

From: "Melinda W. Bradshaw" <BRADSHMW@COLUMB54.DHEC.STATE.SC.US>
To: <jgz@nrc.gov>
Date: 2/14/02 4:12PM
Subject: Recent amendments to Title A, R.61-63, State of SC Rad. Mat.Regs.

Dear Sir:

The attachment below contains our state's most recent amendment to the radioactive material regulations, promulgated as of October, 2001. This is in response to a query made earlier today to James K. Peterson, Director, Radioactive Materials Section.



2600 Bull Street
Columbia, SC 29201-1708

January 25, 2002

Richard L. Woodruff
Nuclear Regulatory Commission
Atlanta Federal Center
61 Forsyth Street, SW
Atlanta, GA 30303-3415

Dear Mr. Woodruff:

Enclosed are copies (hard copy and electronic version) of recent amendments to SC Department Regulation 61-63, Radioactive Materials. These changes are being submitted to NRC for compatibility review. Comments are not needed within a specific timeframe.

If you have any questions concerning this correspondence, please contact me at (803) 545-4407.

Sincerely,

James K. Peterson, Director
Division of Radioactive Material
Licensing and Compliance
Bureau of Radiological Health

Enclosures

BOARD OF HEALTH AND ENVIRONMENTAL CONTROL
SUMMARY SHEET
October 11, 2001

 X ACTION
 INFORMATION

I. **TITLE:** Public Hearing before the Board and Consideration for Final Approval
 Proposed Amendment of Regulation 61-63, Radioactive Material (Title A)
 State Register Document No. 2647
 Exempt from Legislative Review

II. **SUBJECT:** Request for finding of Need and Reasonableness Pursuant to S.C. Code Section
 1-23-111

III. **FACTS:**

1. 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, and the Agreement between the U.S. Nuclear Regulatory Commissioner and the State of South Carolina, require that we adopt federal regulations for compatibility.

2. Pursuant to statutory authority provided in S.C. Code Section 13-7-10 et seq., the Department is requesting approval to amend Regulation 61-63, Radioactive Material (Title A). Proposed revisions are required to maintain compatibility with regulations promulgated by the U.S. Nuclear Regulatory Commission in Title 10, Code of Federal Regulations. The intended Departmental action makes minor correcting and clarifying changes to the requirements in Part III which address standards for protection against radiation. Additional changes will conform Parts I, IV, VIII, and XI to the revised Part III. Subjects include Part III, Conditions Requiring Individual Monitoring of External and Internal Occupational Dose; Exceptions to Posting Requirements; Notification of Incidents; Part IV, Modification of Teletherapy Unit or Room; Part VIII, Radiation Survey Instruments (Well logging); Surveillance of Operations; Part XI, Access Control (Irradiators). Additional amendments in Part V, Industrial Radiography, are solely administrative in that they correct and clarify the text of an existing regulation and do not result in any essential change. Subjects dealt with in Part V clarify implementation dates for certain training requirements. A Table of Revisions and the Text of the Proposed Amendment are submitted as Attachments B and C.

3. A preliminary assessment report and fiscal impact statement are not required because these amendments will comply with federal law.

4. The statutory process for amendment of Regulation 61-63 was initiated by publication of a Notice of Drafting in the State Register on March 23, 2001. No comments were received concerning drafting of these updated regulations. A copy of the Notice is submitted as Attachment E.

5. The proposed amendment was reviewed internally by appropriate staff as required by DHEC administrative policy. Copies of the Proposed regulation were submitted for comment to the Technical Advisory Radiation Control Council (TARCC).

6. Staff were granted initial approval on August 9, 2001, to public notice the proposed regulation and hold a staff-informational forum. A Notice of Proposed Regulation was published in the State Register on August 24, 2001, as Document No. 2647; an excerpt from that publication is submitted as Attachment D. The Notice provided notice of opportunity for the interested public to comment on the proposed regulation in writing, to attend a staff informational forum and to appear at a public hearing before the DHEC Board. Notice was again published on the Department's website.

7. The staff information forum was held on September 24, 2001. No comments were received at the staff informational forum nor during the public comment period.

8. Department staff are requesting a public hearing before the Board and a finding of need and reasonableness of the proposed regulations. If approved by the Board, the regulations will be submitted to the Legislative Council for publication as final in the State Register on October 26, 2001.

IV. ANALYSIS:

1. 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.

2. These revisions incorporate applicable regulatory additions and changes issued by the U.S. Nuclear regulatory Commission since the last revisions were adopted and issued in May, 2000.

3. A Statement of Need and Reasonableness is submitted as Attachment A.

V. RECOMMENDATION: Department staff recommends that based upon the public hearing and attached information, that the Board find for the need and reasonableness of the proposed regulation and approve it for publication as final in the State Register.

Submitted by:

Approved by:

T. Pearce O'Kelley, Chief
Bureau of Radiological Health

Leon Frishman
Deputy Commissioner
Health Regulations

Attachments:

- A. Statement of Need and Reasonableness
- B. Table of Revisions
- C. Text of Revisions
- D. Excerpt from State Register Notice of Proposed Regulation
- E. State Register Notice of Drafting
- F. Applicable Law: copy of S.C. Code Section 13-7-40

ATTACHMENT A
STATEMENT OF NEED AND REASONABLENESS FOR
PROPOSED AMENDMENT OF R. 61-63, RADIOACTIVE MATERIALS (TITLE A)
October 11, 2001

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, 34, 35, and 36.

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 PROPOSED 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:

The proposed regulation provides clarifying and minor correcting changes to definitions regarding standards for protection against radiation.

The proposed regulation revises the criteria for Teletherapy room modification and surveys.

The proposed regulation changes the deep dose equivalent monitoring requirements for minors and pregnant women from one-tenth of the applicable limit or 0.05 rem to 0.1 rem.

The proposed regulation clarifies compliance deadlines for certain training and safety requirements outlined for industrial radiography.

The proposed regulation clarifies radiation survey instrument requirements for well logging programs.

The proposed regulation revises criteria for access control for industrial irradiator programs.

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 the 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 proposed amendments eliminate possible duplicative or redundant requirements.

ATTACHMENT B
 TABLE OF REVISIONS FOR PROPOSED AMENDMENT OF R.61-63
 October 11, 2001

(1) Revises definitions to conform to Part III.

<u>SECTION</u>	<u>REVISION</u>
61-63.1.2.11	Revises definition for "High Radiation Area."

(2) Definition revisions, deletions and renumbering for Part III.

<u>SECTION</u>	<u>REVISION</u>
61-63.3.2.20	Revises definition for "Declared pregnant woman."
61-63.3.2.37	Deletes definition for "Eye dose equivalent."
61-63.3.2.38 through 3.2.40	Renumbered due to deletion of 3.2.37.
61-63.3.2.40	New definition for "High Radiation Area" added.
61-63.3.2.42	Adds new definition for "Individual monitoring devices."
61-63.3.2.42 through 3.2.43	Renumbered.
61-63.3.2.44	Renumbered to 3.2.45 and changed to add new definition for "Lens dose equivalent (LDE)."
61-63.3.2.44 through 3.2.71	Renumbered.
61-63.3.2.72	Renumbered and revised to reflect addition to "Very high radiation area" definition.
61-63.3.2.73 through 3.2.81	Definitions renumbered.

(3) Clarifying changes for radiation protection programs.

<u>SECTION</u>	<u>REVISION</u>
61-63.3.4.2	Section revised to clarify intent.
61-63.3.5.1.2.1	Revised to reference lens dose.

61-63.3.5.3	Section revised to reference lens dose.
61-63.3.7.1	Revises section to reference lens dose.
61-63.3.10.1	Section revised to clarify authorization of planned special exposure.
61-63.3.12.1	Revised section to incorporate term “dose equivalent.”
61-63.3.12.3	Revised section to incorporate term “dose equivalent.”
61-63.3.12.3.2 and 3.12.4	Revised section to incorporate term “dose equivalent.”
61-63.3.16.1.2.1	Revised to expand focus of radiation surveys.
61-63.3.16.1.2.3	Revision to delete redundant phrase.
61-63.3.17.1	Revised section to clarify sources of radiation exposure requiring monitoring.
61-63.3.17.1.2	Revision of limits for monitoring of external radiation exposure to minors.
61-63.3.17.1.3	Renumbers section to revise limits for monitoring of external radiation exposure to declared pregnant women.
61-63.3.17.1.4	Renumbered section.
61-63.3.17.2.1	Clarification for revision to next section.
61-63.3.17.2.2	Revision of limits for monitoring of internal exposure to minors.
61-63.3.17.2.3	Adds section to revise limits for monitoring of internal exposure to declared pregnant women.
61-63.3.23.4 through 3.23.4.2	Adds new section for posting exemptions for Teletherapy rooms in hospitals.
61-63.3.26.4	Clarifies method of licensee notification of the Department.
61-63.3.34.2	Existing section changed to add new section clarifying units used in record keeping.
61-63.3.34.2 through 3.34.6	Renumbered sections due to addition of new material.
61-63.3.35.2	Revision of record retention frequency.
61-63.3.36.1	Revision of record retention frequency.

61-63.3.37.6 Revision of record retention frequency.

61-63.3.39.1.1 Revision to reference lens dose.

61-63.3.39.1.2 Revision deleting term "body burden."

61-63.3.39.1.4 Revision to clarify committed effective dose equivalent assessment requirements.

61-63.3.45.1 Revision to add telephone number.

61-63.3.45.1.1.2 Revision to reference lens dose.

61-63.3.45.2.1.2 Revision to reference lens dose.

61-63.4.5.2 Section revised for typographical error.

61-63.4.7.6.3 Revision of record retention frequency.

61-63.4.7.7.3 Revision of record retention frequency.

61-63.4.8.2.5 Revision of record retention frequency.

61-63.4.8.3.5 Revision of record retention frequency.

61-63.4.8.4.3 Revision of record retention frequency.

61-63.4.8.6.9 Revision of record retention frequency.

61-63.4.8.11.8 Revision of record retention frequency.

61-63.4.8.13.6 Revision of record retention frequency.

61-63.4.8.15.2 Revision of record retention frequency.

61-63.4.10.2.5 Revision of record retention frequency.

61-63.4.11.2.3 Revision of record retention frequency.

61-63.4.11.3.1.4 Revision of record retention frequency.

61-63.4.13.2.3 Revision of record retention frequency.

61-63.4.13.3.1.4 Revision of record retention frequency.

61-63.4.13.4.6 Revision of record retention frequency.

61-63.4.13.5.2 Revision of record retention frequency.

- 61-63.4.14.4.3 Revision of record retention frequency.
- 61-63.4.14.9.5 Revision of record retention frequency.
- 61-63.4.14.13.4 Revision of record retention frequency.
- 61-63.4.14.13.8 Revision of record retention frequency.
- 61-63.4.14.14.1.2.1 Section revised for radiation surveys measuring dose rates in Teletherapy facilities.
- 61-63.4.14.14.1.2.2 Section revised for radiation surveys measuring dose rates in Teletherapy facilities.
- 61-63.4.14.15.3 Revision of record retention frequency.
- 61-63.4.14.16.1 through 4.14.16.1.2 Sections revised referencing requirements for modification of a Teletherapy room before beginning a treatment program.
- 61-63.4.16.2.3 Revision of record retention frequency.
- 61-63.4.16.3.3 Revision of record retention frequency.
- 61-63.4.16.4.2 Revision of record retention frequency.

(4) Clarification of implementation deadlines for industrial radiography.

<u>SECTION</u>	<u>REVISION</u>
61-63.5.9.5	Sentence added to clarify implementation date for depleted uranium leak testing requirements.
61-63.5.12.1.2	Revision to section clarifying implementation date for training requirements.
61-63.5.12.8 and 5.12.9	Revision to sections clarifying implementation dates for training and certification requirements.
61-63.5.21.4	Revision to section to clarify implementation date for meeting requirement of the two-man crew rule.
61-63.5.22.4	Revision to section to clarify implementation date for meeting RSO training requirements.

(5) Miscellaneous administrative, typographical and clarifying changes.

<u>SECTION</u>	<u>REVISION</u>
61-63.7.11.3	Revision correcting typographical error.

- 61-63.8.9.1 Revision clarifying survey meter requirements for well logging programs.
- 61-63.8.24.2 Clarification of reference.
- 61-63.11.8.7 Revision to posting requirements for panoramic or underwater irradiators.

ATTACHMENT C
TEXT OF PROPOSED REVISIONS
R.61-63, Radioactive Materials Regulations, Title A

October 11, 2001

LEGEND:

Underlined text = new text being added.

~~Strikeout text~~ = existing text being deleted.

1.2.11 "High Radiation Area" means any an area, accessible to individuals, in which ~~there exists~~ radiation ~~at such levels~~ from radiation sources external to that the whole the body could result in an individual receiving ~~receive~~ a dose equivalent in excess of 0.1 rem (1 mSv) ~~100 millirem~~ in 1 hour at 30 centimeters from the radiation source or 30 centimeters from any surface that the radiation penetrates.

3.2.20 "Declared pregnant woman" means a woman who has voluntarily informed the licensee her employer, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant.

~~3.2.37 "Eye dose equivalent" applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm²).~~

3.2.387 "Generally applicable environmental radiation standards" means standards issued by the Environmental Protection Agency (EPA) under the authority of the Atomic Energy Act of 1954, as amended, that impose limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.

3.2.398 "Generator" means a licensee operating under a Commission or Agreement State license who (1) is a radioactive waste generator as defined in this part, or (2) is the licensee to whom waste can be attributed within the context of the Low-Level Radioactive Waste Policy Amendments Act of 1985 (e.g. waste generated as a result of decontamination or recycle activities).

3.2.4039 "High Integrity Container (HIC)" means a container commonly designed to meet the structural stability requirements of Appendix E, RHA 3.56.2.2, and to meet Department of Transportation requirements for a Type A package.

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

3.2.42 "Individual monitoring devices (individual monitoring equipment)" means devices designed to be worn by a single individual for the assessment of dose equivalent such as film badges, thermoluminescence dosimeters (TLDs), pocket ionization chambers, and personal ("lapel") air sampling devices.

3.2.423 "Internal dose" means that portion of the dose equivalent received from radioactive material taken into the body.

3.2.434 "Land disposal facility" means the land buildings and structures, and equipment which are intended to be used for the disposal of radioactive wastes.

3.2.45 "Lens dose equivalent (LDE)" applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm²).

3.2.446 "Licensed material" means source material, special nuclear material, or byproduct material received, possessed, used, transferred or disposed of under a general or specific license issued by the Department.

3.2.457 "Limits (dose limits)" means the permissible upper bounds of radiation doses.

3.2.468 "Lost or missing licensed material" means licensed material whose location is unknown. It includes material that has been shipped but has not reached its destination and whose location cannot be readily traced in the transportation system.

3.2.479 "Member of the public" means any individual except when that individual is receiving an occupational dose.

3.2.4850 "Minor" means an individual less than 18 years of age.

3.2.4951 "Monitoring" (radiation monitoring, radiation protection monitoring) means the measurement of radiation levels, concentrations, surface area concentrations or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses.

3.2.502 "Nonstochastic effect" means health effects, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect (also called a deterministic effect).

3.2.513 "NRC Forms 540, 540A, 541, 541A, 542, and 542A" are official NRC forms referenced in this regulation. Licensees need not use originals of these NRC Forms as long as any substitute forms are equivalent to the original documentation in respect to content, clarity, size, and location of information. Upon agreement between the shipper and consignee, NRC Forms 541 (and 541A) and NRC Forms 542 (and 542A) may be completed, transmitted, and stored in electronic media. The electronic media must have the capability for producing legible, accurate, and complete records in the format of the uniform manifest.

3.2.524 "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 and/or 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 in accordance with RHA 4.8.12, or from voluntary participation in medical research programs, or as a member of the public.

3.2.535 "Package" means the assembly of components necessary to ensure compliance with the packaging requirements of DOT regulations, together with its radioactive contents, as presented for transport.

3.2.546 "Physical description" means the items called for on NRC Form 541 to describe a low-level radioactive waste.

3.2.557 "Planned special exposure" means an infrequent exposure to radiation, separate from and in addition to the annual dose limits.

3.2.568 "Public dose" means the dose received by a member of the public from exposure to radiation and/or 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 in accordance with RHA 4.8.12, or from voluntary participation in medical research programs.

3.2.579 "Quality Factor" (Q) means the modifying factor (listed in tables 1 and 2 of RHA 3.3) that is used to derive dose equivalent from absorbed dose.

3.2.5860 "Reference man" means a hypothetical aggregation of human physical and physiological characteristics arrived at by international consensus. These characteristics may be used by researchers and public health workers to standardize results of experiments and to relate biological insult to a common base.

3.2.59.61 "Residual radioactivity" means radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee's control. This includes radioactivity from all licensed and unlicensed sources used by the licensee but excludes background radiation. It also includes radioactive materials remaining at the site as a result of routine or accidental releases of radioactive material at the site and previous burials at the site, even if those burials were made in accordance with this Regulation.

3.2.602 "Residual waste" means low-level radioactive waste resulting from processing or decontamination activities that cannot be easily separated into distinct batches attributable to specific waste generators. This waste is attributable to the processor or decontamination facility, as applicable.

3.2.613 "Respiratory protective device" means an apparatus, such as a respirator, used to reduce the individual's intake of airborne radioactive materials.

3.2.624 "Sanitary sewerage" means a system of public sewers for carrying off waste water and refuse, but excluding sewage treatment facilities, septic tanks, and leach fields owned or operated by the licensee.

3.2.635 "Shallow-dose equivalent" (Hs), which applies to the external exposure of the skin or an extremity, is taken as the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm^2) averaged over an area of 1 square centimeter.

3.2.646 "Shipper" means the licensed entity (i.e. the waste generator, waste collector, or waste processor) who offers low-level radioactive waste for transportation, typically consigning this type of waste to a licensed waste collector, waste processor, or land disposal facility operator.

3.2.657 "Shipping paper" means NRC Form 540 and if required, NRC Form 540A which includes the information required by DOT in 49 CFR Part 172.

3.2.668 "Source material" means (1) uranium or thorium, or any combination thereof, in any physical or chemical form, or (2) ores which contain by weight one-twentieth of one percent (0.05 percent) or more of (a) uranium, (b) thorium, or (c) any combination thereof. Source material does not include special nuclear material (SNM).

3.2.679 "Special nuclear material" means (1) plutonium, uranium-233, uranium-enriched in the isotope-233 or the isotope-235, or (2) any material artificially enriched by any of the foregoing. This definition does not include source material.

3.2.6870 "Stochastic effects" means health effects that occur randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects.

3.2.6971 "Total Effective Dose Equivalent" (TEDE) means the sum of the deep-dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

3.2.702 "Type A quantity" means a quantity of radioactive material, the aggregate radioactivity of which does not exceed A_1 for special form radioactive material or A_2 for normal form radioactive material, where A_1 and A_2 are given in Appendix A 10CFR Part 71 or may be determined by procedures described in Appendix A 10CFR Part 71.

3.2.743 "Uniform Low-Level Radioactive Waste Manifest or uniform manifest" means the combination of NRC Forms 540, 541, and, if necessary, 542, and their respective continuation sheets as needed, or equivalent.

3.2.724 "Very high radiation area" means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving an absorbed dose in excess of 500 rads (5 grays) in 1 hour at 1 meter from a radiation source or 1 meter from any surface that the radiation penetrates.

[Note: At very high doses received at high dose rates, units of absorbed dose (e.g., rads and grays) are appropriate, rather than units of dose equivalent (e.g., rems and sieverts).]

3.2.735 "Waste collector" means an entity, operating under a license issued by the Department, the U.S. Nuclear Regulatory Commission, or another Agreement State, whose principal purpose is to collect and consolidate waste generated by others, and to transfer this waste, without processing or repackaging the collected waste, to another licensed waste collector, licensed waste processor, or licensed land disposal facility.

3.2.746 "Waste description" means the physical, chemical and radiological description of a low-level radioactive waste as called for on NRC Form 541.

3.2.757 "Waste generator" means an entity, operating under a license issued by the Department, the U.S. Nuclear Regulatory Commission, or another Agreement State, who possesses any material or component that contains radioactivity or is radioactively contaminated for which the licensee foresees no

further use, and transfers this material or component to a licensed land disposal facility or to a licensed waste collector or processor for handling or treatment prior to disposal. A licensee performing processing or decontamination services may be a "waste generator" if the transfer of low-level radioactive waste from its facility is defined as "residual waste."

3.2.768 "Waste processor" means an entity, operating under a license issued by the Department, the U.S. Nuclear Regulatory Commission, or another Agreement State, whose principal purpose is to process, repackage, or otherwise treat low-level radioactive material or waste generated by others prior to eventual transfer of waste to a licensed low-level radioactive waste land disposal facility.

3.2.779 "Waste type" means a waste within a disposal container having a unique physical description (i.e., a specific waste descriptor code or description; or a waste solidified in a specifically defined media).

3.2.780 "Weighting factor, W_T ," for an organ or tissue (T) is the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of W_T are:

ORGAN DOSE WEIGHTING FACTORS

Organ or Tissue	W_T
Gonads	0.25
Breast	0.15
Red bone marrow	0.12
Lung	0.12
Thyroid.....	0.03
Bone surfaces.....	0.03
Remainder.....	¹ 0.30
Whole Body.....	² 1.00

¹ 0.30 results from 0.06 for each of 5 "remainder" organs (excluding the skin and the lens of the eye) that receive the highest doses.

² For the purpose of weighting the external whole body dose (for adding it to the internal dose), a single weighting factor, $W_T = 1.0$, has been specified. The use of other weighting factors for external exposure will be approved on a case-by-case basis until such time as specific guidance is issued.

3.2.7981 "Working level" (WL) is any combination of short-lived radon daughters (for radon-222: polonium-218, lead-214, bismuth-214, and polonium-214; and for radon-220: polonium-216, lead-212, bismuth-212, and polonium-212) in 1 liter of air that will result in the ultimate emission of 1.3×10^5 MeV of potential alpha particle energy.

3.2.802 "Working level month" (WLM) means an exposure to 1 working level for 170 hours (2,000 working hours per year/12 months per year = approximately 170 hours per month).

3.2.843 "Year" means the period of time beginning in January used to determine compliance with the provisions of this part. The licensee may change the starting date of the year used to determine compliance by the licensee provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

3.4.2 The licensee shall use, to the extent practical ~~practicable~~, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).

RHA 3.5 OCCUPATIONAL DOSE LIMITS FOR ADULTS

3.5.1 The licensee shall control the occupational dose to individual adults, except for planned special exposures under RHA 3.10 to the following dose limits.

3.5.1.1 An annual limit, which is the more limiting of--

3.5.1.1.1 The total effective dose equivalent being equal to 5 rems (0.05 Sv); or

3.5.1.1.2 The sum of the deep-dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 50 rems (0.5 Sv).

3.5.1.2 The annual limits to the lens of the eye, to the skin, and to the extremities which are:

3.5.1.2.1 ~~An eye~~ A lens dose equivalent of 15 rems (0.15 Sv), and

3.5.3 The assigned deep-dose equivalent and shallow-dose equivalent must be for the part of the body receiving the highest exposure. The deep-dose equivalent, eye 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.

RHA 3.7 DETERMINATION OF EXTERNAL DOSE FROM AIRBORNE RADIOACTIVE MATERIAL

3.7.1 Licensees shall, when determining the dose from airborne radioactive material, include the contribution to the deep-dose equivalent, eye lens dose equivalent, and shallow-dose equivalent from external exposure to the radioactive cloud (see Appendix B, RHA 3.53 footnotes 1 and 2).

3.10.1 The licensee authorizes a planned special exposure only in an exceptional situation when alternatives that might avoid the ~~higher~~ dose estimated to result from the planned special exposure are unavailable or impractical.

3.12.1 The licensee shall ensure that the dose equivalent to ~~an~~ the embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 0.5 rem (5 mSv). (For recordkeeping requirements, see RHA 3.39)

3.12.3 The dose equivalent to ~~an~~ the embryo/fetus ~~shall be taken as~~ is the sum of--

3.12.3.1 The deep-dose equivalent to the declared pregnant woman; and

3.12.3.2 The dose equivalent to the embryo/fetus resulting from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.

3.12.4 If the dose equivalent to the embryo/fetus is found to have exceeded 0.5 rem (5 mSv), or is within 0.05 rem (0.5 mSv) of this dose, by the time the woman declares the pregnancy to the licensee, the licensee shall be deemed to be in compliance with paragraph 3.12.1 of this section if the additional dose equivalent to the embryo/fetus does not exceed 0.05 rem (0.5 mSv) during the remainder of the pregnancy.

RHA 3.16 SURVEYS AND MONITORING

3.16.1 Each licensee shall make or cause to be made, surveys that--

3.16.1.1 May be necessary for the licensee to comply with the regulations in this part; and

3.16.1.2 Are reasonable under the circumstances to evaluate--

3.16.1.2.1 The magnitude and extent of radiation levels; and

3.16.1.2.2 Concentrations or quantities of radioactive material; and

3.16.1.2.3 The potential radiological hazards ~~that could be present~~.

3.17.1 Each licensee shall monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee and shall supply and require the use of individual monitoring devices by--

3.17.1.2 Minors ~~and declared pregnant women~~ likely to receive, in 1 year from radiation sources external to the body, a deep dose equivalent in excess of ~~10 percent of any of the applicable limits in RHA 3.11 or 3.12, and~~ 0.1 rem (1 mSv), a lens dose equivalent in excess of 0.15 rem (1.5 mSv), or a shallow dose equivalent to the skin or to the extremities in excess of 0.5 rem (5 mSv);

3.17.1.3 Declared pregnant women likely to receive during the entire pregnancy, from radiation sources external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv). (Note: All of the occupational doses in RHA 3.5 continue to be applicable to the declared pregnant worker as long as the embryo/fetus dose limit is not exceeded.)

3.17.1.34 Individuals entering a high or very high radiation area.

3.17.2 Each licensee shall monitor (see RHA 3.8) the occupational intake of radioactive material by and assess the committed effective dose equivalent to:

3.17.2.1 Adults likely to receive, in 1 year, an intake in excess of 10 percent of the applicable ALI(s) in Table 1, Columns 1 and 2, of Appendix B, RHA 3.53; ~~and~~

3.17.2.2 Minors ~~and declared pregnant women~~ likely to receive, in 1 year, a committed effective dose equivalent in excess of ~~0.05~~ 0.1 rem (0.5 1 mSv); ~~and~~

3.17.2.3 Declared pregnant women likely to receive, during the entire pregnancy, a committed effective dose equivalent in excess of 0.1 rem (1 mSv).

3.23.4 Rooms in hospitals or clinics that are used for teletherapy are exempt from the requirement to post caution signs under RHA 3.22 if--

3.23.4.1 Access to the room is controlled pursuant to RHA 4.14.6; and

3.23.4.2 Personnel in attendance take necessary precautions to prevent the inadvertent exposure of workers, other patients, and members of the public to radiation in excess of the limits established in this part.

3.26.4 The licensee shall immediately notify the final delivery carrier and, ~~by telephone and telegram, mailgram, or facsimile,~~ the S.C. Department of Health & Environmental Control, Bureau of Radiological Health, ~~2600 Bull Street, Columbia, SC 29201,~~ (803-545-4400 or 803-690-8286), by telephone, when:

3.34.2 In the records required by this part, the licensee may record quantities in SI units in parentheses following each of the units specified in RHA 3.34.1. However, all quantities must be recorded as stated in RHA 3.34.1.

3.34.23 Notwithstanding the requirements of 3.34.1 of this section, when recording information on shipment manifests, as required in 3.32.2 information must be recorded in the International System of Units(SI) or in SI and units as specified in 3.34.1 of this section.

3.34.34 The licensee shall make a clear distinction among the quantities entered on the records required by this part (e.g., total effective dose equivalent, shallow-dose equivalent, ~~eye lens~~ dose equivalent, deep-dose equivalent, committed effective dose equivalent).

3.34.45 Prior to license termination, each licensee authorized to possess radioactive material with a half-life greater than 120 days or source material, in an unsealed form, shall forward the following records to the Department:

3.34.45.1 Records of disposal of licensed material made under RHA 3.28 thru 3.31; and

3.34.45.2 Records required by RHA 3.36.2.4.

3.34.56 If licensed activities are transferred or assigned in accordance with RHA 2.10.2, each licensee authorized to possess radioactive material with a half-life greater than 120 days or source material, in an unsealed form, shall transfer the following records to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated:

3.34.56.1 Records of disposal of licensed material made under RHA 3.28 thru 3.31; and

3.34.56.2 Records required by RHA 3.36.2.4.

3.34.67 Prior to license termination, each licensee shall forward the records required by RHA 1.15.11 to the Department.

3.35.2 The licensee shall retain the records required by paragraph 3.35.1.1 of this section until the Department terminates each pertinent license requiring the record. The licensee shall retain the records required by paragraph 3.35.1.2 of this section for ~~23~~ years after the record is made.

3.36.1 Each licensee shall maintain records showing the results of surveys and calibrations required by RHA 3.16 and 3.26.2. The licensee shall retain these records for ~~43~~ years after the record is made.

3.37.6 The licensee shall retain the records on S.C. Form 4 or equivalent until the Department terminates each pertinent license requiring this record. The licensee shall retain records used in preparing S.C. Form 4 for ~~23~~ years after the record is made.

3.39.1.1 The deep-dose equivalent to the whole body, eye lens dose equivalent, shallow-dose equivalent to the skin, and shallow-dose equivalent to the extremities; and

3.39.1.2 The estimated intake ~~or body burden~~ of radionuclides (see RHA 3.6); and

3.39.1.3 The committed effective dose equivalent assigned to the intake ~~or body burden~~ of radionuclides; and

3.39.1.4 The specific information used to ~~calculate~~ assess the committed effective dose equivalent pursuant to RHA 3.8.1 and RHA 3.8.3, and when required by RHA 3.17, and

RHA 3.45 NOTIFICATION OF INCIDENTS

3.45.1 Immediate notification. Notwithstanding any other requirements for notification, each licensee shall immediately notify the S.C. Department of Health & Environmental Control, Bureau of Radiological Health, 2600 Bull Street, Columbia, SC 29201, by telephone (803-545-4400) and confirming letter of any event involving radioactive material possessed by the licensee that may have caused or threatens to cause any of the following conditions--

3.45.1.1 An individual to receive:

3.45.1.1.1 A total effective dose equivalent of 25 rems (0.25 Sv) or more; or

3.45.1.1.2 ~~An eye~~ A lens dose equivalent of 75 rems (0.75 Sv) or more;

3.45.2.1.2 ~~An eye~~ A lens dose equivalent exceeding 15 rems (0.15 Sv);

4.5.2 Before it permits anyone ~~except to work as~~ an authorized user or authorized nuclear pharmacist under the license, except an individual who is:

4.7.6.3 The licensee shall retain records documenting each visiting authorized user's stay at the licensed facility as specified in RHA 4.7.6.1 for ~~two~~three years from the date of the last visit, but may discard these records if the visiting authorized user has been listed as an authorized user on the licensee's license.

4.7.7.3 Mobile nuclear medicine service licensees shall obtain a letter signed by the management of each client for which services are rendered that authorizes use of radioactive material at the client's address of use. The mobile nuclear medicine service licensee shall retain the letter for ~~two~~three years after the last provision of service. The client of mobile nuclear medicine services is responsible for assuring that services are conducted in accordance with these regulations while the mobile nuclear medicine service is under the client's direction.

4.8.2.5 The licensee shall retain a record of each check and test required by this section for ~~two~~three years. The records required by RHA 4.8.2.2.1 through 4.8.2.2.4 shall include:

4.8.3.5 The licensee shall retain a record of each calibration required in RHA 4.8.3.1 for ~~two~~three years. The record shall include:

4.8.4.3 Retain a record of the assays required by RHA 4.8.4.1 and 4.8.4.2, for ~~two~~three years. To satisfy this requirement, the record shall contain the:

4.8.6.9 The licensee shall retain a record of each survey required in RHA 4.8.6.8 for ~~two~~three years. The record must include the date of the survey, a sketch of each area that was surveyed, the measured dose rate at several points in each area expressed in millirem per hour, the model number and serial number of the survey instrument used to make the survey, and the signature of the Radiation Safety Officer.

4.8.11.8 The licensee shall retain a record of each survey required by RHA 4.8.11.1, 4.8.11.2 and 4.8.11.5 for ~~two~~three years. The record must include the date of the survey, a sketch of each area surveyed, action levels established for each area, the measured dose rate at several points in each area expressed in millirem per hour or the removable contamination in each area expressed in disintegrations per minute per 100 square centimeters, the instrument used to make the survey or analyze the samples, and the initials of the individual who performed the survey.

4.8.13.6 Retain a record of each survey required by RHA 4.8.13.5 for ~~two~~three years. The record must include the date of the survey, a sketch of each area that was surveyed, the measured dose rate at several points in each area of use expressed in millirem per hour, the instrument used to make the survey, the initials of the individual who performed the survey.

4.8.15.2 For radioactive material disposed in accordance with RHA 4.8.15.1, the licensee shall retain a record of each disposal for ~~two~~three years. The record must include the date of the disposal, the date on which the radioactive material was placed in storage, the model and serial number of the survey instrument used, the background dose rate, the radiation dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

4.10.2.5 The licensee who must measure Molybdenum concentration shall retain a record of each measurement for ~~two~~three years. The record shall include, for each elution or extraction of Technetium-99m, the measured activity of the Technetium expressed in millicuries, the measured activity of the Molybdenum expressed in microcuries, the ratio of the measures expressed as microcuries of Molybdenum per millicurie of Technetium, the date and time of the test, and the initials of the individual who performed the test.

4.11.2.3 The licensee shall keep for ~~two~~three years, a list of individuals receiving instruction required by RHA 4.11.2.1, a description of the instruction, the date of instruction, and the name of the individual who gave the instruction.

4.11.3.1.4 Promptly after administration of the dosage, measure the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of Part III of these regulations and retain for ~~two~~three years a record of each survey that includes the time and date of the survey, a sketch of the area or list of points surveyed,

the measured dose rate at several points expressed in millirem per hour, the instrument used to make the survey, and the initials of the individual who made the survey;

4.13.2.3 The licensee shall retain for ~~two~~three years a record of individuals receiving instruction required by RHA 4.13.2.1, a description of the instructions, the date of instruction, and the name of the individual who gave the instructions.

4.13.3.1.4 Promptly after implanting the sources, survey the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of Part III of these regulations and retain for ~~two~~three years a record of each survey that includes the time and date of the survey, a sketch of the area or list of points surveyed, the measured dose rate at several points expressed in mrem per hour, the instrument used to make the survey, and the initials of the individual who made the survey; and

4.13.4.6 The licensee shall retain the records required in RHA 4.13.4.2 and 4.13.4.3 for ~~two~~three years.

4.13.5.2 The licensee shall retain a record of patient or human research subject surveys which demonstrate compliance with RHA 4.13.5.1 for ~~two~~three years. Each record must include the date of the survey, the name of the patient or the human research subject, the dose rate from the patient or the human research subject expressed as millirem per hour and measured at 1 meter from the patient or the human research subject, the survey instrument used, and the initials of the individual who made the survey.

4.14.4.3 The licensee shall retain for ~~two~~three years a record of individuals receiving instruction required by RHA 4.14.4.2, a description of the instruction, the date of instruction, and the name of the individual who gave the instruction.

4.14.9.5 The licensee shall maintain a record of the check required by RHA 4.14.9.4 for ~~two~~three years. The record shall include the date of the check, notation that the monitor indicates when its detector is and is not exposed, and the initials of the individual who performed the check.

4.14.13.4 The licensee shall have the teletherapy physicist review the results of each output spot-check within fifteen days. The teletherapy physicist shall promptly notify the licensee in writing of the results of each output spot-check. The licensee shall keep a copy of each written notification for ~~two~~three years.

4.14.13.8 The licensee shall retain a record of each spot-check required by RHA 4.14.13.1 and 4.14.13.5 for ~~two~~three years. The record shall include the date of the spot-check, the manufacturer's name, model number, and serial number for both the teletherapy unit and source, the manufacturer's name, model number and serial number of the instrument used to measure the output of the teletherapy unit, an assessment of timer linearity and constancy, the calculated on-off error, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, the measured timer accuracy for a typical treatment time, the determined accuracy of each distance measuring or localization device, the difference between the anticipated output and the measured output, notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system and doors, and the signature of the individual who performed the periodic spot-check.

4.14.14.1.2.1 Radiation dose ~~quantities per unit time rates~~ in restricted areas are not likely to cause ~~personnel exposures~~ any occupationally exposed individual to receive a dose in excess of the limits specified in RHA 3.5 of these regulations; and

4.14.14.1.2.2 Radiation dose ~~quantities per unit time rates in controlled or in~~ unrestricted areas ~~do not exceed~~ likely to cause any individual member of the public to receive a dose in excess of the limits specified in RHA 3.13-1.2 of these regulations.

4.14.15.3 The licensee shall retain for ~~two~~three years a record of the facility checks following installation of a source. The record shall include notations indicating the operability of each entrance door interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system, and doors, and the signature of the Radiation Safety Officer.

4.14.16.1 If the survey required by RHA 4.14.14 indicates that ~~an~~ any individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by member of the public is likely to receive a dose in excess of the limits specified in RHA 3.13-1.2 of these regulations, the licensee shall, before beginning the treatment program the licensee shall:

4.14.16.1.1 Either equip the unit with stops or add additional radiation shielding to ensure compliance with ~~RHA 3.13-1.2 of these regulations;~~

4.14.16.1.2 Perform the survey required by RHA 4.14.14 again; and

4.16.2.3 Retain records of each review, including the evaluations and findings of the review, in an auditable form for ~~two~~three years.

4.16.3.3 Retaining a record, in an auditable form for ~~two~~three years, of the relevant facts and what corrective action, if any, was taken.

4.16.4.2 A record of each administered radiation dose or radiopharmaceutical dosage where a written directive is required in RHA 4.16.1.1 above, in an auditable form, for ~~two~~three years after the date of administration.

5.9.5 Each exposure device using depleted uranium (DU) shielding and an "S" tube configuration must be tested for DU contamination at intervals not to exceed 12 months. The analysis must be capable of detecting the presence of .005 microcuries (185 Bq) of radioactive material on the test sample and must be performed by a person specifically authorized by the Department or an Agreement State to perform the analysis. Should such testing reveal the presence of .005 microcuries (185 Bq) or more of removable DU contamination, the exposure device must be removed from use until an evaluation of the wear on the S-tube has been made. Should the evaluation reveal that the S-tube is worn through, the device may not be used again. DU shielded devices do not have to be tested for DU contamination while in storage and not in use. Before using or transferring such a device however, the device must be tested for DU contamination if the interval of storage exceeded 12 months. A record of the DU leak-test must be made in accordance with RHA 5.9.3. Licensees will have until May 26, 2001, to comply with the DU leak-testing requirements of this paragraph.

5.12.1.2 The licensee may, until May 26, 2002, ~~for two years following the effective date of regulations,~~ allow an individual who has not met the requirements of RHA 5.12.1.1 to act as a radiographer after the individual has received training in the subjects outlined in RHA 5.12.7 and

demonstrated an understanding of these subjects by successful completion of a written examination that was previously submitted to and approved by the Department.

5.12.8 Licensees will have until May 26, 2001, ~~one year following the effective date of these regulations~~ to comply with the additional training requirements specified in RHA 5.12.2.1 and RHA 5.12.3.1.

5.12.9 Licensees will have until May 26, 2002, ~~two years following the effective date of these regulations~~ to comply with the certification requirements specified in RHA 5.12.1.1. Records of radiographer certification maintained in accordance with RHA 5.12.10.1 provide appropriate affirmation of certification requirements specified in RHA 5.12.1.1.

5.21.4 Licensees will have until May 26, 2001, ~~one year from the effective date of these regulations~~ to meet the requirements for having two qualified individuals present at locations other than a permanent radiographic installation as specified in RHA 5.21.1.

5.22.4 Licensees will have until May 26, 2002, ~~two years following the effective date of these regulations~~ to meet the requirements of RHA 5.22.1 or 5.22.2.

7.11.3 The license will be ~~terminated~~ transferred only on the full implementation of the final closure plan as approved by the Department including postclosure observation and maintenance.

RHA 8.9 RADIATION SURVEY INSTRUMENTS

8.9.1 The licensee shall keep a calibrated and operable radiation survey instrument capable of detecting beta and gamma radiation at each field station and temporary jobsite to make the radiation surveys required by this Part and by Part III of these regulations. To satisfy this requirement, the radiation survey instrument must be capable of measuring ~~0.1 milliroentgen~~ 0.001 mSv (0.1 mrem) per hour through at least ~~50 milliroentgens~~ 0.5 mSv (50 mrem) per hour. ~~Survey instruments acquired before the effective date and capable of measuring 0.1 milliroentgen per hour through at least 20 milliroentgens per hour also satisfy this requirement until July 14, 1992.~~

8.24.2 During well logging, ~~except~~ when radiation sources are below ground or in shipping or storage containers, the logging supervisor or other individual designated by the logging supervisor shall maintain direct surveillance of the operation to prevent unauthorized entry into a restricted area, as defined in RHA ~~1.2.24~~ of these regulations.

11.8.7 Each entrance to the radiation room of a panoramic irradiator and each entrance to the area within the personnel access barrier of an underwater irradiator must ~~have a sign bearing the radiation symbol and the words, "Caution (or danger) radioactive material."~~ be posted as required by RHA 3.22. Panoramic irradiators must also have a sign stating "High radiation area," but the Radiation postings for panoramic irradiators must comply with the posting requirements of RHA 3.22, except that signs may be removed, covered, or otherwise made inoperative when the sources are fully shielded.

ATTACHMENT D

**EXCERPT FROM STATE REGISTER
NOTICE OF PROPOSED REGULATION
October 11, 2001**

PROPOSED REGULATIONS 47

Document No. 2647

**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)

Preamble:

The Nuclear Regulatory Commission continually updates regulations, and state regulations are amended regularly to incorporate federal updates. The Department plans to adopt into regulation the Nuclear Regulatory Commission updates as an item of compatibility. Section 274 of the Atomic Energy Act of 1954, as amended, requires that the states adopt federal regulations for compatibility. The Department intends to make changes to R.61-63 to this extent. The intended action makes minor correcting and clarifying changes to the requirements in Part III which address standards for protection against radiation. Additional changes will conform Parts I, IV, VIII, and XI to the revised Part III. Subjects include Part III, Conditions Requiring Individual Monitoring of External and Internal Occupational Dose; Exceptions to Posting Requirements; Notification of Incidents; Part IV, Modification of Teletherapy Unit or Room; Part VIII, Radiation Survey Instruments (Well Logging); Surveillance of Operations; Part XI, Access Control (Irradiators). Additional amendments in Part V, Industrial Radiography, are solely administrative in that they correct and clarify the text of an existing regulation and do not result in any essential change. Subjects dealt with in Part V clarify implementation dates for certain training requirements. Proposed regulations will comply with 10 CFR Parts 20, 34, 35, and 36, Final Rules, published in the Federal Register on July 9, 1998, July 23, 1998 and August 26, 1998. Legislative review will not be required.

A Notice of Drafting for this amendment was published in the State Register on March 23, 2001. The revision is being promulgated to comply with federal law; neither a fiscal impact statement nor preliminary assessment report is required. See discussion of proposed revisions below and a statement of need and reasonableness provided herein.

Discussion of Proposed Revisions:

- (1) Revises definitions to conform to Part III.

SECTION

REVISION

61-63.1.2.11

Revises definition for "High Radiation Area."

- (2) Definition revisions, deletions and renumbering for Part III.

SECTION

REVISION

61-63.3.2.20

Revises definition for “Declared pregnant woman.”

61-63.3.2.37

Deletes definition for “Eye dose equivalent.”

61-63.3.2.38
through 3.2.40

Renumbered due to deletion of 3.2.37.

61-63.3.2.40

New definition for “High Radiation Area” added.

61-63.3.2.42

Adds new definition for “Individual monitoring devices.”

South Carolina State Register Vol. 25, Issue 8
August 24, 2001

ATTACHMENT E

Drafting Notice for Regulation 61-63, Radioactive Material (Title A)

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61

Statutory Authority: S.C. Code Sections 13-7-10 et seq.; 13-7-40

Notice of Drafting:

The Department of Health and Environmental Control proposes to amend R. 61-63, Radioactive Materials (Title A). Interested persons may submit comments to Pearce O'Kelley, Chief, Bureau of Radiological Health, S.C. Department of Health and Environmental Control, 2600 Bull Street, Columbia, S.C. 29201. To be considered, comments must be received by 5 p.m. on April 23, 2001.

Synopsis:

The Nuclear Regulatory Commission continually updates regulations, and state regulations are amended regularly to incorporate federal updates. The Department plans to adopt into regulation the Nuclear Regulatory Commission updates as an item of compatibility. Section 274 of the Atomic Energy Act of 1954, as amended, requires that the states adopt federal regulations for compatibility. The Department intends to make changes to R. 61-63 to this extent. The intended action makes minor correcting and clarifying changes to the requirements in Part III which address standards for protection against radiation. Additional changes will conform Parts I, IV, VIII, and XI to the revised Part III. Subjects include Part III, Conditions Requiring Individual Monitoring of External and Internal Occupational Dose; Exceptions to Posting Requirements; Notification of Incidents; Part IV, Modification of Teletherapy Unit or Room; Part VIII, Radiation Survey Instruments (Well logging); Surveillance of Operations; Part XI, Access Control (Irradiators). Additional amendments in Part V, Industrial Radiography, are solely administrative in that they correct and clarify the text of an existing regulation and do not result in any essential change. Subjects dealt with in Part V clarify implementation dates for certain training requirements. Proposed regulations will comply with 10 CFR Parts 20, 34, 35, and 36, Final Rules, published in the Federal Register on July 9, 1998, July 23, and August 26, 1998. Legislative review will not be required.

ATTACHMENT F
APPLICABLE LAW: SC CODE SECTION 13-7-40

SECTION 13-7-40. Powers and duties of Department of Health and Environmental Control; Technical Advisory Radiation Control Council; regulation of persons controlling or using sources of ionizing radiation.

(A) The Department of Health and Environmental Control is designated as the agency of the State which is responsible for the control and regulation of radiation sources but, notwithstanding anything in this article, does not have the power to regulate, license, or control nuclear reactors of facilities or operations incident to them in duplication of an activity of the federal government which has not been discontinued by agreement pursuant to Section 13-7-60.

(B) The department shall employ, compensate, and prescribe the powers and duties of individuals necessary to carry out the provisions of this article as it pertains to the department. The department shall establish a technical advisory council to assist it in performing its specialized responsibilities.

(C) There is established a Technical Advisory Radiation Control Council responsible and reporting to the department which shall advise the department on matters pertaining to ionizing and nonionizing radiation and standards and regulations to be adopted, modified, promulgated, or repealed by the department. No standards or regulations may be adopted, modified, promulgated, or repealed by the department except after consultation with the council. The council consists of six members and one ex officio member from the department, designated by the department or its designated agent. The six members of the council must be appointed by the Governor as follows: one member from the South Carolina Medical Association, one member from the South Carolina Dental Association, one member from the South Carolina Radiological Society, one member from the South Carolina Chiropractic Association, one member having recognized knowledge in the field of radiation and its biological effects from the Associated Industries of South Carolina, and one member from the State at large having recognized knowledge in the field of radiation and its biological effects. The terms of office of the members first appointed are as follows: The member from the South Carolina Medical Association must be appointed for one year, the members from the South Carolina Dental Association and the South Carolina Radiological Society must be appointed for two years, and the other three members must be appointed for three years. The successors must be appointed for three years each.

(D) When on business of the council, members are allowed the usual mileage, per diem, and subsistence as provided by law for members of state boards, committees, and commissions. The council shall meet at least as frequently as semiannually or at call of the chairman. Minutes of meetings of the council must be included in the minutes of the meeting of the department next occurring after the preparation of the minutes.

(E) A consulting radiation physicist, certified by the American Board of Radiology, must be available to the Advisory Council at its regular meetings and on request. The consulting physicist must be paid on a per diem basis from budgeted funds.

(F) The department in connection with the control and regulation of radiation sources, in addition to its other duties as imposed by law shall:

(1) develop and conduct programs for evaluation of hazards associated with the use of radiation sources;

(2) develop and conduct programs for the control, surveillance, and regulation of radiation sources, not inconsistent with those prescribed by the United States Atomic Energy Commission, and with due regard for controls and regulations in effect in other states;

(3) formulate, adopt, promulgate, and repeal regulations relating to the control of ionizing and nonionizing radiation;

(4) issue orders or modifications of them as may be necessary in connection with proceedings under this article;

(5) advise the Governor, the legislature, and relevant state agencies with regard to the status of radiation control and consult and cooperate with the various departments, agencies, and political subdivisions of the State, the federal government, other states, and interstate agencies and with public and private groups concerned with the control of radiation sources and hazards;

(6) accept and administer loans, grants, or other funds or gifts, conditional or otherwise, in furtherance of its functions, from the federal government and from other sources, public or private;

(7) encourage, participate in, or conduct studies, investigations, training, and demonstrations relating to control of radiation sources;

(8) collect and disseminate information relating to control of radiation sources;

(9) provide by regulation for the licensing or registration of radiation sources or devices or equipment utilizing these sources. These regulations must provide for amendment, suspension, or revocation of licenses;

(10) promulgate and repeal regulations pertaining to the qualifications of operators applying ionizing or nonionizing radiation to humans.

(G) No person may possess, use, or transfer a source of ionizing or nonionizing radiation unless registered, licensed, or exempted by the department.

(H) The department may exempt certain radiation sources or kinds of uses or users from the licensing or regulation requirements set forth in this section when the department makes a finding that the exemption of these radiation sources or kinds of uses or users will not constitute a significant risk to the health of the public.

(I) The department or its authorized representatives may enter at all reasonable times upon private or public property for the purpose of determining whether or not there is compliance with or violation of the provisions of this article and regulations promulgated under it. A report of investigation or inspection or information concerning trade secrets or secret industrial processes obtained under this article must not be disclosed or opened to public inspection except as necessary for the performance of the functions of the department. The department shall require each person who possesses or uses a radiation source to maintain records relating to its receipt, storage, transfer, or disposal and other records the department may require, subject to exemptions as may be provided by regulations. Copies of these records must be submitted to the department on written request. The department shall require each person who possesses or uses a radiation source to maintain appropriate records showing the radiation exposure of all individuals for whom personnel monitoring is required by the regulations of the department. Copies of these records and those required to be kept must be submitted to the department on written request.

(J) A person possessing or using a radiation source shall furnish to each employee for whom personnel monitoring is required, or to the employee's physician, a copy of the employee's personal record at times the department by regulation may prescribe.

(K) Opportunity for public hearing must be provided by the department for the issuance of a modification of regulations; the granting, suspending, revoking, or amending a license; and determining compliance with or granting exceptions from regulations of the department. A final order entered in a proceeding is subject to judicial review.

(L) Whenever, in the judgment of the department, a person has engaged in or is about to engage in acts or practices which constitute a violation of a provision of this article or a regulation or an order issued under it, the department, or, at the request of the department, the Attorney General may make application to the court of common pleas for an order enjoining these acts or practices, or for an order directing compliance. Upon a showing by the department that the person has engaged in or is about to engage in these acts or practices, a permanent or temporary injunction, restraining order, or other order may be granted.

(M) In an emergency the department may impound sources of ionizing or nonionizing radiation in the possession of a person who is not equipped to comply with or fails to comply with the provisions of the article or the regulations.

(N) The department, subject to the approval of the Governor, may enter into agreements with the federal government or other state or interstate agencies for the purpose of performing on a cooperative basis inspections or other functions relating to the control of sources of ionizing or nonionizing radiation. The department may institute training programs for the purpose of qualifying personnel to carry out the provisions of this article.

(O) Ordinances, resolutions, or regulations in effect now or in the future of the governing body of an agency or political subdivision of the State relating to radiation sources are not superseded by this article if the ordinances or regulations are and continue to be consistent with the provisions of this article, amendments to it, and regulations under it.

(P) No person may apply ionizing or nonionizing radiation to humans unless certified or exempted by the department.