 1st Mon. in Feb. - the following Sat. 2nd Mon. in Feb. – the following Sat.	Hogs only, no limit

(CC) Hickory Top WMA

Muzzleloader (No Dogs)	First Monday in November through Jan. 1.	2 deer per day, either-sex.
Small Game (No open season for fox squirrels)	No hunting before Sept. 1 or after Mar. 1; otherwise Game Zone 9 seasons apply.	Game Zone 9 bag limits. Except quail 8 per day.

(GG) McBee WMA

Still Gun Hunts (No Dogs)	Oct. 1 - Sat. after Thanksgiving.	Total of 10, 2 per day, buck only except on either-sex on Fridays and Saturdays from Oct. 11 to Thanksgiving Day. Total not to include more than 5 bucks.

(JJ) Longleaf Pine WMA

Deer

Still Gun Hunts	Mon. after the last Sat. in Oct. through the 3rd Sat. in Nov.	1 deer per day, either-sex during scheduled county-wide either-sex days.

(KK) delete Bucksport WMA

(VV) Bonneau Ferry WMA

Horse riding is prohibited. No camping is allowed. All terrain vehicles are prohibited. Hunting access by boat is prohibited. Adult/youth fishing only. For fishing, each youth may be accompanied by no more than two adults 18 years old or older. For deer and small game hunting Sides A and B will alternate each year. Bonneau Ferry WMA is closed to public access one hour after sunset until one hour before sunrise except, for special hunts regulated by DNR. All impoundments and adjacent posted buffers are closed to all public access Nov. 1 – Mar. 1 except for special waterfowl hunts regulated by DNR during the regular waterfowl season.

Deer

Side A (Adult/Youth Only)

Still Gun Hunts	Sept. 15 – Jan. 1, Wed., Fri., Sat., except week of Thanksgiving and 5 days before Christmas until Jan. 1.	Total 8 deer, 2 deer per day, either-sex except only 2 antlered bucks per season. Hogs no limit.
Side B		
Archery	1st Mon. – Sat. in Sept. 1st Mon. – Sat. after Sept. 15	2deer per day, either-sex Hogs no limit.
Still Gun Hunts	No open season except for hunters selected by computer drawing.	Total 3 deer, either-sex except only one buck. Hogs no limit.

Draw deer hunts are for two and one half days (afternoon on the first day and 2 full days). Hunt periods begin in early October and continue until early December. Hunters are required to have permit in possession and must sign in and sign out (Name, permit # and deer killed each day). Area is closed to the general public access during scheduled deer hunts.

Small Game

Side A (Adult/Youth Only)
Youth must be accompanied by an adult 21 years of age or older. Youth hunters must carry a firearm and hunt. Adults with youth hunters may also carry a firearm and hunt.

No open season for fox Squirrels, quail or fox. Dogs allowed during gun seasons only.	Jan. 2 – Mar. 1	Game Zone 6 bag limits.
Side B		
No open season for fox Squirrels, quail or fox. Dogs allowed during gun seasons only.	Jan. 2 – Mar. 1	Game Zone 6 bag limits.

2.12 On WMA lands, during the designated statewide youth deer hunt day, still hunting only, two deer, either-sex.

3.1 On WMA lands hunters may use any shotgun, rifle, bow and arrow or hand gun except that specific weapons may be prohibited on certain hunts. Small game hunters may possess or use shotguns with shot no larger than No. 2 or .22 rimfire rifles/handguns or primitive muzzle-loading rifles of .40 caliber or smaller. Small game hunters may not possess or use buckshot, slugs or shot larger than No. 2. Blow guns, dart guns or drugged arrows are not permitted. Small game hunters using archery equipment must use small game tips on the arrows (judo points, bludgeon points, etc.). The use of crossbows during any archery only season is unlawful except as allowed by 50-11-565.

3.3 On WMA lands, big game hunters are not allowed to use military or hard-jacketed bullets or .22 or smaller rimfire. Buckshot is prohibited during still hunts for deer or hogs on the Santee Coastal Reserve, Bucksport,

Edisto WMA, Pee Dee Station Site, Lewis Ocean Bay, Great Pee Dee, Crackerneck, Webb Center, Marsh Furniture, Manchester State Forest, Palachucola, Waccamaw River Heritage Preserve, Donnelley, Francis Marion, and Moultrie WMA lands.

7.1 On all WMA lands during any gun and muzzleloader hunting seasons for deer, bear and hogs, all hunters must wear either a hat, coat, or vest of solid visible international orange, except hunters for dove and duck are exempt from this requirement while hunting for those species.

10.8 Sandy Beach Waterfowl Area is closed to hunting during the period 01 Nov.-01 Mar. except for special hunts designated by the Department.

10.10 Impoundments on Bear Island, Donnelly, Samworth, Santee Coastal Reserve and Santee Delta WMAs are closed to all public access during the period 15 Oct.- 31 Jan. except during special hunts designated by the Department. All public access during the period 01 Feb.- Oct. 14 is limited to designated areas.

10.15 Category I Designated Waterfowl Areas include Beaverdam, Bonneau Ferry, Broad River, Clemson, Santee Cooper, Sandy Beach, Samworth, Santee Coastal Reserve, Santee-Delta, Tibwin, Bear Island, and Donnelley Wildlife Management Areas. Hunting in Category I Designated Waterfowl Areas is by special permit obtained through annual computer drawing.

10.16 Category II Designated Waterfowl Areas include Biedler Impoundment, Lake Cunningham, Russell Creek, Monticello Reservoir, Parr Reservoir, Duncan Creek, Dunaway, Dungannon, Enoree River, Moultrie, Hatchery, Hickory Top, Hickory Top Greentree Reservoir, Lancaster Reservoir, Turtle Island, Little Pee Dee River Complex (including Ervin Dargan, Horace Tilghman), Great Pee Dee River, Oak Lea, Potato Creek Hatchery, Samson Island Unit (Bear Island), Tyger River, Marsh and Wee Tee Waterfowl Management Areas. Hunting on Category II Designated Waterfowl Areas is in accordance with scheduled dates and times.

DESIGNATED WATERFOWL AREAS

Area	Open dates inclusive	Bag Limits
Bonneau Ferry	Hunters selected by drawing during regular season.	Federal Limits
Lancaster Reservoir	Mon. and Fri. AM only during regular season.	Federal Limits
Monticello Reservoir	Wed. and Sat. AM only during regular season.	Federal Limits
Wee Tee	Wed. and Sat. AM only during regular season.	Federal Limits

123-51. Turkey Hunting Rules and Seasons

AREA	DATES	LIMIT	Other Restrictions
Bonneau Ferry	April 1 – May 1	1/hunter	Hunting by public draw only. (closed to public access during hunts)
Draper	April 1 – May 1	2	Wed. and Sat. Only
Worth Mountain	April 1 – May 1	2	Wed. and Sat. Only

123-52. Deer Hunting on Private Lands in Game Zones 1, 2 and 4 (50-11-310, 50-11-350, 50-11-390).

2. Hunters may use any shotgun, rifle, bow and arrow or handgun except that specific weapons may be prohibited on certain hunts.
4. Hunters are not allowed to take deer with military or hard-jacketed bullets or .22 or smaller rimfire.

Fiscal Impact Statement:

This amendment of Regulations 123.40, 123-51 and 123-52 will result in increased public hunting opportunities that should generate additional State revenue through license sales. In addition, the local economy should benefit from sales of hunting supplies, food and overnight accommodations. Sales taxes on these items will also directly benefit government.

Statement of Rational:

Rationale for the formulation of these regulations is based on over 60 years of experience by SCDNR in establishing public hunting areas. New areas are evaluated on location, size, current wildlife presence, access and recreation use potential. Contractual agreements with the landowners provide guidelines for the use and management of the property. Wildlife Management Area agreements are on file with the Wildlife Management Section of the Department of Natural Resources, Room 267, Dennis Building, 1000 Assembly Street, Columbia.

Document No. 2899
SOUTH CAROLINA STATE LIBRARY
CHAPTER 75
Statutory Authority: 1976 Code Section 60-1-80

75-2. Certification Program for Public Librarians.

Synopsis: Certification aids public library boards and librarians in selecting competent personnel; it gives the funding bodies assurance that the public funds are spent for quality service; and it improves the status of librarianship as a profession.

Instructions: Add new Regulation 75-2, Certification Program for Public Librarians, to Chapter 75 regulations.

Text:

75-2. Certification Program for Public Librarians.

A. Employment Regulations.

(1) Each public library serving a population of 10,000 or more shall employ in professional positions and in pre-professional positions covered by State Aid and grant programs only those librarians and assistants holding the appropriate certificate.

(2) Failure by the trustees of any public library to meet these requirements or observe these regulations shall be deemed a valid reason for withholding all public funds unless the library board files a formal application for excuse of default and is granted exemption by the South Carolina State Library. The exemption granted shall be valid for one year only unless renewed.

B. Requirements and Types of Certificates.

(1) Professional.

(a) Professional certificate is issued to library staff who are graduates from an accredited undergraduate college or university, who have a degree from a graduate program of library study accredited by the American Library Association, and who are currently and have been employed in a professional full-time position in a public library for three years of continuous service.

(b) Provisional Professional certificate is issued to library staff members who have less than three years of continuous full-time professional experience in a public library. Although the Provisional Professional certificate is valid for four years it can be exchanged for a permanent Professional certificate upon completion of three years of full-time public library experience.

(2) Pre-Professional.

(a) Pre-Professional certificate is issued to library staff members who have satisfactorily completed a bachelor's degree in a college or university approved by an agency of more than statewide standing and who have completed not less than 18 semester hours in library science. This certification is initially valid for five years and renewable by continuous full-time library experience and the successful completion of six semester hours in academic and/or library science courses. After five year´ experience and the additional six hours credit, the certification remains valid so long as the holder is continuously employed in a full-time library position.

(b) Provisional Pre-Professional certificate is issued to library staff members who have completed a bachelor's degree in a college or university of recognized standing. This certificate is valid for three years and renewable by continuous full-time library experience and successful completion of six semester hours of library science courses. After completion of 18 semester hours in library science, the Provisional certificate may be exchanged for the regular Pre-Professional certificate.

(3) Exemption of positions.

(a) The South Carolina State Library may at its discretion, based on a formal application, from the public library board, stating clearly the steps that have been taken to locate a qualified person, excuse the default of a library board employing a librarian not properly certified and legalize the time so served.

(b) If a public library serving a population of over 150,000 at any time shall find it impossible to employ a satisfactory holder of a public librarian’s professional certificate for a position requiring unusual background and education in a special field, the library board may submit to the South Carolina State Library a statement of facts involved and request that the position be exempt from certification regulations.

(4) Reciprocity.

(a) A librarian’s certificate duly issued by the State authority in a State meeting South Carolina State Library’s standards and currently in full force and effect shall be endorsed provided the holder of such certificate shall have had not less than three years of professional library experience one of which has been within the past three years prior to request or that applicant can submit evidence of the satisfactory completion of a refresher course.

(5) Renewal of Certificate.

(a) The Provisional and Preprofessional certificates are renewable. It is the responsibility of the applicant and the library board to request renewals before the expiration date. Renewal blanks may be obtained from the South Carolina State Library and should be filled out and returned, together with the certificate to be renewed, to the South Carolina State Library prior to the expiration date.

Fiscal Impact Statement: None.

Statement of Rationale: The purpose of the public library certification program is to improve the public library profession in South Carolina. The program applies only to persons currently employed in full time positions in South Carolina public libraries. There are four types of certificates: Professional, Provisional Professional, Pre-Professional and Provisional Pre-Professional as outlined in the text.