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2600 Bull Street
Columbia, SC 29201-1708

February 19, 2003

Attention: John Zebco

Enclosed please find the final regulation changes on disk for SC Rad. Materials Regulations. These changes were sent previously with a cover letter from James K. Peterson (dated January 22, 2003) but the disk was unreadable. Please note that the format does not contain highlighted material but rather gives specific directives on the changes. Please contact me at (803)545-4411 if you have any problems with this.

Sincerely,

Melinda Bradshaw

Melinda Bradshaw
Section Manager-Medical
Division of Radioactive Material
Licensing and Compliance
Bureau of Radiological Health

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SP 06

Revise R.61-63.2.4.1 to read:

2.4.1 Purpose and Scope

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

Revise R.61-63.2.4.2 to read:

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

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

Revise R.61-63.2.4.2.2 to read:

2.4.2.2 The general license in RHA 2.4.2.1 of this section applies only to radioactive material contained in devices which have been manufactured or initially transferred and labeled in accordance with the specifications contained in a specific license issued under RHA 2.7 of this part or an equivalent specific license issued by the U.S. Nuclear Regulatory Commission or an Agreement State.

The devices must have been received from one of the specific licensees described in the above paragraph or through a transfer made under RHA 2.4.2.3.8 of this part.

Revise R.61-63.2.4.2.3.5 to read:

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

Revise R.61-63.2.4.2.3.7 through 2.4.2.3.7.2 to read:

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

2.4.2.3.7.1 Shall furnish a report to the Department within 30 days after the transfer of a device to a specific licensee. The report must contain the identification of the device by manufacturer's (or initial transferor's) name, model number, and serial number; the name, address, and license number of the person receiving the device; and the date of the transfer.

2.4.2.3.7.2 Shall obtain written Departmental approval before transferring the device to any other specific licensee not specifically identified in RHA 2.4.2.3.7.

Revise R.61-63.2.4.2.3.8 through 2.4.2.3.8.2 to read:

2.4.2.3.8 Shall transfer the device to another general licensee only:

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

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

Add new sections R.61-63.2.4.2.3.10 through 2.4.2.3.13:

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

2.4.2.3.11 Shall register generally licensed devices:

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

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

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

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

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

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

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

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

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

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

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

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

Revise R.61-63.2.7.1.1.3.3 to read:

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

Receipt, possession, use, and transfer of this device Model[3]*, Serial No [3]*, containing (Identity and quantity of radioactive material) are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION-RADIOACTIVE MATERIAL

_____

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

Add new sections R.61-63.2.7.1.1.4 through 2.7.1.1.5:

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

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

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

Revise R.61-63.2.7.1.4 through 2.7.1.4.5 to read:

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

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

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

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

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

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

Add new sections R.61-63.2.7.1.5 through 2.7.1.9.2:

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

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

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

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

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

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

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

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

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

2.7.1.9.1 The person shall report all transfers of devices to persons for use under the general license in RHA 2.4.2 of these regulations and for use under equivalent NRC regulations (10CFR31.5) or other Agreement State's regulations and all receipts of devices from persons licensed under RHA 2.4.2 to the Department or to the appropriate NRC office or other Agreement State office. The report must be submitted on a quarterly basis on NRC Form 653—"Transfers of Industrial Devices Report" or in a clear and legible

report containing all of the data required by the form. (NRC Form 653 may be obtained from the Department or found in NUREG-1556, Vol. 16.)

2.7.1.9.1.1 The required information for transfers to general licensees includes--

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

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

(iii) The date of transfer;

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

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

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

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

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

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

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

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

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

Revise R.61-63.2.10.6 to read:

2.10.6 Each general licensee that is required to register by RHA 2.4.2.3.11 of this Part and each specific licensee shall notify the Department, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against:

Add new definition for R.61-63.3.2.5:

3.2.5 "Air-purifying respirator" means a respirator with an air-purifying filter, cartridge, or canister that removes specific air contaminants by passing ambient air through the air-purifying element.

Renumber existing R.61-63.3.2.5 to 3.2.6:

3.2.6 "ALARA" (acronym for "as low as is reasonably achievable") means making every reasonable effort to maintain exposures to radiation as far below the dose limits in this part as is practical consistent with the purpose for which the licensed activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed materials in the public interest.

Renumber existing R.61-63.3.2.6 to 3.2.7:

3.2.7 "Annual limit on intake" (ALI) means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent of 5 rems (0.05 Sv) or a committed dose equivalent of 50 rems (0.5 Sv) to any individual organ or tissue. (ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Table 1, Columns 1 and 2, of Appendix B, RHA 3.53).

Add new definition for R.61-63.3.2.8:

3.2.8 "Assigned protection factor" (APF) means the expected workplace level of respiratory protection that would be provided by a properly functioning respirator or a class of respirators to properly fitted and trained users. Operationally, the inhaled concentration can be estimated by dividing the ambient airborne concentration by the APF.

Add new definition for R.61-63.3.2.9:

3.2.9 "Atmosphere-supplying respirator" means a respirator that supplies the respirator user with breathing air from a source independent of the ambient atmosphere, and includes supplied-air respirators (SARs) and self-contained breathing apparatus (SCBA) units.

Renumber existing R.61-63.3.2.7 to 3.2.10:

3.2.10 "Background radiation" means radiation from cosmic sources; naturally occurring radioactive materials, including radon (except as a decay product of source or special nuclear material) and global fallout

as it exists in the environment from the testing of nuclear explosive devices. "Background radiation" does not include radiation from source, byproduct, or special nuclear materials regulated by the Department.

Renumber existing R.61-63.3.2.8 to 3.2.11:

3.2.11 "Bioassay" (radiobioassay) means the determination of kinds, quantities or concentrations, and, in some cases, the locations of radioactive material in the human body, whether by direct measurement (in vivo counting) or by analysis and evaluation of materials excreted or removed from the human body.

Renumber existing R.61-63.3.2.9 to 3.2.12:

3.2.12 "Chelating agent" means amine polycarboxylic acids, hydrocarboxylic, gluconic acid, and polycarboxylic acids.

Renumber existing R.61-63.3.2.10 to 3.2.13:

3.2.13 "Chemical description" means a description of the principal chemical characteristics of a low-level radioactive waste.

Renumber existing R.61-63.3.2.11 to 3.2.14:

3.2.14 "Class" (or lung class or inhalation class) means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or Y, which applies to a range of clearance half-times: for Class D (Days) of less than 10 days, for Class W (Weeks) from 10 to 100 days, and for Class Y (Years) of greater than 100 days.

Renumber existing R.61-63.3.2.12 to 3.2.15:

3.2.15 "Collective dose" is the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

Renumber existing R.61-63.3.2.13 to 3.2.16:

3.2.16 "Committed dose equivalent" (H) means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

Renumber existing R.61-63.3.2.14 to 3.2.17:

3.2.17 "Committed effective dose equivalent" ($H_{E,50}$) is the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to these organs or tissues ($H_{E,50} = \sum W_T H_{T,50}$).

Renumber existing R.61-63.3.2.15 to 3.2.18:

3.2.18 "Computer-readable medium" means a medium selected from the available technologies, as authorized by the Department, that can be used to transfer the information to the Department's computer.

Renumber existing R.61-63.3.2.16 to 3.2.19:

3.2.19 "Consignee" means the designated receiver of the shipment of low-level radioactive waste.

Renumber existing R.61-63.3.2.17 to 3.2.20:

3.2.20 "Constraint (dose constraint)" means a value above which specified licensee actions are required.

Renumber existing R.61-63.3.2.18 to 3.2.21:

3.2.21 "Controlled area" means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason.

Renumber existing R.61-63.3.2.19 to 3.2.22:

3.2.22 "Critical Group" means the group of individuals reasonably expected to receive the greatest exposure to residual radiation for any applicable set of circumstances.

Renumber existing R.61-63.3.2.20 to 3.2.23:

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

Renumber existing R.61-63.3.2.21 to 3.2.24:

3.2.24 "Decommission" means to remove a facility or site safely from service and reduce residual radioactivity to level that permits 1) release of the property for unrestricted use and termination of the license; or 2) release of the property under restricted conditions and termination of the license.

Renumber existing R.61-63.3.2.22 to 3.2.25:

3.2.25 "Decontamination facility" means a facility operating under a license whose principal purpose is decontamination of equipment or materials to accomplish recycle, reuse, or other waste management objectives, and, for purposes of this part, is not considered to be a consignee for LLW shipments.

Renumber existing R.61-63.3.2.23 to 3.2.26:

3.2.26 "Deep-dose equivalent" (H_d), which applies to external whole-body exposure, is the dose equivalent at a tissue depth of 1 cm (1000 mg/cm^2).

Add new definition for R.61-63.3.2.27:

3.2.27 "Demand respirator" means an atmosphere-supplying respirator that admits breathing air to the facepiece only when a negative pressure is created inside the facepiece by inhalation.

Renumber existing R.61-63.3.2.24 to 3.2.28:

3.2.28 "Derived air concentration" (DAC) means the concentration of a given radionuclide in air which, if breathed by the reference man for a working year of 2,000 hours under conditions of light work (inhalation rate 1.2 cubic meters of air per hour), results in an intake of one ALI. DAC values are given in Table 1, Column 3, of Appendix B, RHA 3.53.

Renumber existing R.61-63.3.2.25 to 3.2.29:

3.2.29 "Derived air concentration-hour" (DAC-hour) is the product of the concentration of radioactive material in air (expressed as a fraction or multiple of the derived air concentration for each radionuclide) and the time of exposure to that radionuclide, in hours. A licensee may take 2,000 DAC-hours to represent one ALI, equivalent to a committed effective dose equivalent of 5 rems (0.05 Sv).

Renumber existing R.61-63.3.2.26 to 3.2.30:

3.2.30 "Disposal container" means a container principally used to confine low-level radioactive waste during disposal operations at a land disposal facility (also see "high integrity container"). Note that for some shipments, the disposal container may be the transport package.

Add new definition for R.61-63.3.2.31:

3.2.31 "Disposable respirator" means a respirator for which maintenance is not intended and that is designed to be discarded after excessive breathing resistance, sorbent exhaustion, physical damage, or end-of-service-life renders it unsuitable for use. Examples of this type of respirator are a disposable half-mask respirator or a disposable escape-only self-contained breathing apparatus (SCBA).

Renumber existing R.61-63.3.2.27 to 3.2.32:

3.2.32 "Distinguishable from Background" means that the detectable concentration of a radionuclide is statistically different from the background concentration of that radionuclide in the vicinity of the site or, in the case of structures, in similar materials using adequate measurement technology, survey, and statistical techniques.

Renumber existing R.61-63.3.2.28 to 3.2.33:

3.2.33 "Dose or radiation dose" is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent, as defined in other paragraphs of this section.

Renumber existing R.61-63.3.2.29 to 3.2.34:

3.2.34 "Dose equivalent" (H_T) means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the rem and sievert (Sv).

Renumber existing R.61-63.3.2.30 to 3.2.35:

3.2.35 "Effective dose equivalent" (H_E) is the sum of the products of the dose equivalent to the organ or tissue (H_T) and the weighting factors (W_T) applicable to each of the body organs or tissues that are irradiated ($H_E = \sum W_T H_T$).

Renumber existing R.61-63.3.2.31 to 3.2.36:

3.2.36 "Embryo/fetus" means the developing human organism from conception until the time of birth.

Renumber existing R.61-63.3.2.32 to 3.2.37:

3.2.37 "Entrance or access point" means any location through which an individual could gain access to radiation areas or to radioactive materials. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

Renumber existing R.61-63.3.2.33 to 3.2.38:

3.2.38 "EPA identification number" means the number received by a transporter following application to the administrator of EPA as required by 40 CFR Part 263.

Renumber existing R.61-63.3.2.34 to 3.2.39:

3.2.39 "Exposure" means being exposed to ionizing radiation or to radioactive material.

Renumber existing R.61-63.3.2.35 to 3.2.40:

3.2.40 "External dose" means that portion of the dose equivalent received from radiation sources outside the body.

Renumber existing R.61-63.3.2.36 to 3.2.41:

3.2.41 "Extremity" means hand, elbow, arm below the elbow, foot, knee, and leg below the knee.

Add new definition for R.61-63.3.2.42:

3.2.42 "Filtering facepiece" (dust mask) means a negative pressure particulate respirator with a filter as an integral part of the facepiece or with the entire facepiece composed of the filtering medium, not equipped with elastomeric sealing surfaces and adjustable straps.

Add new definition for R.61-63.3.2.43:

3.2.43 "Fit factor" means a quantitative estimate of the fit of a particular respirator to a specific individual, and typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn.

Add new definition for R.61-63.3.2.44:

3.2.44 "Fit test" means the use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator on an individual.

Renumber existing R.61-63.3.2.37 to 3.2.45:

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

Renumber existing R.61-63.3.2.38 to 3.2.46:

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

Add new definition for R.61-63.3.2.47:

3.2.47 "Helmet" means a rigid respiratory inlet covering that also provides head protection against impact and penetration.

Renumber existing R.61-63.3.2.39 to 3.2.48:

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

Renumber existing R.61-63.3.2.40 to 3.2.49:

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

Add new definition for R.61-63.3.2.50:

3.2.50 "Hood" means a respiratory inlet covering that completely covers the head and neck and may also cover portions of the shoulders and torso.

Renumber existing R.61-63.3.2.41 to 3.2.51:

3.2.51 "Individual monitoring" means:

. (1) The assessment of dose equivalent by the use of devices designed to be worn by an individual;

. (2) The assessment of committed effective dose equivalent by bioassay (see Bioassay) or by determination of the time-weighted air concentrations to which an individual has been exposed, i.e., DAC-hours; or

. (3) The assessment of dose equivalent by the use of survey data.

Renumber existing R.61-63.3.2.42 to 3.2.52:

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

Renumber existing R.61-63.3.2.43 to 3.2.53:

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

Renumber existing R.61-63.3.2.44 to 3.2.54:

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

Renumber existing R.61-63.3.2.45 to 3.2.55:

3.2.55 "Lens dose equivalent (LDE)" applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm^2).

Renumber existing R.61-63.3.2.46 to 3.2.56:

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

Renumber existing R.61-63.3.2.47 to 3.2.57:

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

Add new definition for R.61-63.3.2.58:

3.2.58 "Loose-fitting facepiece" means a respiratory inlet covering that is designed to form a partial seal with the face.

Renumber existing R.61-63.3.2.48 to 3.2.59:

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

Renumber existing R.61-63.3.2.49 to 3.2.60:

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

Renumber existing R.61-63.3.2.50 to 3.2.61:

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

Renumber existing R.61-63.3.2.51 to 3.2.62:

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

Add new definition for R.61-63.3.2.63:

3.2.63 "Negative pressure respirator" (tight fitting) means a respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside the respirator.

Renumber existing R.61-63.3.2.52 to 3.2.64:

3.2.64 "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).

Renumber existing R.61-63.3.2.53 to 3.2.65:

3.2.65 "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.

Renumber existing R.61-63.3.2.54 to 3.2.66:

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 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.

Renumber existing R.61-63.3.2.55 to 3.2.67:

3.2.67 "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.

Renumber existing R.61-63.3.2.56 to 3.2.68:

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

Renumber existing R.61-63.3.2.57 to 3.2.69:

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

Add new definition for R.61-63.3.2.70:

3.2.70 "Positive pressure respirator" means a respirator in which the pressure inside the respiratory inlet covering exceeds the ambient air pressure outside the respirator.

Add new definition for R.61-63.3.2.71:

3.2.71 "Powered air-purifying respirator" (PAPR) means an air-purifying respirator that uses a blower to force the ambient air through air-purifying elements to the inlet covering.

Add new definition for R.61-63.3.2.72:

3.2.72 "Pressure demand respirator" means a positive pressure atmosphere-supplying respirator that admits breathing air to the facepiece when the positive pressure is reduced inside the facepiece by inhalation.

Renumber existing R.61-63.3.2.58 to 3.2.73:

3.2.73 "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.

Add new definition for R.61-63.3.2.74:

3.2.74 "Qualitative fit test" (QLFT) means a pass/fail fit test to assess the adequacy of respirator fit that relies on the individual's response to the test agent.

Renumber existing R.61-63.3.2.59 to 3.2.75:

3.2.75 "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.

Add new definition for R.61-63.3.2.76:

3.2.76 "Quantitative fit test" (QNFT) means an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

Renumber existing R.61-63.3.2.60 to 3.2.77:

3.2.77 "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.

Renumber existing R.61-63.3.2.61 to 3.2.78:

3.2.78 "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.

Renumber existing R.61-63.3.2.62 to 3.2.79:

3.2.79 "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.

Renumber existing R.61-63.3.2.63 to 3.2.80:

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

Renumber existing R.61-63.3.2.64 to 3.2.81:

3.2.81 "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.

Add new definition for R.61-63.3.2.82:

3.2.82 "Self-contained breathing apparatus" (SCBA) means an atmosphere-supplying respirator for which the breathing air source is designed to be carried by the user.

Renumber existing R.61-63.3.2.65 to 3.2.83:

3.2.83 "Shallow-dose equivalent" (H^s), 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.

Renumber existing R.61-63.3.2.66 to 3.2.84:

3.2.84 "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.

Renumber existing R.61-63.3.2.67 to 3.2.85:

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

Renumber existing R.61-63.3.2.68 to 3.2.86:

3.2.86 "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).

Renumber existing R.61-63.3.2.69 to 3.2.87:

3.2.87 "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.

Renumber existing R.61-63.3.2.70 to 3.2.88:

3.2.88 "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.

Add new definition for R.61-63.3.2.89:

3.2.89 "Supplied-air respirator" (SAR) or airline respirator means an atmosphere-supplying respirator for which the source of breathing air is not designed to be carried by the user.

Add new definition for R.61-63.3.2.90:

3.2.90 "Tight-fitting facepiece" means a respiratory inlet covering that forms a complete seal with the face.

Renumber existing R.61-63.3.2.71 to 3.2.91:

3.2.91 "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).

Renumber existing R.61-63.3.2.72 to 3.2.92:

3.2.92 "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.

Renumber existing R.61-63.3.2.73 to 3.2.93:

3.2.93 "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.

Add new definition for R.61-63.3.2.94:

3.2.94 "User seal check" (fit check) means an action conducted by the respirator user to determine if the respirator is properly seated to the face. Examples include negative pressure check, positive pressure check, irritant smoke check, or isoamyl acetate check.

Renumber existing R.61-63.3.2.74 to 3.2.95:

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

ı dose rates, units of absorbed dose (e.g., rads and grays) are appropriate, ... rather than units of dose equivalent (e.g., rems and sieverts).]

Renumber existing R.61-63.3.2.75 to 3.2.96:

3.2.96 "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.

Renumber existing R.61-63.3.2.76 to 3.2.97:

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

Renumber existing R.61-63.3.2.77 to 3.2.98:

3.2.98 "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."

Renumber existing R.61-63.3.2.78 to 3.2.99:

3.2.99 "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.

Renumber existing R.61-63.3.2.79 to 3.2.100:

3.2.100 "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).

Renumber existing R.61-63.3.2.80 to 3.2.101:

3.2.101 "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.

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[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.

Renumber existing R.61-63.3.2.81 to 3.2.102:

3.2.102 "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.

Renumber existing R.61-63.3.2.82 to 3.2.103:

3.2.103 "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).

Renumber existing R.61-63.3.2.83 to 3.2.104:

3.2.104 "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.

Revise R.61-63.3.19.1.1 to read:

. 3.19.1.1 The licensee shall use, to the extent practical, process or other engineering controls (e.g., containment, decontamination or ventilation) to control the concentrations of radioactive material in air.

Revise R.61-63.3.19.2 to read:

3.19.2 Use of Other Controls

When it is not practical to apply process or other engineering controls to control the concentrations of radioactive material in air to values below those that define an airborne radioactivity area, the licensee shall, consistent with maintaining the total effective dose equivalent ALARA, increase monitoring and limit intakes by one or more of the following means:

3.19.2.1 Control of access;.....

3.19.2.2 Limitation of exposure times;.....

3.19.2.3 Use of respiratory protection equipment; or.....

3.19.2.4 Other controls.....

If the licensee performs an ALARA analysis to determine whether or not respirators should be used, the licensee may consider safety factors other than radiological factors. The licensee should also consider the impact of respirator use on workers' industrial health and safety.

Revise R.61-63.3.19.3.1.1 to read:

3.19.3.1.1 The licensee shall use only respiratory protection equipment that is tested and certified by the National Institute for Occupational Safety and Health (NIOSH), except as otherwise noted in this regulation.

Revise R.61-63.3.19.3.1.2 to read:

3.19.3.1.2 If the licensee wishes to use equipment that has not been tested or certified by NIOSH or for which there is no schedule for testing or certification, the licensee shall submit an application for authorized use of that equipment, except as provided in this regulation, including a demonstration by testing, or a demonstration on the basis of reliable test information, that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use.

Revise R.61-63.3.19.3.1.3.1 to read:

3.19.3.1.3.1 Air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate doses;

Revise R.61-63.3.19.3.1.3.3 to read:

3.19.3.1.3.3 Testing of respirators for operability (user seal check for face sealing devices and functional check for others) immediately prior to each use;

Revise R.61-63.3.19.3.1.3.4 to read:

3.19.3.1.3.4 Written procedures regarding selection, fitting, issuance, maintenance, and testing of respirators, including testing for operability immediately prior to each use; supervision and training of personnel; breathing air quality; storage; inventory and control; repair; quality assurance of respiratory protection equipment; limitations on periods of respirator use and relief from respirator use; monitoring, including air sampling and bioassays; and recordkeeping; and

Revise R.61-63.3.19.3.1.3.5 to read:

3.19.3.1.3.5 Determination by a physician prior to initial fitting of face sealing respirators or before the first field use of non-face sealing respirators, and either every 12 months thereafter or periodically at a frequency determined by a physician, that the individual user is medically fit to use the respiratory protection equipment.

Add new R.61-63.3.19.3.1.3.6 to read:

3.19.3.1.3.6 Fit testing, with fit factor ≥ 10 times the APF for negative pressure devices, and a fit factor ≥ 500 for any positive pressure, continuous flow, and pressure-demand devices, before the first field use of tight fitting, face-sealing respirators and periodically thereafter at a frequency not to exceed 1 year. Fit testing must be performed with the facepiece operating in the negative pressure mode.

Replace existing R.61-63.3.19.3.1.4 through 3.19.3.1.4.3 to read:

. 3.19.3.1.4 The licensee shall advise each respirator user that the user may leave the area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other conditions that might require such relief.

Revise and renumber existing R.61-63.3.19.3.1.6 to 3.19.3.1.5 to read:

. 3.19.3.1.5 The licensee shall use equipment within limitations for type and mode of use and shall provide proper visual, communication, and other special capabilities (such as low temperature work environments) when needed. The licensee shall also provide for the concurrent use of other safety or radiological protection equipment. The licensee shall use equipment in such a way as not to interfere with the proper operation of the respirator.

Add new R.61-63.3.19.3.1.6 to read:

. 3.19.3.1.6 Standby rescue persons are required whenever one-piece atmosphere-supplying suits, or any combination of supplied air respiratory protection device and personnel protective equipment are used from which an unaided individual would have difficulty extricating himself or herself. The standby persons must be equipped with respiratory protection devices or other apparatus appropriate for the potential hazards. The standby rescue persons shall observe or otherwise maintain continuous communication with the workers (visual, voice, signal line, telephone, radio, or other suitable means), and be immediately available to assist them in case of a failure of the air supply or for any other reason that requires relief from distress. A sufficient number of standby rescue persons must be immediately available to assist all users of this type of equipment and to provide effective emergency rescue if needed.

Add new R.61-63.3.19.3.1.7 to read:

. 3.19.3.1.7 Atmosphere-supplying respirators must be supplied with respirable air of grade D quality or better as defined by the Compressed Gas Association in publication G-7.1, "Commodity Specification for Air," 1997 and included in the regulations of the Occupational Safety and Health Administration (29 CFR 1910.134 (i) (1) (ii) (A) through (E). Grade D quality air criteria include:

. (1) Oxygen content (v/v) of 19.5-23.5%;
. (2) Hydrocarbon (condensed) content of 5 milligrams per cubic meter of air or less;
. (3) Carbon monoxide (CO) content of 10 ppm or less;
. (4) Carbon dioxide content of 1,000 ppm or less; and
. (5) Lack of noticeable odor.

Add new R.61-63.3.19.3.1.8 to read:

. 3.19.3.1.8 The licensee shall ensure that no objects, materials or substances, such as facial hair, or any conditions that interfere with the face--facepiece seal or valve function, and that are under the control of the respirator wearer, are present between the skin of the wearer's face and the sealing surface of a tight-fitting respirator facepiece.

Replace existing R.61-63.3.19.3.2 to read:

. 3.19.3.2 In estimating the dose to individuals from intake of airborne radioactive materials, the concentration of radioactive material in the air that is inhaled when respirators are worn is initially assumed to be the ambient concentration in air without respiratory protection, divided by the assigned protection factor. If the dose is later found to be greater than the estimated dose, the corrected value must be used. If the dose is later found to be less than the estimated dose, the corrected value may be used.

Delete existing R.61-63.3.19.3.2.1 in its entirety.

Delete existing R.61-63.3.19.3.2.2 in its entirety.

Delete existing R.61-63.3.19.3.2.2.1 in its entirety.
Delete existing R.61-63.3.19.3.2.2.2 in its entirety.

Delete existing R.61-63.3.19.3.3 in its entirety.

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Delete existing R.61-63.3.19.3.4 in its entirety.

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Revise existing R.61-63.3.19.4.1 to read:

3.19.4.1 Ensure that the respiratory protection program of the licensee is adequate to limit doses to individuals from intakes of airborne radioactive materials consistent with maintaining total effective dose equivalent ALARA; and

Add new R.61-63.3.19.5:

d protection fa:tors 3.19.5

The licensee shall obtain authorization from the Department before using assigned protection factors in excess of those specified in Appendix A, RHA 3.52. The Department may authorize a licensee to use higher assigned protection factors on receipt of an application that--

Add new R.61-63.3.19.5.1:

3.19.5.1 Describes the situation for which a need exists for higher protection factors; and

Add new R.61-63.3.19.5.2:

3.19.5.2 Demonstrates that the respiratory protection equipment provides these higher protection factors under the proposed conditions of use.

Replace existing R.61-63.3.52, Appendix A in its entirety:

APPENDIX A – RHA 3.52 PROTECTION FACTORS FOR RESPIRATORS[a]

	Operating Mode	Assigned Protection Factors
I. Air Purifying Respirators (Particulate[b] only)[c]		
Filtering facepiece disposable[d]	Negative Pressure	([d])
Facepiece, half[e]	Negative Pressure	10
Facepiece, full	Negative Pressure	100
Facepiece, half	Powered air-purifying respirators	50
Facepiece, full	Powered air-purifying respirators	1000
Helmet/hood	Powered air-purifying respirators	1000
Facepiece, loose-fitting	Powered air-purifying respirators	25
II. Atmosphere supplying respirators (particulate, gases and vapors[f])		
1. Air-line respirator:		
Facepiece, half	Demand	10
Facepiece, half	Continuous Flow	50
Facepiece, half	Pressure Demand	50
Facepiece, full	Demand	100
Facepiece, full	Continuous Flow	1000
Facepiece, full	Pressure Demand	1000
Helmet/hood	Continuous Flow	1000
Facepiece, loose-fitting	Continuous Flow	25
Suit	Continuous Flow	([g])
2. Self-contained breathing Apparatus (SCBA):		
Facepiece, full	Demand	[h]100
Facepiece, full	Pressure Demand	[i]10,000
Facepiece, full	Demand, Recirculating	[h]100
Facepiece, full	Positive Pressure Recirculating	[i]10,000
II. Combination Respirators; Any combination of air-purifying and atmosphere-supplying respirators	(1) Assigned protection factor for type and mode of operation as listed above.	

[a] These assigned protection factors apply only in a respiratory protection program that meets the requirements of this Part. They are applicable only to airborne radiological hazards and may not be appropriate to circumstances when chemical or other respiratory hazards exist instead of, or in addition to, radioactive hazards. Selection and use of respirators for such circumstances must also comply with Department of Labor regulations.

Radioactive contaminants for which the concentration values in Table 1, Column 3 of Appendix B, RHA 3.53 are based on internal dose due to inhalation may, in addition, present external exposure hazards at higher concentrations. Under these circumstances, limitations on occupancy may have to be governed by external dose limits.

[b] Air purifying respirators with APF<100 must be equipped with particulate filters that are at least 95 percent efficient. Air purifying respirators with APF = 100 must be equipped with particulate filters that are at least 99 percent efficient. Air purifying respirators with APFs >100 must be equipped with particulate filters that are at least 99.97 percent efficient.

[c] The licensee may apply to the Department for the use of an APF greater than 1 for sorbent cartridges as protection against airborne radioactive gases and vapors (e.g., radioiodine).

[d] Licensees may permit individuals to use this type of respirator who have not been medically screened or fit tested on the device provided that no credit be taken for their use in estimating intake or dose. It is also recognized that it is difficult to perform an effective positive or negative pressure pre-use user seal check on this type of device. All other respiratory protection program requirements listed in RHA 3.19.3 apply. An assigned protection factor has not been assigned for these devices. However, an APF equal to 10 may be used if the licensee can demonstrate a fit factor of at least 100 by use of a validated or evaluated, qualitative or quantitative fit test.

[e] Under-chin type only. No distinction is made in this Appendix between elastomeric half-masks with replaceable cartridges and those designed with the filter medium as an integral part of the facepiece (e.g., disposable or reusable disposable). Both types are acceptable so long as the seal area of the latter contains some substantial type of seal-enhancing material such as rubber or plastic, the two or more suspension straps are adjustable, the filter medium is at least 95 percent efficient and all other requirements of this Part are met.

[f] The assigned protection factors for gases and vapors are not applicable to radioactive contaminants that present an absorption or submersion hazard. For tritium oxide vapor, approximately one-third of the intake occurs by absorption through the skin so that an overall protection factor of 3 is appropriate when atmosphere-supplying respirators are used to protect against tritium oxide. Exposure to radioactive noble gases is not considered a significant respiratory hazard, and protective actions for these contaminants should be based on external (submersion) dose considerations.

[g] No NIOSH approval schedule is currently available for atmosphere supplying suits. This equipment may be used in an acceptable respiratory protection program as long as all the other minimum program requirements, with the exception of fit testing, are met (i.e., RHA 3.19.3).

[h] The licensee should implement institutional controls to assure that these devices are not used in areas immediately dangerous to life or health (IDLH).

[i] This type of respirator may be used as an emergency device in unknown concentrations for protection against inhalation hazards. External radiation hazards and other limitations to permitted exposure such as skin absorption shall be taken into account in these circumstances. This device may not be used by any individual who experiences perceptible outward leakage of breathing gas while wearing the device.

Revise existing R.61-63.5.14.1 to read:

5.14.1 The licensee may not permit any individual to act as a radiographer or a radiographer's assistant unless, at all times during radiographic operations, each individual wears, on the trunk of the body, a direct reading dosimeter, an operating alarm rate meter and a personnel dosimeter that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor. At permanent radiography facilities where other appropriate alarming or warning devices are in routine use, the wearing of an alarming rate meter is not required. Pocket dosimeters must have a range from zero to at least 200 milliroentgens and must be recharged at the start of each shift. Electronic personal dosimeters may only be used in place of ion-chamber pocket dosimeters. Each personnel dosimeter must be assigned to and worn by only one individual.

Revise existing R.61-63.5.14.2. to read:

5.14.2 Pocket dosimeters or electronic personal dosimeters must be read and exposures recorded at the beginning and end of each shift. The licensee shall retain each record of these exposures in accordance with RHA 5.14.7.1.

Revise existing R.61-63.5.14.3 to read:

5.14.3 Pocket dosimeters or electronic personal dosimeters shall be checked at periods not to exceed one year for correct response to radiation. Acceptable dosimeters shall read within plus or minus 20 percent of the true radiation exposure. Records must be maintained in accordance with RHA 5.14.7.1.

Revise existing R.61-63.5.14.4 to read:

5.14.4 If an individual's pocket chamber is found to be off scale, or if his or her electronic personal dosimeter reads greater than 2 millisieverts (200 millirems), and the possibility of radiation exposure cannot be ruled out as the cause, the individual's personnel dosimeter must be sent for processing within 24 hours. In addition, the individual may not resume work associated with licensed material use until a determination of the individual's radiation exposure has been made. This determination must be made by the RSO or the RSO's designee. The results of this determination must be included in records to be maintained by the licensee until the Department terminates the license.

If the personnel dosimeter that is required by RHA 5.14.1 is lost or damaged, the worker shall cease work immediately until a replacement personnel dosimeter meeting the requirements is provided and the exposure is calculated for the time period from issuance to loss or damage of the personnel dosimeter. The results of the calculated exposure and the time period for which the personnel dosimeter was lost or damaged must be included in the records to be maintained until the Department terminates the license.

Revise existing R.61-63.5.14.5 to read:

5.14.5 Film badges must be replaced at periods not to exceed one month and other personnel dosimeters processed and evaluated by an accredited NVLAP processor must be replaced at periods not to exceed three months. After replacement, each personnel dosimeter must be processed as soon as possible. Dosimetry reports received from the accredited NVLAP personnel dosimeter processor must be retained in accordance with RHA 5.14.7.3.

Revise existing R.61-63.5.14.6.4 to read:

5.14.6.4 Be calibrated at periods not to exceed one year for correct response to radiation: Acceptable rate meters must alarm within plus or minus 20 percent of the true radiation dose rate.
Records of these calibrations must be maintained in accordance with RHA 5.14.7.2.

Add new R.61-63.5.14.7 through 5.14.7.4 to read:

5.14.7 Each licensee shall maintain the following exposure records specified in RHA 5.14:

5.14.7.1 Direct reading dosimeter readings and yearly operability checks required by RHA 5.14.2 and 5.14.3 for 3 years after the record is made.

5.14.7.2 Records of alarm ratemeter calibrations for 3 years after the record is made.

5.14.7.3 Personnel dosimeter results received from the accredited NVLAP processor until the Department terminates the license.

5.14.7.4 Records of estimates of exposures as a result of: off-scale personal direct reading dosimeters, or lost or damaged personnel dosimeters until the Department terminates the license.

Add new definition for R.61-63.8.3.1:

8.3.1 "Energy compensation source" (ECS) means a small sealed source, with an activity not exceeding 100 microcuries (3.7 MBq), used within a logging tool, or other tool components, to provide a reference standard to maintain the tool's calibration when in use.

Renumber existing R.61-63.8.3.1 to 8.3.2:

8.3.2 "Field station" means a facility where radioactive material may be stored or used and from which equipment is dispatched to temporary jobsites.

Renumber existing R.61-63.8.3.2 to 8.3.3:

8.3.3 "Fresh water aquifer", for the purpose of this Part, means a geologic formation that is capable of yielding fresh water to a well or spring.

Renumber existing R.61-63.8.3.3 to 8.3.4:

8.3.4 "Injection tool" means a device used for controlled subsurface injection of radioactive tracer material.

Renumber existing R.61-63.8.3.4 to 8.3.5:

8.3.5 "Irretrievable well logging source" means any sealed source containing radioactive material that is pulled off or not connected to the wireline that suspends the source in the well and for which all reasonable effort at recovery has been expended.

Renumber existing R.61-63.8.3.5 to 8.3.6:

8.3.6 "Logging assistant" means any individual who, under the personal supervision of a logging supervisor, handles sealed sources or tracers that are not in logging tools or shipping containers or who performs surveys required by RHA 8.22.

Renumber existing R.61-63.8.3.6 to 8.3.7:

8.3.7 "Logging supervisor" means an individual who uses radioactive material or provides personal supervision in the use of radioactive material at a temporary jobsite and who is responsible to the licensee for assuring compliance with the requirements of the Department's regulations and the conditions of the license.

Renumber existing R.61-63.8.3.7 to 8.3.8:

8.3.8 "Logging tool" means a device used subsurface to perform well logging.

Renumber existing R.61-63.8.3.8 to 8.3.9:

8.3.9 "Personal supervision" means guidance and instruction by a logging supervisor, who is physically present at a temporary jobsite, who is in personal contact with logging assistants, and who can give immediate assistance.

Renumber existing R.61-63.8.3.9 to 8.3.10:

8.3.10 "Radioactive marker" means radioactive material used for depth determination or direction orientation. For purposes of this Part, this term includes radioactive collar markers and radioactive iron nails.

Renumber existing R.61-63.8.3.10 to 8.3.11:

. 8.3.11 "Safety review" means a periodic review provided by the licensee for its employees on radiation safety aspects of well logging. The review may include, as appropriate, the results of internal inspections, new procedures or equipment, accidents or errors that have been observed, and opportunities for employees to ask safety questions.

Renumber existing R.61-63.8.3.11 to 8.3.12:

8.3.12 "Sealed source" means any radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.

Renumber existing R.61-63.8.3.12 to 8.3.13:

8.3.13 "Source holder" means a housing or assembly into which a sealed source is placed to facilitate the handling and use of the source in well logging.

Renumber existing R.61-63.8.3.13 to 8.3.14:

8.3.14 "Subsurface tracer study" means the release of unsealed radioactive material or a substance labeled with radioactive material in a single well for the purpose of tracing the movement or position of the material or substance in the well or adjacent formation.

Renumber existing R.61-63.8.3.14 to 8.3.15:

. 8.3.15 "Surface casing for protecting fresh water aquifers" means a pipe or tube used as a lining in a well to isolate fresh water aquifers from the well.

Renumber existing R.61-63.8.3.15 to 8.3.16:

. 8.3.16 "Temporary jobsite" means a place where radioactive materials are present for the purpose of performing well logging or subsurface tracer studies.

Add new definition for R.61-63.8.3.17:

8.3.17 "Tritium neutron generator target source" means a tritium source used within a neutron generator tube to produce neutrons for use in well logging applications.

Renumber existing R.61-63.8.3.16 to 8.3.18:

8.3.18 "Uranium sinker bar" means a weight containing depleted uranium used to pull a logging tool toward the bottom of a well.

Renumber existing R.61-63.8.3.17 to 8.3.19:

. 8.3.19 "Well" means a drilled hole in which well logging may be performed. As used in this Part, "well" includes drilled holes for the purpose of oil, gas, mineral, groundwater, or geological exploration.

Renumber existing R.61-63.8.3.18 to 8.3.20:

. 8.3.20 "Well logging" means, unless otherwise specified, all operations involving the lowering and raising of measuring devices or tools which contain radioactive material or are used to detect radioactive material in wells for the purpose of obtaining information about the well or adjacent formations which may be used in oil, gas, mineral, groundwater, or geological exploration.

Revise existing R.61-63.8.5.1.5.2 to read:

. . 8.5.1.5.2 A means to prevent inadvertent intrusion on the source, unless the source is not accessible to any subsequent drilling operations; and

Revise existing R.61-63.8.10.2 to read:

Method of testing. The wipe of a sealed source must be performed using a leak test kit or method approved by the Department, the U.S. Nuclear Regulatory Commission, or any Agreement State. The wipe sample must be taken from the nearest accessible point to the sealed source where contamination might accumulate. The wipe sample must be analyzed for radioactive contamination. The analysis must be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample and must be performed by a person approved by the Department, the U.S. Nuclear Regulatory Commission, or an Agreement State to perform the analysis.

Revise existing R.61-63.8.10.3 to read:

8.10.3 Test frequency. Each sealed source (except an energy compensation source (ECS)) shall be tested for leakage at intervals not to exceed six (6) months. In the absence of a certificate from a transferor that a leak test has been made within the 6 month period prior to the transfer, the sealed source shall not be put into use until leak tested. Each ECS that is not exempt from testing in accordance with RHA 8.10.5 of this section must be tested at intervals not to exceed 3 years. In the absence of a certificate from a transferor that a test has been made within the 3 years before the transfer, the ECS may not be used until tested.

Revise existing R.61-63.8.10.4 to read:

. 8.10.4 Removal of leaking source from service. Any test conducted pursuant to RHA 8.10.1, 8.10.2 and 8.10.3 which reveals the presence of 0.005 microcurie or more of removable radioactive material shall be considered evidence that the sealed source is leaking. The licensee shall immediately remove the sealed source involved from use and shall cause it to be decontaminated and repaired or to be disposed of by a licensee authorized by the Department, the NRC or an Agreement State to perform these functions. The licensee shall check the equipment associated with the leaking source for radioactive contamination and, if contaminated, have it decontaminated or disposed of by a licensee authorized by the Department, the NRC or an Agreement State to perform these functions. Within five (5) days after obtaining results of the leak test, the licensee shall file a report with the Department describing the equipment involved, the test results and the corrective action taken.

Revise existing R.61-63.8.10.5.1 to read:

. 8.10.5.1 Hydrogen-3 (tritium) sources;

Revise existing R.61-63.8.13.1 to read:

. 8.13.1 A licensee may use a sealed source in well logging applications if:

Revise existing R.61-63.8.13.1.3 to read:

. 8.13.1.3 The sealed source meets the requirements of RHA 8.13.2, 8.13.3 or 8.13.4.

Delete R.61-63.8.13.1.3.1 through 8.13.1.3.5.

Revise existing R.61-63.8.13.2 to read:

. 8.13.2 For a sealed source manufactured on or before July 14, 1989, a licensee may use the sealed source, for use in well logging applications if it meets the requirements of USASI N5.10-1968,_"Classification of Sealed Radioactive Sources," or the requirements in RHA 8.13.3 or 8.13.4 of this section.

Add new R.61-63.8.13.3 to read:

. 8.13.3 For a sealed source manufactured after July 14, 1989, a licensee may use the sealed source, for use in well logging applications if it meets the oil-well logging requirements of ANSI/HPS N43.6-1997, "Sealed Radioactive Sources—Classification."

Add new R.61-63.8.13.4 to read:

. 8.13.4 For a sealed source manufactured after July 14, 1989, a licensee may use the sealed source, for use in well logging applications, if--

Add new R.61-63.8.13.4.1 to read:

. 8.13.4.1 The sealed source's prototype has been tested and found to maintain its integrity after each of the following tests:

Add new R.61-63.8.13.4.1.1 to read:

8.13.4.1.1 Temperature. The test source must be held at -40° C for 20 minutes, 600° C for 1 hour, and then be subject to a thermal shock test with a temperature drop from 600° C to 20° C within 15 seconds.

Add new R.61-63.8.13.4.1.2 to read:

8.13.4.1.2 Impact Test. A 5kg steel hammer, 2.5cm in diameter, must be dropped from a height of 1m onto the test source.

Add new R.61-63.8.13.4.1.3 to read:

8.13.4.1.3 Vibration Test. The test source must be subject to a vibration from 25Hz to 500Hz at 5g amplitude for 30 minutes.

Add new R.61-63.8.13.4.1.4 to read:

8.13.4.1.4 Puncture Test. A 1 gram hammer and pin, 0.3cm pin diameter, must be dropped from a height of 1m onto the test source.

Add new R.61-63.8.13.4.1.5 to read:

8.13.4.1.5 Pressure Test. The test source must be subjected to an external pressure of 24,600 pounds per square inch absolute (1.695×10^7 pascals).

Add new R.61-63.8.13.5 to read:

8.13.5 The requirements in RHA 8.13.1, 8.13.2, 8.13.3 and 8.13.4 do not apply to sealed sources that contain radioactive material in gaseous form.

Add new R.61-63.8.13.6 to read:

. . 8.13.6 The requirements in RHA 8.13.1, 8.13.2, 8.13.3 and 8.13.4 of this section do not apply to energy compensation sources (ECS). ECSs must be registered with the Department under RHA 2.29 or with the NRC under Sec. 32.210.

Add new R.61-63.8.13.7 to read:

. . 8.13.7 Energy compensation source. The licensee may use an energy compensation source (ECS) which is contained within a logging tool, or other tool components, only if the ECS contains quantities of licensed material not exceeding 100 microcuries (3.7 MBq).

(a) For well logging applications with a surface casing for protecting fresh water aquifers, use of the ECS is only subject to the requirements of RHA 8.10, 8.11, and 8.12.

. (b) For well logging applications without a surface casing for protecting fresh water aquifers, use of the ECS is only subject to the requirements of RHA 8.5, 8.10, 8.11, 8.12, 8.18, and 8.27.

Add new R.61-63.8.13.8 to read:

8.13.8 Tritium neutron generator target source.

. (a) Use of a tritium neutron generator target source, containing quantities not exceeding 30 curies (1,110 MBq) and in a well with a surface casing to protect fresh water aquifers, is subject to the requirements of this part except RHA 8.5, 8.13, and 8.27.

(b) Use of a tritium neutron generator target source, containing quantities exceeding 30 curies (1,110 MBq) or in a well without a surface casing to protect fresh water aquifers, is subject to the requirements of this part except RHA 8.13.

Revise existing R.61-63.8.17 to read:

RHA 8.17 URANIUM SINKER BARS

The licensee may use a uranium sinker bar in well logging applications, only if it is legibly impressed with the words "CAUTION - RADIOACTIVE DEPLETED URANIUM" and "NOTIFY CIVIL AUTHORITIES (or COMPANY NAME) IF FOUND."

Revise existing R.61-63.8.21.1 to read:

. 8.21.1 The licensee may not permit an individual to act as a logging supervisor or logging assistant unless that person wears, at all times during the handling of radioactive materials, a personnel dosimeter that is

processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor. Each personnel dosimeter must be assigned to and worn by only one individual. Film badges must be replaced at least monthly and other personnel dosimeters replaced at least quarterly. After replacement, each personnel dosimeter must be promptly processed.

Revise existing R.61-63.8.21.3 to read:

. 8.21.3 The licensee shall retain records of personnel dosimeters and bioassay results for inspection until the Department authorizes disposition of the records.

Revise existing R.61-63.8.27.3.1 to read:

8.27.3.1 Notify the Department by telephone of the circumstances that resulted in the inability to retrieve the source and request approval to implement abandonment procedures; or that the licensee implemented abandonment before receiving Departmental approval because the licensee believed there was an immediate threat to public health and safety; and

Replace existing R.61-63.8.27.4.9 to read:

. 8.27.4.9 The immediate threat to public health and safety justification for implementing abandonment if prior Departmental approval was not obtained in accordance with RHA 8.27.3.1 of this section.

Renumber existing R.61-63.8.27.4.9 to 8.27.4.10:

. 8.27.4.10 Any other information (e.g. warning statement) contained on the permanent identification plaque; and

Renumber existing R.61-63.8.27.4.10 to 8.27.4.11:

8.27.4.11 State and Federal agencies receiving copy of this report.

Revise R.61-63.11.20.1 to read:

11.20.1 Irradiator operators shall wear a personnel dosimeter while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator. The personnel dosimeter processor must be accredited by the National Voluntary Laboratory Accreditation Program for high energy photons in the normal and accident dose ranges (see RHA 3.16.3). Each personnel dosimeter must be assigned to and worn by only one individual. Film badges must be processed at least monthly, and other personnel dosimeters must be processed at least quarterly.

Revise R.61-63.11.28.5 to read:

11.28.5 Evaluations of personnel dosimeters required by RHA 11.20 until the Department terminates the license.