

## REGULATIONS

VOL. 37 ISS. 25 - AUGUST 02, 2021

**TITLE 12. HEALTH**[« Previous](#) | [Next »](#) | [Table of Contents »](#)**DEPARTMENT OF HEALTH****Chapter 481***Final*

**REGISTRAR'S NOTICE:** The following regulatory action is exempt from Article 2 of the Administrative Process Act in accordance with § 2.2-4006 A 4 c of the Code of Virginia, which excludes regulations that are necessary to meet the requirements of federal law or regulation provided such regulations do not differ materially from those required by federal law or regulation. The State Board of Health is also claiming an exemption from the Administrative Process Act in accordance with § 2.2-4006 A 3 of the Code of Virginia, which excludes regulations that consist only of changes in style or form or corrections of technical errors. The board will receive, consider, and respond to petitions by any interested person at any time with respect to reconsideration or revision.

**Title of Regulation:** 12VAC5-481. Virginia Radiation Protection Regulations (amending 12VAC5-481-10, 12VAC5-481-440, 12VAC5-481-451, 12VAC5-481-480, 12VAC5-481-590, 12VAC5-481-1350, 12VAC5-481-1490, 12VAC5-481-1690, 12VAC5-481-1700, 12VAC5-481-1720, 12VAC5-481-1730, 12VAC5-481-1750, 12VAC5-481-1760, 12VAC5-481-1770, 12VAC5-481-1780, 12VAC5-481-1910, 12VAC5-481-1930, 12VAC5-481-1940, 12VAC5-481-1950, 12VAC5-481-1980, 12VAC5-481-1990, 12VAC5-481-2000, 12VAC5-481-2001, 12VAC5-481-2010, 12VAC5-481-2016, 12VAC5-481-2018, 12VAC5-481-2019, 12VAC5-481-2020, 12VAC5-481-2030, 12VAC5-481-2040, 12VAC5-481-2043, 12VAC5-481-2048, 12VAC5-481-2070, 12VAC5-481-2080, 12VAC5-481-2850, 12VAC5-481-3000, 12VAC5-481-3120, 12VAC5-481-3290).

**Statutory Authority:** § 32.1-229 of the Code of Virginia.

**Effective Date:** January 14, 2022.

**Agency Contact:** Lea Anna Perlas, Office of Radiological Health, Department of Health, 109 Governor Street, Richmond, VA 23219, telephone (804) 864-8170, FAX (804) 864-8155, or email lea.perlas@vdh.virginia.gov.

**Summary:**

*The amendments revise the Radiation Protection Regulations (12VAC5-481, Virginia Radiation Protection Regulations) to make the provisions of the radiation protection program compatible with 2018, 2019, and 2020 revisions to Title 10 of the Code of Federal Regulations by the U.S. Nuclear Regulatory Commission (NRC), which Virginia agrees to do as an NRC Agreement State. Included are (i) changes to medical event definitions and training and experience requirements; (ii) corrections to NRC organizational references; and (iii) updates to requirements for individual monitoring devices, access authorization, general security program, physical protection, and prevention of social security fraud.*

**12VAC5-481-10. Definitions.**

The following words and terms as used in this chapter shall have the following meanings unless the context clearly indicates otherwise:

"A<sub>1</sub>" means the maximum activity of special form radioactive material permitted in a Type A package. This value is listed in Table 1 of 12VAC5-481-3770 F.

"A<sub>2</sub>" means the maximum activity of radioactive material, other than special form radioactive material, LSA, and SCO material, permitted in a Type A package. This value is listed in Table 1 of 12VAC5-481-3770 F.

"Absorbed dose" means the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the gray (Gy) and the rad.

"Absorbed dose rate" means absorbed dose per unit time, for machines with timers, or dose monitor unit per unit time for linear accelerators.

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

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

"Access control" means a system for allowing only approved individuals to have unescorted access to the security zone and for ensuring that all other individuals are subject to escorted access.

"Accessible surface" means the external surface of the enclosure or housing of the radiation producing machine as provided by the manufacturer. It also means surface of equipment or of an equipment part that can be easily or accidentally touched by persons without the use of a tool.

"Act" means §§ 32.1-227 through 32.1-238 of the Code of Virginia.

"Active maintenance" means any significant activity needed during the period of institutional control to maintain a reasonable assurance that the performance objectives in 12VAC5-481-2490 and 12VAC5-481-2500 are met. Such active maintenance includes ongoing activities such as the pumping and treatment of water from a disposal unit or one-time measures such as replacement of a disposal unit cover. Active maintenance does not include custodial activities such as repair of fencing, repair or replacement of monitoring equipment, revegetation, minor additions to soil cover, minor repair of disposal unit covers, and general disposal site upkeep such as mowing grass.

"Activity" means the rate of disintegration or transformation or decay of radioactive material. The units of activity are the becquerel (Bq) and the curie (Ci).

"Acute" means a single radiation dose or chemical exposure event or multiple radiation dose or chemical exposure events occurring within a short time (24 hours or less).

"Address of use" means the building or buildings that are identified on the license and where radioactive material may be produced, prepared, received, used, or stored.

"Adult" means an individual 18 or more years of age.

"Agency" means the Radiological Health Program of the Virginia Department of Health.

"Aggregated" means accessible by the breach of a single physical barrier that would allow access to radioactive material in any form, including any devices that contain the radioactive material, when the total activity equals or exceeds a Category 2 quantity of radioactive material as listed in 12VAC5-481-451.

"Agreement state" means any state with which the NRC or the Atomic Energy Commission has entered into an effective agreement under subsection 274b of the Atomic Energy Act of 1954, as amended (42 USC § 2021(b)).

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

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

1. In excess of the derived air concentrations (DACs) specified in Appendix B to 10 CFR Part 20; or
2. To such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6% of the annual limit on intake (ALI) or 12 DAC hours.

"Air kerma" or "K" means kerma in air (see definition of "kerma").

"Air kerma rate" or "AKR" means the air kerma per unit time.

"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.

"Alert" means events may occur, are in progress, or have occurred that could lead to a release of radioactive material but that the release is not expected to require a response by offsite response organizations to protect persons off site.

"Aluminum equivalent" means the thickness of type 1100 aluminum alloy affording the same attenuation, under specified conditions, as the material in question. The nominal chemical composition of type 100 aluminum is 99.00% minimum aluminum, 0.12% copper.

"Analytical x-ray equipment" means equipment used for x-ray diffraction or fluorescence analysis.

"Analytical x-ray system" means a group of components utilizing x-rays or gamma-rays to determine the elemental composition or to examine the microstructure of materials.

"Annual limit on intake" or "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 0.05 Sv (5 rem) or a committed dose equivalent of 0.5 Sv (50 rem) to any individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Tables 1 and 2 in Appendix B to 10 CFR Part 20.

"Annual refresher safety training" means a review conducted or provided by the licensee or registrant for its employees on radiation safety aspects of industrial radiography. The review shall include, as a minimum, any results of internal inspections, new procedures or equipment, new or revised regulations, and accidents or errors that have been observed. The review shall also provide opportunities for employees to ask safety questions.

"Annually" means at intervals not to exceed one year.

"ANSI" means the American National Standards Institute.

"Approved individual" means an individual whom the licensee has determined to be trustworthy and reliable for unescorted access in accordance with 12VAC5-481-451 and has completed the training required in 12VAC5-481-451.

"Area of use" means a portion of a physical structure that has been set aside for the purpose of producing, preparing, receiving, using, or storing radioactive material.

"Articulated joint" means a joint between two separate sections of a tabletop that provides the capacity for one of the sections to pivot on the line segment along which the sections join.

"As low as is reasonably achievable" or "ALARA" means making every reasonable effort to maintain exposures to radiation as far below the dose limits in these regulations as is practical, consistent with the purpose for which the licensed or registered 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 or registered sources of radiation in the public interest.

"Assembler" means any person engaged in the business of assembling, replacing, or installing one or more components into an x-ray system or subsystem. The term includes the owner of an x-ray system or his employee or agent who assembles components into an x-ray system that is subsequently used to provide professional or commercial services.

"Assigned protection factor" or "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.

"Associate radiation safety officer" means an individual who (i) meets the requirements of 12VAC5-481-1750 and 12VAC5-481-1790 and (ii) is currently identified as an associate radiation safety officer for the types of use of byproduct material for which the individual has been assigned duties and tasks by the radiation safety officer on (a) a specific medical use license issued by the agency, NRC, or another agreement state or (b) a medical use permit issued by a NRC master material licensee.

"Associated equipment" means equipment that is used in conjunction with a radiographic exposure device to make radiographic exposures that drive, guide, or come in contact with the source.

"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.

"Attenuation block" means a block or stack, having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters, of type 1100 aluminum alloy or other materials having equivalent attenuation. The nominal chemical composition of type 100 aluminum is 99.00% minimum aluminum, 0.12% copper.

"Authorized medical physicist" means an individual who:

1. Meets the requirements in 12VAC5-481-1760 and 12VAC5-481-1790; or
2. Is identified as an authorized medical physicist or teletherapy physicist on:
  - a. A specific medical use license issued by the NRC or another Agreement state;
  - b. A medical use permit issued by an NRC master material licensee;
  - c. A permit issued by an NRC or another Agreement state broad scope medical use licensee; or
  - d. A permit issued by an NRC master material license broad scope medical use permittee.

"Authorized nuclear pharmacist" means a pharmacist who:

1. Meets the requirements in 12VAC5-481-1770 and 12VAC5-481-1790;
2. Is identified as an authorized nuclear pharmacist on:
  - a. A specific license issued by the NRC or another Agreement state that authorizes medical use or the practice of nuclear pharmacy;
  - b. A permit issued by an NRC master material licensee that authorizes medical use or the practice of nuclear pharmacy;
  - c. A permit issued by an NRC or another Agreement state broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or
  - d. A permit issued by an NRC master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy;
3. Is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or
4. Is designated as an authorized nuclear pharmacist in accordance with 12VAC5-481-440 I 2.

"Authorized user" means a practitioner of the healing arts who:

1. Meets the requirements in 12VAC5-481-1790 and any of the following:
  - a. 12VAC5-481-1910;
  - b. 12VAC5-481-1940;

- c. 12VAC5-481-1980;
- d. 12VAC5-481-1990;
- e. 12VAC5-481-2000;
- f. 12VAC5-481-2018;
- g. 12VAC5-481-2030;
- h. 12VAC5-481-2040 A; or

2. Is identified as an authorized user on:

- a. A specific license issued by the NRC or another Agreement state that authorizes medical use;
- b. A permit issued by an NRC master material licensee that authorizes medical use;
- c. A permit issued by an NRC or another Agreement state broad scope medical use licensee that authorizes medical use; or
- d. A permit issued by an NRC master material license broad scope medical use permittee that authorizes medical use.

"Automatic exposure control" or "AEC" means a device that automatically controls one or more technique factors in order to obtain, at a preselected location, a required quantity of radiation (includes devices such as phototimers and ion chambers).

"Background investigation" means the investigation conducted by a licensee or applicant to support the determination of trustworthiness and reliability.

"Background radiation" means radiation from cosmic sources, naturally occurring radioactive materials, that have not been technologically enhanced, including radon, except as a decay product of source or special nuclear material, and including global fallout as it exists in the environment from the testing of nuclear explosive devices, or from past nuclear accidents such as Chernobyl that contribute to background radiation and are not under the control of the licensee or registrant. "Background radiation" does not include sources of radiation from radioactive materials regulated by the agency.

"Barrier" (See "Protective barrier").

"Beam axis" means a line from the source through the centers of the x-ray fields.

"Beam-limiting device" means a device that provides a means to restrict the dimensions of the x-ray field or useful beam.

"Beam monitoring system" means a system designed and installed in the radiation head to detect and measure the radiation present in the useful beam.

"Beam scattering foil" means a thin piece of material (usually metallic) placed in the beam to scatter a beam of electrons in order to provide a more uniform electron distribution in the useful beam.

"Becquerel" or "Bq" means the SI unit of activity. One becquerel is equal to one disintegration or transformation per second (dps or tps).

"Beneficial attribute" means, as used in Part XVI (12VAC5-481-3460 et seq.) of this chapter, the radioactivity of the product necessary to the use of the product.

"Beneficial to the product" (See "Beneficial attribute").

"Bent beam linear accelerator" means a linear accelerator geometry in which the accelerated electron beam must change direction by passing through a bending magnet.

"Bioassay" 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. For purposes of these regulations, "radiobioassay" is an equivalent term.

"Board" means the State Board of Health.

"Brachytherapy" means a method of radiation therapy in which sealed sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary, or interstitial application.

"Buffer zone" means a portion of the disposal site that is controlled by the licensee and that lies under the disposal units and between the disposal units and the boundary of the site.

"Byproduct material" means:

1. Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material;
2. The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition;

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

b. Any material that:

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

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

4. Any discrete source of naturally occurring radioactive material, other than source material, that:

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

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

"C-arm fluoroscope" means an x-ray system in which the image receptor and x-ray tube housing assembly are connected by a common mechanical support system in order to maintain a desired spatial relationship. This system is designed to allow a change in the projection of the beam through the patient without a change in the position of the patient.

"Cabinet radiography" means industrial radiography conducted in an enclosure or cabinet so shielded that every location on the exterior meets the dose limits for individual members of the public as specified in 12VAC5-481-720.

"Cabinet x-ray system" means an x-ray system with the x-ray tube installed in an enclosure independent of existing architectural structures except the floor on which it may be placed. The cabinet x-ray system is intended to contain at least that portion of a material being irradiated, provide radiation attenuation, and exclude personnel from its interior during generation of radiation. Included are all x-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad, and bus terminals, and in similar facilities. An x-ray tube used within a shielded part of a building, or x-ray equipment that may temporarily or occasionally incorporate portable shielding, is not considered a cabinet x-ray system.

"Calendar quarter" means not less than 12 consecutive weeks nor more than 14 consecutive weeks. The first calendar quarter of each year shall begin in January and subsequent calendar quarters shall be so arranged such that no day is included in more than one calendar quarter and no day in any one year is omitted from inclusion within a calendar quarter. The method observed by the licensee or registrant for determining calendar quarters shall only be changed at the beginning of a year.

"Calibration" means the determination of (i) the response or reading of an instrument relative to a series of known radiation values over the range of the instrument or (ii) the strength of a source of radiation relative to a standard.

"Camera" (See "Radiographic exposure device").

"Carrier" means a person engaged in the transportation of passengers or property by land or water as a common, contract, or private carrier, or by civil aircraft.

"Cassette holder" means a device, other than a spot-film device, that supports or fixes the position of an x-ray film (imaging) cassette during an x-ray exposure.

"Category 1 quantities of radioactive material" or "Category 1" means a quantity of radioactive material meeting or exceeding the Category 1 threshold in Table 1 of 12VAC5-481-451. This is determined by calculating the ratio of the total activity of each radionuclide to the Category 1 threshold for that radionuclide and adding the ratios together. If the sum is equal to or exceeds 1, the quantity would be considered a Category 1 quantity. Category 1 quantities of radioactive material do not include the radioactive material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet.

"Category 2 quantities of radioactive material" or "Category 2" means a quantity of radioactive material meeting or exceeding the Category 2 threshold but less than the Category 1 threshold in Table 1 of 12VAC5-481-451. This is determined by calculating the ratio of the total activity of each radionuclide to the Category 2 threshold for that radionuclide and adding the ratios together. If the sum is equal to or exceeds 1, the quantity would be considered a Category 2 quantity. Category 2 quantities of radioactive material do not include the radioactive material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet.

"Certifiable cabinet x-ray system" means an existing uncertified x-ray system that has been modified to meet the certification requirements specified in 21 CFR 1020.40.

"Certificate holder" means a person who has been issued a certificate of compliance or other package approval by the NRC.

"Certificate of compliance" or "CoC" means the certificate issued by the NRC that approves the design of a package for the transportation of radioactive material.

"Certified cabinet x-ray system" means an x-ray system that has been certified in accordance with 21 CFR 1010.2 as being manufactured and assembled pursuant to the provisions of 21 CFR 1020.40.

"Certified components" means components of x-ray systems that are subject to regulations promulgated under P.L. 90-602, the Radiation Control for Health and Safety Act of 1968 of the Food and Drug Administration.

"Certifying entity" means an independent certifying organization meeting the agency's requirements for documenting applicant's training in topics set forth in 12VAC5-481-1320 or equivalent state or NRC regulations.

"CFR" means Code of Federal Regulations.

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

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

"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. For purposes of these regulations, "lung class" and "inhalation class" are equivalent terms.

"Closed transport vehicle" means a transport vehicle equipped with a securely attached exterior enclosure that during normal transportation restricts the access of unauthorized persons to the cargo space containing the radioactive material. The enclosure may be either temporary or permanent but shall limit access from top, sides, and ends. In the case of packaged materials, it may be of the "see-through" type.

"cm" means centimeters.

"Coefficient of variation or "C" means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$C = \frac{s}{\bar{x}} = \frac{1}{\bar{x}} \left[ \frac{\sum_{i=1}^n (x_i - \bar{x})^2}{n-1} \right]^{1/2}$$

where:

s = Standard deviation of the observed values;

$\bar{x}$  = Mean value of observations in sample;

$x_i$  =  $i$ th observation in sample;

n = Number of observations in sample.

"Collective dose" means 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.

"Collimator" means a device used to limit the size, shape, and direction of the primary radiation beam. For industrial radiography it means a radiation shield that is placed on the end of the guide tube or directly onto a radiographic exposure device to restrict the size of the radiation beam when the sealed source is cranked into position to make a radiographic exposure.

"Commencement of construction" means taking any action defined as "construction" or any other activity at the site of a facility subject to the regulations in this chapter that has a reasonable nexus to radiological health and safety.

"Committed dose equivalent" or " $H_{T,50}$ " 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.

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

"Computed tomography" means the production of a tomogram by the acquisition and computer processing of x-ray transmission data.

"Computed tomography dose index" means the integral from  $-7T$  to  $+7T$  of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan, that is:

$$\overline{CTDI} = \frac{1}{nT} \int_{-7T}^{+7T} D(z) dz$$

where:

z = Position along a line perpendicular to the tomographic plane;

D(z) = Dose at position z;

T = Nominal tomographic section thickness;

n = Number of tomograms produced in a single scan.

This definition assumes that the dose profile is centered around  $z = 0$  and that, for a multiple tomogram system, the scan increment between adjacent scans is  $nT$ .

"Computer-readable medium" means that the regulatory agency's computer can transfer the information from the medium into its memory.

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

"Consignment" means each shipment of a package or groups of packages or load of radioactive material offered by a shipper for transport.

"Consortium" means an association of medical use licensees and a PET radionuclide production facility in the same geographical area that jointly own or share in the operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use in producing radioactive drugs within the consortium for noncommercial distributions among its associated members for medical use. The PET radionuclide production facility within the consortium must be located at an educational institution or a federal facility or a medical facility.

"Constraint" means each shipment of a package or groups of packages or load of radioactive material offered by a shipper for transport.

"Constraint" or "dose constraint" means a value above which specified licensee actions are required.

"Construction" means the installation of foundations, or in-place assembly, erection, fabrication, or testing for any structure, system, or component of a facility or activity subject to this chapter. The term "construction" does not include:

1. Changes for temporary use of the land for public recreational purposes;
2. Site exploration, including necessary borings to determine foundation conditions or other preconstruction monitoring to establish background information related to the suitability of the site, the environmental impacts of construction or operation, or the protection of environmental values;
3. Preparation of the site for construction of the facility, including clearing of the site, grading, installation of drainage, erosion and other environmental mitigation measures, and construction of temporary roads and borrow areas;
4. Erection of fences and other access control measures that are not related to the safe use of, or security of, radiological materials subject to this chapter;
5. Excavation;
6. Erection of support buildings (e.g., construction equipment storage sheds, warehouse and shop facilities, utilities, concrete mixing plants, docking and unloading facilities, and office buildings) for use in connection with the construction of the facility;
7. Building of service facilities (e.g., paved roads, parking lots, railroad spurs, exterior utility and lighting systems, potable water systems, sanitary sewerage treatment facilities, and transmission lines);
8. Procurement or fabrication of components or portions of the proposed facility occurring at other than the final, in-place location at the facility; or
9. Taking any other action that has no reasonable nexus to radiological health and safety.

"Contact therapy system" means a therapeutic radiation machine with a short target to skin distance (TSD), usually less than five centimeters.

"Contamination" means, as applicable to Part XIII (12VAC5-481-2950 et seq.) of this chapter, the presence of a radioactive substance on a surface in quantities in excess of  $0.4 \text{ Bq/cm}^2$  ( $1 \times 10^{-5} \text{ } \mu\text{Ci/cm}^2$ ) for beta and gamma emitters and low toxicity alpha emitters, or  $0.04 \text{ Bq/cm}^2$  ( $1 \times 10^{-6} \text{ } \mu\text{Ci/cm}^2$ ) for all other alpha emitters.

1. Fixed contamination means contamination that cannot be removed from a surface during normal conditions of transport.
2. Nonfixed contamination means contamination that can be removed from a surface during normal conditions of transport.

"Contrast scale" means the change in the linear attenuation coefficient per CTN relative to water, that is:

$$\overline{CS} = \frac{\mu_x - \mu_w}{\overline{CTN}_x - \overline{CTN}_w}$$

where:

$\mu_x$  = Linear attenuation coefficient of the material of interest;

$\mu_w$  = Linear attenuation coefficient of water;

$\overline{CTN}_x$  = of the material of interest;

$\overline{CTN}_w$  = of water.

"Control cable" or "drive" means the cable that is connected to the source assembly and used to drive the source to and from the exposure location.

"Control drive mechanism" means a device that enables the source assembly to be moved into and out of the exposure device.

"Control panel" means that part of the x-ray control upon which are mounted the switches, knobs, pushbuttons, and other hardware necessary for manually setting the technique factors.

"Control tube" means a protective sheath for guiding the control cable. The control tube connects the control drive mechanism to the radiographic exposure device.

"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.

"Conventional simulator" means any x-ray system designed to reproduce the geometric conditions of the radiation therapy equipment.

"Conveyance" means:

1. For transport by public highway or rail any transport vehicle or large freight container;
2. For transport by water any vessel, or any hold, compartment, or defined deck area of a vessel including any transport vehicle on board the vessel; and
3. For transport by any aircraft.

"Cooling curve" means the graphical relationship between heat units stored and cooling time.

"Cradle" means either:

1. A removable device that supports and may restrain a patient above an x-ray table; or
2. A device:
  - a. Whose patient support structure is interposed between the patient and the image receptor during normal use;
  - b. Which is equipped with means for patient restraint; and
  - c. Which is capable of rotation about its long (longitudinal) axis.

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

"Criticality safety index" or "CSI" means the dimensionless number (rounded up to the next tenth) assigned to and placed on the label of a fissile material package, to designate the degree of control of accumulation of packages, overpacks or freight containers containing fissile material during transportation. Determination of the criticality safety index is described in 12VAC5-481-3040, 12VAC5-481-3051, and 10 CFR 71.59. The criticality safety index for an overpack, freight container, consignment, or conveyance containing fissile material packages is the arithmetic sum of the criticality safety indices of all the fissile material packages contained within the overpack, freight container, consignment, or conveyance.

"CS" (See "Contrast scale").

"CT" (See "Computed tomography").

"CT conditions of operation" means all selectable parameters governing the operation of a CT x-ray system including, but not limited to, nominal tomographic section thickness, filtration, and the technique factors as defined in these regulations.

"CTDI" (See "Computed tomography dose index").

"CT gantry" means the tube housing assemblies, beam-limiting devices, detectors, and the supporting structures and frames which hold these components.

"CTN" (See "CT number").

"CT number" means the number used to represent the x-ray attenuation associated with each elemental area of the CT image.

$$\overline{CTN} = \frac{k(\mu_x - \mu_w)}{\mu_w}$$

where:

$k$  = A constant, a normal value of 1,000 when the Hounsfield scale of CTN is used;

$\mu_x$  = Linear attenuation coefficient of the material of interest;

$\mu_w$  = Linear attenuation coefficient of water.

"Cumulative air kerma" means the total air kerma accrued from the beginning of an examination or procedure and includes all contribution from fluoroscopic and radiographic irradiation.



"Curie" is a unit of quantity of activity. One curie (Ci) is that quantity of radioactive material that decays at the rate of  $3.7 \times 10^{10}$  disintegrations or transformations per second (dps or tps).

"Custodial agency" means an agency of the government designated to act on behalf of the government owner of the disposal site.

"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.

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

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

"Dedicated check source" means a radioactive source that is used to assure the constant operation of a radiation detection or measurement device over several months or years. This source may also be used for other purposes.

"Deep dose equivalent" or " $H_d$ ," which applies to external whole body exposure, means the dose equivalent at a tissue depth of one centimeter ( $1000 \text{ mg/cm}^2$ ).

"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.

"Department of Energy" means the Department of Energy established by P.L. 95-91, August 4, 1977, 91 Stat. 565, 42 USC § 7101 et seq., to the extent that the Department exercises functions formerly vested in the Atomic Energy Commission, its Chairman, members, officers and components and transferred to the Energy Research and Development Administration and to the Administrator thereof pursuant to §§ 104(b), (c) and (d) of the Energy Reorganization Act of 1974 (P.L. 93-438, October 11, 1974, 88 Stat. 1233 at 1237, 42 USC § 5814, effective January 19, 1975) and retransferred to the U.S. Secretary of Energy pursuant to § 301(a) of the Department of Energy Organization Act (P.L. 95-91, August 4, 1977, 91 Stat. 565 at 577-578, 42 USC § 7151, effective October 1, 1977).

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

"Derived air concentration" or "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, results in an intake of one ALI. For purposes of these regulations, the condition of light work is an inhalation rate of 1.2 cubic meters of air per hour for 2,000 hours in a year. DAC values are given in Appendix B to 10 CFR Part 20.

"Derived air concentration-hour" or "DAC hour" means 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 or registrant may take 2,000 DAC hours to represent one ALI, equivalent to a committed effective dose equivalent of 0.05 Sv (5 rem).

"Detector" (See "Radiation detector").

"Deuterium" means, for the purposes of Part XIII (12VAC5-481-2950 et seq.) of this chapter, deuterium and any deuterium compounds, including heavy water, in which the ratio of deuterium atoms to hydrogen atoms exceeds 1:5000.

"Diagnostic clinical procedures manual" means a collection of written procedures that describes each method (and other instructions and precautions) by which the licensee performs diagnostic clinical procedures, where each diagnostic clinical procedure has been approved by the authorized user and includes the radiopharmaceutical, dosage, and route of administration.

"Diagnostic source assembly" means the tube housing assembly with a beam-limiting device attached.

"Diagnostic x-ray system" means an x-ray system designed for irradiation of any part of the human or animal body for the purpose of diagnosis or visualization.

"Direct scattered radiation" means that scattered radiation that has been deviated in direction only by materials irradiated by the useful beam (See "Scattered radiation").

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

"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 and a disposable escape-only self-contained breathing apparatus (SCBA).

"Disposal" means the isolation of wastes from the biosphere inhabited by man and his food chains by emplacement in a land disposal facility.

"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.

"Disposal site" means that portion of a land disposal facility that is used for disposal of waste. It consists of disposal units and a buffer zone.

"Disposal unit" means a discrete portion of the disposal site into which waste is placed for disposal. For near-surface disposal, the unit is usually a trench.

"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.

"Diversion" means the unauthorized movement of radioactive material subject to 12VAC5-481-451 to a location different from the material's authorized destination inside or outside of the site at which the material is used or stored.

"Dose" is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, total organ dose equivalent, or total effective dose equivalent. For purposes of these regulations, "radiation dose" is an equivalent term.

"Dose commitment" means the total radiation dose to a part of the body that will result from retention in the body of radioactive material. For purposes of estimating the dose commitment, it is assumed that from the time of intake the period of exposure to retained material will not exceed 50 years.

"Dose equivalent" or " $H_T$ " 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 sievert (Sv) and rem.

"Dose limits" means the permissible upper bounds of radiation doses established in accordance with these regulations. For purposes of these regulations, "limits" is an equivalent term.

"Dose monitor unit" or "DMU" means a unit response from the beam monitoring system from which the absorbed dose can be calculated.

"Dose profile" means the dose as a function of position along a line.

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

"Doubly encapsulated sealed source" means a sealed source in which the radioactive material is sealed within an inner capsule and that capsule is sealed within an outer capsule.

"Drive cable" (See "Control cable").

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

"Electronic brachytherapy" means a method of radiation therapy where an electrically generated source of ionizing radiation is placed in or near the tumor or target tissue to deliver therapeutic radiation dosage.

"Electronic brachytherapy device" means the system used to produce and deliver therapeutic radiation including the x-ray tube, the control mechanism, the cooling system, and the power source.

"Electronic brachytherapy source" means the x-ray tube component used in an electronic brachytherapy device.

"Elemental area" means the smallest area within a tomogram for which the x-ray attenuation properties of a body are depicted. (See also "Picture element").

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

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

"Engineered barrier" means a manmade structure or device that is intended to improve the land disposal facility's ability to meet the performance objectives in these regulations.

"Enriched uranium" (See "Uranium - natural, depleted, enriched").

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

"EPA identification number" means the number received by a transporter following application to the Administrator of the U.S. Environmental Protection Agency as required by 40 CFR Part 263.

"Equipment" (See "x-ray equipment").

"Escorted access" means accompaniment while in a security zone by an approved individual who maintains continuous direct visual surveillance at all times over an individual who is not approved for unescorted access.

"Exclusive use" means the sole use by a single consignor of a conveyance for which all initial, intermediate, and final loading and unloading are carried out in accordance with the direction of the consignor or consignee. The consignor and the carrier must ensure that any loading or unloading is performed by personnel having radiological training and resources appropriate for safe handling of the consignment. The consignor must issue specific instructions, in writing, for maintenance of exclusive use shipment controls, and include them with the shipping paper information provided to the carrier by the consignor.

"Explosive material" means any chemical compound, mixture, or device that produces a substantial instantaneous release of gas and heat spontaneously or by contact with sparks or flame.

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

"Exposure head" means a device that locates the gamma radiography sealed source in the selected working position.

"Exposure rate" means the exposure per unit of time, such as roentgen per minute and milliroentgen per hour.

"External beam radiation therapy" means therapeutic irradiation in which the source of radiation is at a distance from the body.

"External dose" means that portion of the dose equivalent received from any source of radiation outside the body.

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

"Facility" means the location, building, vehicle, or complex under one administrative control, at which one or more radiation machines are installed, located or used.

"Fail-safe characteristics" means a design feature that causes beam port shutters to close, or otherwise prevents emergence of the primary beam, upon the failure of a safety or warning device.

"Field emission equipment" means equipment that uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field.

"Field-flattening filter" means a filter used to homogenize the absorbed dose rate over the radiation field.

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

"Filter" means material placed in the useful beam to preferentially absorb selected radiations. It also means material placed in the useful beam to change beam quality in therapeutic radiation machines subject to Part XV (12VAC5-481-3380 et seq.) of this chapter.

"Filtering facepiece" or "dusk 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.

"Fingerprint orders" means the requirements of 12VAC5-481-451 B or orders issued by the U.S. Nuclear Regulatory Commission or the legally binding requirements issued by Agreement states that require fingerprints and criminal history records checks for individuals with unescorted access to Category 1 and Category 2 quantities of radioactive material or safeguards information-modified handling.

"Fissile material" means the radionuclides uranium-233, uranium-235, plutonium-239, and plutonium-241, or any combination of these radionuclides.

"Fissile material" means the fissile nuclides themselves, not material containing fissile nuclides. Unirradiated natural uranium and depleted uranium and natural uranium or depleted uranium, that has been irradiated in thermal reactors only, are not included in this definition. Certain exclusions from fissile material controls are provided in 10 CFR 71.15.

1. Fissile Class I: A package that may be transported in unlimited numbers and in any arrangement, and that requires no nuclear criticality safety controls during transportation. A transport index is not assigned for purposes of nuclear criticality safety but may be required because of external radiation levels.

2. Fissile Class II: A package that may be transported together with other packages in any arrangement but, for criticality control, in numbers that do not exceed an aggregate transport index of 50. These shipments require no other nuclear criticality safety control during transportation. Individual packages may have a transport index not less than 0.1 and not more than 10.

"Fissile material package" means a fissile material packaging together with its fissile material contents.

"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.

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

"Fluoroscopic imaging assembly" means a subsystem in which x-ray photons produce a set of fluoroscopic images or radiographic images recorded from the fluoroscopic image receptor. It includes the image receptors, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

"Fluoroscopic irradiation time" means the cumulative duration during an examination or procedure of operator-applied continuous pressure to the device, enabling x-ray tube activation in any fluoroscopic mode of operation.

"Fluoroscopy" means a technique for generating x-ray images and presenting them simultaneously and continuously as visible images. This term has the same meaning as the term "radioscopy" in the standards of the International Electrotechnical Commission.

"Focal spot" or "actual" means the area projected on the anode of the x-ray tube bombarded by the electrons accelerated from the cathode and from which the useful beam originates.

"Former Atomic Energy Commission or NRC licensed facilities" means nuclear reactors, nuclear fuel reprocessing plants, uranium enrichment plants, or critical mass experimental facilities where Atomic Energy Commission or NRC licenses have been terminated.

"Gantry" means that part of a radiation therapy system supporting and allowing movements of the radiation head about a center of rotation.

"Generally applicable environmental radiation standards" means standards issued by the U.S. Environmental Protection Agency under the authority of the Atomic Energy Act of 1954, as amended, (42 USC § 2011 et seq.) 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.

"General environment" means, as used in Part XVI (12VAC5-481-3460 et seq.) of this chapter, the total terrestrial, atmospheric, and aquatic environments outside the site boundary within which any activity, operation, or process authorized by a general or specific license issued under Part XVI, is performed.

"General purpose radiographic x-ray system" means any radiographic x-ray system that, by design, is not limited to radiographic examination of specific anatomical regions.

"Generator" means a licensee who (i) is a waste generator as defined in this chapter, or (ii) is the licensee to whom waste can be attributed within the context of the Low-Level Radioactive Waste Policy Amendments Act of 1985 (42 USC § 2021) (e.g., waste generated as a result of decontamination or recycle activities).

"Gonad shield" means a protective barrier for the testes or ovaries.

"Gray" or "Gy" means the SI unit of absorbed dose. One gray is equal to an absorbed dose of one joule per kilogram (100 rad).

"Guide tube (protection sheath)" means a flexible or rigid tube, or "J" tube, for guiding the source assembly and the attached control cable from the exposure device to the exposure head. The guide tube may also include the connections necessary for attachment to the exposure device and to the exposure head.

"Half-value layer" or "HVL" means the thickness of a specified material that attenuates the beam of radiation to an extent that the AKR is reduced by one-half of its original value. In this definition, the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

"Hand-held radiographic unit" means x-ray equipment that is designed to be hand-held during operation.

"Hands-on experience" means experience in all of those areas considered to be directly involved in the radiography process, and includes taking radiographs, calibration of survey instruments, operational and performance testing of survey instruments and devices, film development, posting of radiation areas, transportation of radiography equipment, posting of records and radiation area surveillance, etc., as applicable. Excessive time spent in only one or two of these areas, such as film development or radiation area surveillance, should not be counted toward the 2,000 hours of hands-on experience required for a radiation safety officer in 12VAC5-481-1310 B 2 or the hands-on experience for a radiographer as required by 12VAC5-481-1320 A.

"Hazardous waste" means those wastes designated as hazardous by the U.S. Environmental Protection Agency regulations in 40 CFR Part 261.

"Healing arts" means the art or science or group of arts or sciences dealing with the prevention and cure or alleviation of ailments, diseases or infirmities, and has the same meaning as "medicine" when the latter term is used in its comprehensive sense.

"Healing arts screening" means the testing of human beings using x-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized to prescribe such x-ray tests for the purpose of diagnosis or treatment.

"Heat unit" means a unit of energy equal to the product of the peak kilovoltage, milliamperes, and seconds, such as (kVp) times (mA) times (seconds).

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

"High integrity container" or "HIC" means a container commonly designed to meet the structural stability requirements of 12VAC5-481-2572 and to meet U.S. Department of Transportation requirements for a Type A package.

"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 one mSv (0.1 rem) in one hour at 30 centimeters from any source of radiation or 30 centimeters from any surface that the radiation penetrates.

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

"Human use" means the internal or external administration of radiation or radioactive material to human beings.

"Hydrogeologic unit" means any soil or rock unit or zone which by virtue of its porosity or permeability, or lack thereof, has a distinct influence on the storage or movement of groundwater.

"Image intensifier" means a device, installed in its housing, that instantaneously converts an x-ray pattern into a corresponding light image of higher intensity.

"Image receptor" means any device, such as a fluorescent screen, radiographic film, x-ray image intensifier tube, solid-state detector, or gaseous detector that transforms incident x-ray photons either into a visible image or into another form that can be made into a visible image by further transformations. In those cases where means are provided to preselect a portion of the image receptor, the term "image receptor" shall mean the preselected portion of the device.

"Image receptor support device" means, for mammographic systems, that part of the system designed to support the image receptor during mammographic examination and to provide a primary protective barrier.

"Inadvertent intruder" means a person who might occupy the disposal site after closure and engage in normal activities, such as agriculture, dwelling construction, or other pursuits in which an individual might be unknowingly exposed to radiation from the waste.

"Indian tribe" means an Indian or Alaska Native tribe, band, nation, pueblo, village, or community that the U.S. Secretary of the Interior acknowledges to exist as an Indian tribe pursuant to the Federally Recognized Indian Tribe List Act of 1994 (25 USC § 479a).

"Independent certifying organization" means an independent organization that meets the agency's criteria for documenting applicant's training in topics set forth in 12VAC5-481-1320 or equivalent Agreement state or NRC regulations.

"Individual" means any human being.

"Individual monitoring" means the assessment of:

1. Dose equivalent (i) by the use of individual monitoring devices or (ii) by the use of survey data; or
2. Committed effective dose equivalent (i) by bioassay or (ii) by determination of the time-weighted air concentrations to which an individual has been exposed, that is, DAC hours. (See the definition of DAC).

"Individual monitoring devices" means devices designed to be worn by a single individual for the assessment of dose equivalent. For purposes of these regulations, "personnel dosimeter" and "dosimeter" are equivalent terms. Examples of individual monitoring devices are film badges, thermoluminescent dosimeters (TLDs), pocket ionization chambers, optically stimulated luminescence (OSL) dosimeters and personal air sampling devices.

"Industrial radiography" means an examination of the structure of materials by the nondestructive method of utilizing ionizing radiation to make radiographic images.

"Inhalation class" (See "Class").

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

"Inspection" means an official examination or observation including, but not limited to, tests, surveys, and monitoring to determine compliance with rules, regulations, orders, requirements, and conditions of the agency.

"Institutional controls" means: (i) permanent markers placed at a disposal site, (ii) public records and archives, (iii) government ownership and regulations regarding land or resource use, and (iv) other methods of preserving knowledge about the location, design, and contents of a disposal system.

"Instrument traceability" (for ionizing radiation measurements) means the ability to show that an instrument has been calibrated at specified time intervals using a national standard or a transfer standard. If a transfer standard is used, the calibration must be at a laboratory accredited by a program that requires continuing participation in measurement quality assurance with the National Institute of Standards and Technology or other equivalent national or international program.

"Intensity modulated radiation therapy" or "IMRT" means radiation therapy that uses nonuniform radiation beam intensities that have been determined by various computer-based optimization techniques.

"Interlock" means a device arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.

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

"Interruption of irradiation" means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.

"Intruder barrier" means a sufficient depth of cover over the waste that inhibits contact with waste and helps to ensure that radiation exposures to an inadvertent intruder will meet the performance objectives set forth in these regulations, or engineered structures that provide equivalent protection to the inadvertent intruder.

"Irradiation" means the exposure of matter to ionizing radiation.

"Irradiator" means a facility that uses radioactive sealed sources for the irradiation of objects or materials and in which radiation dose rates exceeding five grays (500 rads) per hour exist at one meter from the sealed radioactive sources in air or water, as applicable for the irradiator type, but does not include irradiators in which both the sealed source and the area subject to irradiation are contained within a device and are not accessible to personnel.

"Irradiator operator" means an individual who has successfully completed the training and testing described in 12VAC5-481-2830 and is authorized by the terms of the license to operate the irradiator without a supervisor present.

"Irradiator operator supervisor" means an individual who meets the requirements for an irradiator operator and who physically oversees operation of the irradiator by an individual who is currently receiving training and testing described in 12VAC5-481-2830.

"Isocenter" means the center of the smallest sphere through which the beam axis passes when the equipment moves through a full range of rotations about its common center.

"kBq" means kilobecquerel.

"Kerma" or "K" means the quantity defined by the International Commission on Radiation Units and Measurements. The kerma is the quotient of  $dE_{tr}$  by  $dm$ , where  $dE_{tr}$  is the sum of the initial kinetic energies of all charged particles liberated by uncharged particles in a mass  $dm$  of materials; thus  $K=dE_{tr}/dm$ , in units of J/kg, where the special name for the units of kerma is gray (Gy). When the material is air, the quantity is referred to as "air kerma."

"Kilovolt" or "kV" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of 1,000 volts in a vacuum. Current convention is to use kV for photons and keV for electrons.

"Kilovolts peak" (See "Peak tube potential").

"kV" means kilovolts.

"kVp" (See "Peak tube potential").

"kWs" means kilowatt second.

"Land disposal facility" means the land, buildings, structures and equipment that are intended to be used for the disposal of wastes into the subsurface of the land. For purposes of this chapter, a "geologic repository" as defined in 10 CFR Part 60 or 10 CFR Part 63 is not considered a land disposal facility.

"Last image hold radiograph" or "LIH" means an image obtained either by retaining one or more fluoroscopic images, which may be temporarily integrated, at the end of a fluoroscopic exposure or by initiating a separate and distinct radiographic exposure automatically and immediately in conjunction with termination of the fluoroscopic exposure.

"Lay-barge radiography" means industrial radiography performed on any water vessel used for laying pipe.

"Lead equivalent" means the thickness of the material in question affording the same attenuation, under specified conditions, as lead.

"Leakage radiation" means radiation emanating from the diagnostic source assembly or the radiation therapy system except for:

1. The useful beam; and
2. Radiation produced when the exposure switch or timer is not activated.

"Leakage technique factors" means the technique factors associated with the diagnostic source assembly that are used in measuring leakage radiation. They are defined as follows:

1. For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs, (10 mAs), or the minimum obtainable from the unit, whichever is larger;
2. For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in an hour for operation at the maximum-rated peak tube potential; or
3. For all other diagnostic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

"Lens dose equivalent" or "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 cm (300 mg/cm<sup>2</sup>).

"License" means a license issued by the agency in accordance with the regulations adopted by the board.

"Licensed material" means radioactive material received, possessed, used, transferred or disposed of under a general or specific license issued by the agency.

"Licensee" means any person who is licensed by the agency in accordance with these regulations and the Act.

"Light field" means the area illuminated by light, simulating the radiation field.

"Limits" (See "Dose limits").

"Line-voltage regulation" means the difference between the no-load and the load line potentials expressed as a percent of the load line potential as follows:

$$\text{Percent line-voltage regulation} = 100 (V_n - V_l) / V_l$$

where:

$V_n$  = No-load line potential; and

$V_l$  = Load line potential.

"Lixiscope" means a portable light-intensified imaging device using a sealed source.

"Local components" means part of an analytical x-ray system and include areas that are struck by x-rays such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors, and shielding, but do not include power supplies, transformers, amplifiers, readout devices, and control panels.

"Local law-enforcement agency" or "LLEA" means a public or private organization that has been approved by a federal, state, or local government to carry firearms and make arrests, and is authorized and has the capability to provide an armed response in the jurisdiction where the licensed Category 1 or Category 2 quantity of radioactive material is used, stored, or transported.

"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 Part XIV (12VAC5-481-3140 et seq.) of this chapter.

"Logging supervisor" means the individual who uses licensed material or provides personal supervision in the use of licensed material at a temporary jobsite and who is responsible to the licensee for assuring compliance with the requirements of this chapter and the conditions of the license.

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

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

"Lost or missing licensed material" means licensed (or registered) source of radiation whose location is unknown. This definition includes, but is not limited to, radioactive material that has been shipped but has not reached its planned destination and whose location cannot be readily traced in the transportation system.

"Lot tolerance percent defective" means, expressed in percent defective, the poorest quality in an individual inspection lot that should be accepted.

"Low specific activity material" or "LSA material" means radioactive material with limited specific activity that is nonfissile or is excepted under 12VAC5-481-2970 C, and that satisfies the descriptions and limits set forth below. Shielding materials surrounding the LSA material may not be considered in determining the estimated average specific activity of the package contents. LSA material must be in one of three groups:

#### 1. LSA-I

- a. Uranium and thorium ores, concentrates of uranium and thorium ores, and other ores containing naturally occurring radionuclides that are intended to be processed for the use of these radionuclides;
- b. Natural uranium, depleted uranium, natural thorium or their compounds or mixtures, provided they are unirradiated and in solid or liquid form;
- c. Radioactive material other than fissile material, for which the  $A_2$  value is unlimited; or
- d. Other radioactive material in which the activity is distributed throughout and the estimated average specific activity does not exceed 30 times the value for exempt material activity concentration determined in accordance with 12VAC5-481-3720.

#### 2. LSA-II

- a. Water with tritium concentration up to 0.8 terabecquerel per liter (20.0 Ci/L); or
- b. Other radioactive material in which the activity is distributed throughout and the estimated average specific activity does not exceed 1.0 E-04  $A_2/g$  for solids and gases, and 1.0 E-05  $A_2/g$  for liquids.

#### 3. LSA-III

Solids (e.g., consolidated wastes, activated materials), excluding powders, that satisfy the requirements of 10 CFR 71.77) in which:

- a. The radioactive material is distributed throughout a solid or a collection of solid objects, or is essentially uniformly distributed in a solid compact binding agent (e.g., concrete, bitumen, or ceramic);
- b. The radioactive material is relatively insoluble, or it is intrinsically contained in a relatively insoluble material, so that, even under loss of packaging, the loss of radioactive material per package by leaching, when placed in water for seven days, would not exceed 0.1  $A_2$ ; and
- c. The estimated average specific activity of the solid, excluding any shielding material, does not exceed 2.0 E-03  $A_2/g$ .

"Low toxicity alpha emitters" means natural uranium, depleted uranium, natural thorium; uranium-235, uranium-238, thorium-232, thorium-228 or thorium-230 when contained in ores or physical or chemical concentrates or tailings; or alpha emitters with a half-life of less than 10 days.

"Lung class" (See "Class").

"mA" means milliampere.

"mAs" means milliampere second.

"Major processor" means a user processing, handling, or manufacturing radioactive material exceeding Type A quantities as unsealed sources or material, or exceeding four times Type B quantities as sealed sources, but does not include nuclear medicine programs, universities, industrial radiographers, or small industrial programs. Type A and B quantities are defined in this section.

"Management" means the chief executive officer or that individual's designee.

"MBq" means megabecquerels.

"Medical event" means an event that meets the criteria in 12VAC5-481-2080.

"Medical institution" means an organization in which several medical disciplines are practiced.

"Medical use" means the intentional internal or external administration of radioactive material or the radiation from radioactive material to patients or human research subjects under the supervision of an authorized user.

"Megavolt" or "MV" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one million volts in a vacuum. (Note: current convention is to use MV for photons and MeV for electrons.)

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

"Mineral logging" means any logging performed for the purpose of mineral exploration other than oil or gas.

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

"Misadministration" means either:

1. An x-ray teletherapy radiation dose:

a. Involving the wrong patient;

b. Involving the wrong mode of treatment;

c. Involving the wrong treatment site;

d. Where the calculated total administered dose differs from the total prescribed dose by more than 10% when the treatment consists of three or fewer fractions;

e. Where the calculated weekly administered dose differs from the weekly prescribed dose by 30%; or

f. Where the calculated total administered dose differs from the total prescribed dose by more than 20%; or

2. An x-ray brachytherapy radiation dose:

a. Involving the wrong patient;

b. Involving the wrong treatment site; or

c. Where the calculated administered dose differs from the prescribed dose by more than 20%.

"mm" means millimeters.

"Mobile device" means a piece of equipment containing licensed radioactive materials that is either mounted on wheels or casters, or otherwise equipped for moving without a need for disassembly or dismounting, or designed to be hand carried. Mobile devices do not include stationary equipment installed in a fixed location.

"Mobile electronic brachytherapy service" means transportation of an electronic brachytherapy device to provide electronic brachytherapy at an address that is not the address of record.

"Mobile nuclear medicine service" means the transportation and medical use of radioactive material.

"Mobile x-ray equipment" (See "x-ray equipment").

"Mode of operation" means, for fluoroscopy systems, a distinct method of fluoroscopy or radiography provided by the manufacturer and selected with a set of several technique factors or other control settings uniquely associated with the mode. The set of distinct technique factors and control settings for the mode may be selected by the operation of a single control. Examples of distinct modes of operation include normal fluoroscopy (analog or digital), high-level control fluoroscopy, cineradiography (analog and digital), digital subtraction angiography, electronic radiography using the fluoroscopic image receptor, and photospot recording. In a specific mode of operation, certain system variables affecting kerma, AKR, or image quality, such as image magnification, x-ray field size, pulse rate, pulse duration, number of pulses, source-image receptor distance (SID), or optical aperture, may be adjustable or may vary; their variation per se does not comprise a mode of operation different from the one that has been selected.

"Monitor unit" or "MU" (See "Dose monitor unit").

"Monitoring" means the measurement of radiation, radioactive material concentrations, surface area activities or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses. For purposes of these regulations, "radiation monitoring" and "radiation protection monitoring" are equivalent terms. For Part XI (12VAC5-481-2330 et seq.) of this chapter, it means observing and making measurements to provide data to evaluate the performance and characteristics of the disposal site.

"Movement control center" means an operation center that is remote from the transport activity and that maintains the position information on the movement of radioactive material, receives reports of attempted attacks or thefts, provides a means for reporting these and other problems to appropriate agencies and can request and coordinate appropriate aid.

"Moving beam radiation therapy" means radiation therapy with any planned displacement of radiation field or patient relative to each other, or with any planned change of absorbed dose distribution. It includes arc, skip, conformal, intensity modulation and rotational therapy.

"Multiple tomogram system" means a computed tomography x-ray system that obtains x-ray transmission data simultaneously during a single scan to produce more than one tomogram.

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



"National Sealed Source and Device Registry" or "SSDR" means the national registry that contains the registration certificates, maintained by the NRC, that summarize the radiation safety information for sealed sources and devices, and describes the licensing and use conditions approved for the product.

"Nationally tracked source" means a sealed source containing a quantity equal to or greater than Category 1 or Category 2 levels of any radioactive material listed in 12VAC5-481-3780. In this context a sealed source is defined as radioactive material that is sealed in a capsule or closely bonded, in a solid form and that is not exempt from regulatory control. It does not mean material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet. Category 1 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 1 threshold. Category 2 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 2 threshold but less than the Category 1 threshold.

"Natural radioactivity" means radioactivity of naturally occurring nuclides.

"Natural thorium" means thorium with the naturally occurring distribution of thorium isotopes, which is essentially 100 weight percent thorium-232.

"Natural uranium" (See "Uranium - natural, depleted, enriched").

"Near-surface disposal facility" means a land disposal facility in which waste is disposed of within approximately the upper 30 meters of the earth's surface.

"Negative pressure respirator" or "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.

"No-later-than arrival time" means the date and time that the shipping licensee and receiving licensee have established as the time at which an investigation will be initiated if the shipment has not arrived at the receiving facility. The no-later-than arrival times may not be more than six hours after the estimated arrival time for shipments of Category 2 quantities of radioactive material.

"Noise" means the standard deviation of the fluctuations in CTN expressed as a percentage of the attenuation coefficient of water. Its estimate ( $S_n$ ) is calculated using the following expression:

$$S_n = \frac{100 \oplus \overline{CS} \oplus s}{\mu_w}$$

where:

$\overline{CS}$  = Linear attenuation coefficient of the material of interest.

$\mu_w$  = Linear attenuation coefficient of water.

s = Standard deviation of the CTN of picture elements in a specified area of the CT image.

"Nominal tomographic section thickness" means the full width at half-maximum of the sensitivity profile taken at the center of the cross-sectional volume over which x-ray transmission data are collected.

"Non-image-intensified fluoroscopy" means fluoroscopy using only a fluorescent screen.

"Nonstochastic effect" means a health effect, 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. For purposes of these regulations, "deterministic effect" is an equivalent term.

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

"Normal form radioactive material" means radioactive material that has not been demonstrated to qualify as special form radioactive material.

"Normal operating procedures" mean step-by-step instructions necessary to accomplish the analysis. These procedures shall include sample insertion and manipulation, equipment alignment, routine maintenance by the registrant (or licensee), and data recording procedures, which are related to radiation safety.

"Nominal treatment distance" means:

1. For electron irradiation, the distance from the scattering foil, virtual source, or exit window of the electron beam to the entrance surface of the irradiated object along the central axis of the useful beam.
2. For x-ray irradiation, the virtual source or target to isocenter distance along the central axis of the useful beam. For nonisocentric equipment, this distance shall be that specified by the manufacturer.

"NRC Forms 540, 540A, 541, 541A, 542, and 542A" means official NRC forms referenced in this chapter. 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.

"Nuclear Regulatory Commission" or "NRC" means the NRC or its duly authorized representatives.

"Nuclear waste" means a quantity of source, byproduct or special nuclear material (the definition of nuclear waste in this chapter is used in the same way as in 49 CFR 173.403) required to be in NRC-approved specification packaging while transported to, through or across a state boundary to a disposal site, or to a collection point for transport to a disposal site.

"Occupational dose" means the dose received by an individual in the course of employment in which the individual's assigned duties for the licensee or registrant involve exposure to sources of radiation, whether or not the sources of radiation are in the possession of the licensee, registrant, 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 12VAC5-481-1870, from voluntary participation in medical research programs, or as a member of the public.

"Offshore platform radiography" means industrial radiography conducted from a platform over a body of water.

"Offshore waters" means that area of land and water, beyond the Commonwealth of Virginia's jurisdiction, on or above the U.S. Outer Continental Shelf.

"Open-beam configuration" means an analytical x-ray system in which an individual could accidentally place some part of his body in the primary beam path during normal operation.

"Ophthalmic physicist" means an individual who (i) meets the requirements of 12VAC5-481-1790 and 12VAC5-481-2016 A 2 and (ii) is identified as an ophthalmic physicist on a specific medical use license issued by the agency, NRC, or another agreement state; permit issued by agency, NRC, or another agreement state broad scope licensee; medical use permit issued by a NRC master material licensee; or a permit issued by a NRC master material broad scope medical use permittee.

"Output" means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a teletherapy unit for a specified set of exposure conditions.

"Package" means the packaging together with its radioactive contents as presented for transport.

1. Fissile material package or Type AF package, Type BF package, Type B(U)F package, or Type B(M)F package means a fissile material packaging together with its fissile material contents.

2. Type A package means a Type A packaging together with its radioactive contents. A Type A package is defined and must comply with the DOT regulations in 49 CFR Part 173.

3. Type B package means a Type B packaging together with its radioactive contents. On approval, a Type B package design is designated by NRC as B(U) unless the package has a maximum normal operating pressure of more than 700 kPa (100 lbs/in<sup>2</sup>) gauge or a pressure relief device that would allow the release of radioactive material to the environment under the tests specified in 10 CFR 71.73 (hypothetical accident conditions), in which case it will receive a designation B(M). B(U) refers to the need for unilateral approval of international shipments; B(M) refers to the need for multilateral approval of international shipments. There is no distinction made in how packages with these designations may be used in domestic transportation. To determine their distinction for international transportation, see DOT regulations in 49 CFR Part 173. A Type B package approved before September 6, 1983, was designated only as Type B. Limitations on its use are specified in 10 CFR 71.19.

"Packaging" means the assembly of components necessary to ensure compliance with the packaging requirements of these regulations. It may consist of one or more receptacles, absorbent materials, spacing structures, thermal insulation, radiation shielding, and devices for cooling or absorbing mechanical shocks. The vehicle, tie-down system, and auxiliary equipment may be designated as part of the packaging.

"Panoramic dry-source-storage irradiator" means an irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored in shields made of solid materials. The term includes beam-type dry-source-storage irradiators in which only a narrow beam of radiation is produced for performing irradiations.

"Panoramic irradiator" means an irradiator in which the irradiations are done in air in areas potentially accessible to personnel. The term includes beam-type irradiators.

"Panoramic wet-source-storage irradiator" means an irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored under water in a storage pool.

"Particle accelerator" (See "Accelerator").

"Patient" means an individual or animal subjected to healing arts examination, diagnosis, or treatment.

"PBL" (See "Positive beam limitation").

"Peak tube potential" means the maximum value of the potential difference across the x-ray tube during an exposure.

"Periodic quality assurance check" means a procedure that is performed to ensure that a previous calibration continues to be valid.

"Permanent radiographic installation" means an enclosed shielded room, cell, or vault, not located at a temporary jobsite, in which radiography is performed.

"Person" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, department of the Commonwealth other than the Department of Health, political subdivision of the Commonwealth, any other state or political subdivision or department thereof, and any legal successor, representative, agent, or department of the foregoing, but not including federal government agencies.

"Personal supervision" means guidance and instruction by the supervisor who is physically present at the jobsite and watching the performance of the operation in such proximity that contact can be maintained and immediate assistance given as required. In radiography it means guidance and instruction provided to a radiographer trainee by a radiographer instructor who is present at the site, in visual contact with the trainee while the trainee is using sources of radiation, and in such proximity that immediate assistance can be given if required.

"Personnel monitoring equipment" (See "Individual monitoring devices").

"Phantom" means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation. This requires that both the atomic number (Z) and the density of the material be similar to that of tissue.

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

"Pool irradiator" means any irradiator at which the sources are stored or used in a pool of water including panoramic wet-source-storage irradiators and underwater irradiators.

"Pharmacist" means an individual licensed by this state to compound and dispense drugs, prescriptions, and poisons.

"Physician" means an individual licensed by this state to prescribe drugs in the practice of medicine.

"Picture element" means an elemental area of a tomogram.

"PID" (See "Position indicating device").

"Pigtail" (See "Source assembly").

"Pill" (See "Sealed source").

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

"Portable x-ray equipment" (See "x-ray equipment").

"Position indicating device" means a device on dental x-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.

"Positive beam limitation" means the automatic or semi-automatic adjustment of an x-ray beam to the size of the selected image receptor, whereby exposures cannot be made without such adjustment.

"Positron emission tomography radionuclide production facility" or "PET" means a facility operating a cyclotron or other particle accelerator for the purpose of producing radionuclides that decay by positron emission.

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

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

"Practical examination" means a demonstration through application of the safety rules and principles in industrial radiography including use of all procedures and equipment to be used by radiographic personnel.

"Practical range of electrons" corresponds to classical electron range where the only remaining contribution to dose is from bremsstrahlung x-rays. A further explanation may be found in "Clinical Electron Beam Dosimetry: Report of AAPM Radiation Therapy Committee Task Group 25" (Medical Physics 18(1): 73-109, Jan/Feb. 1991) and ICRU Report 35, "Radiation Dosimetry: Electron Beams with Energies Between 1 and 50 MeV", International Commission on Radiation Units and Measurements, September 15, 1984.

"Preceptor" means an individual who provides, directs, or verifies training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, ~~or~~ a radiation safety officer, or an associate radiation safety officer.

"Prescribed dosage" means the quantity of radiopharmaceutical activity as documented:

1. In a written directive; or
2. Either in the diagnostic clinical procedures manual or in any appropriate record in accordance with the directions of the authorized user for diagnostic procedures.

"Prescribed dose" means:

1. For gamma stereotactic radiosurgery, the total dose as documented in the written directive;
2. For teletherapy, the total dose and dose per fraction as documented in the written directive. The prescribed dose is an estimation from measured data from a specified therapeutic machine using assumptions that are clinically acceptable for that treatment technique and historically consistent with the clinical calculations previously used for patients treated with the same clinical technique; or
3. For brachytherapy, either the total source strength and exposure time, or the total dose, as documented in the written directive.

"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.

"Primary beam" means radiation that passes through an aperture of the source housing by a direct path from the x-ray tube or a radioactive source located in the radiation source housing.

"Primary dose monitoring system" means a system that will monitor the useful beam during irradiation and that will terminate irradiation when a preselected number of dose monitor units have been delivered.

"Primary protective barrier" means the material, excluding filters, placed in the useful beam to reduce the radiation exposure (beyond the patient and cassette holder) for protection barriers.

"Principal activities," as used in this chapter, means activities authorized by the license that are essential to achieving the purposes for which the license was issued or amended. Storage during which no licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.

"Private inspector" means an individual who meets the requirements set forth in 12VAC5-481-340 and who has demonstrated to the satisfaction of the agency that such individual possesses the knowledge, training and experience to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs.

"Product" means, as used in Part XVI (12VAC5-481-3460 et seq.) of this chapter, something produced, made, manufactured, refined, or benefited.

"Product conveyor system" means a system for moving the product to be irradiated to, from, and within the area where irradiation takes place.

"Projection sheath" (See "Guide tube").

"Projector" (See "Radiographic exposure device").

"Protective apron" means an apron made of radiation-attenuating or absorbing materials used to reduce exposure to radiation.

"Protective glove" means a glove made of radiation absorbing materials used to reduce radiation exposure.

"Public dose" means the dose received by a member of the public from exposure to sources of radiation released by the licensee or registrant, or to any other source of radiation under the control of the licensee or registrant. "Public dose" does not include occupational dose, or 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 12VAC5-481-1870, or from voluntary participation in medical research programs.

"Pulsed mode" means operation of the x-ray system such that the x-ray tube is pulsed by the x-ray control to produce one or more exposure intervals of duration less than one-half second.

"Pyrophoric material" means any liquid that ignites spontaneously in dry or moist air at or below 130°F (54.4°C) or any solid material, other than one classed as an explosive, which under normal conditions is liable to cause fires through friction, retained heat from manufacturing or processing, or that can be ignited readily and, when ignited, burns so vigorously and persistently as to create a serious transportation, handling, or disposal hazard. Included are spontaneously combustible and water-reactive materials.

"Qualified inspector" means an individual who is granted professional privileges based on education and experience to provide clinical services in diagnostic and therapeutic medical physics.

"Qualified medical physicist" means an individual qualified in accordance with 12VAC5-481-3390 D.

"Qualitative fit test" or "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.

"Quality factor" or "Q" means the modifying factor, that is referenced in 12VAC5-481-240, that is used to derive dose equivalent from absorbed dose.

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

"Quarter" means a period of time equal to one-fourth of the year observed by the licensee, approximately 13 consecutive weeks, providing that the beginning of the first quarter in a year coincides with the starting date of the year and that no day is omitted or duplicated in consecutive quarters.

"Rad" means the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 erg per gram or 0.01 joule per kilogram (0.01 gray).

"Radiation" means alpha particles, beta particles, gamma rays, x-rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions. For purposes of these regulations, ionizing radiation is an equivalent term. Radiation, as used in these regulations, does not include nonionizing radiation, such as radiowaves or microwaves, visible, infrared, or ultraviolet light.

"Radiation area" means any area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.05 mSv (0.005 rem) in one hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates.

"Radiation dose" (See "Dose").

"Radiation field" (See "Useful beam").

"Radiation head" means the structure from which the useful beam emerges.

"Radiation machine" means any device capable of producing radiation except those devices with radioactive material as the only source of radiation.

"Radiation room" means a shielded room in which irradiations take place. Underwater irradiators do not have radiation rooms.

"Radiation safety officer" or "RSO" means an individual who has the knowledge and responsibility to apply appropriate radiation protection regulations and has been assigned such responsibility by the licensee or registrant.

"Radiation safety officer for industrial radiography" means an individual with the responsibility for the overall radiation safety program on behalf of the licensee or registrant and who meets the requirements of 12VAC5-481-1310.

"Radiation safety officer for medical" means an individual who meets the requirements of 12VAC5-481-1750 and 12VAC5-481-1790 or is identified as an RSO on: a medical use license issued by the agency, NRC, or another Agreement state, or a medical use permit issued by an NRC masters material licensee.

"Radiation therapy physicist" means an individual qualified in accordance with 12VAC5-481-340.

"Radiation therapy simulation system" means a radiographic or fluoroscopic x-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

"Radiation therapy system" means a device that delivers radiation to a specific area of the body where cancer cells or tumors are located.

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

"Radioactive marker" means radioactive material placed subsurface or on a structure intended for subsurface use for the purpose of depth determination or direction orientation.

"Radioactivity" means the transformation of unstable atomic nuclei by the emission of radiation.

"Radiobioassay" (See "Bioassay").

"Radiograph" means an image receptor on which the image is created directly or indirectly by an x-ray pattern and results in a permanent record.

"Radiographer" means any individual who performs or who, in attendance at the site where the sources of radiation are being used, personally supervises industrial radiographic operations and who is responsible to the licensee or registrant for assuring compliance with the requirements of the agency's regulations and the conditions of the license or registration.

"Radiographer certification" means written approval received from a certifying entity stating that an individual has satisfactorily met the radiation safety, testing, and experience criteria in 12VAC5-481-1320.

"Radiographer instructor" means any radiographer who has been authorized by the agency to provide on-the-job training to radiographer trainees in accordance with Part V (12VAC5-481-1170 et seq.) of this chapter.

"Radiographer trainee" means any individual who, under the personal supervision of a radiographer instructor, uses sources of radiation, related handling tools, or radiation survey instruments during the course of his instruction.

"Radiographer's assistant" means any individual who under the direct supervision of a radiographer, uses radiographic exposure devices, sources of radiation, related handling tools, or radiation survey instruments in industrial radiography.

"Radiographic exposure device" means any instrument containing a sealed source fastened or contained therein, in which the sealed source or shielding thereof may be moved, or otherwise changed, from a shielded to unshielded position for purposes of making a radiographic exposure.

"Radiographic operations" means all activities performed with a radiographic exposure device, or with a radiation machine. Activities include using, transporting except by common or contract carriers, or storing at a temporary job site, performing surveys to confirm the adequacy of boundaries, setting up equipment, and any activity inside restricted area boundaries. Transporting a radiation machine is not considered a radiographic operation.

"Radiographic personnel" means any radiographer, radiographer instructor, or radiographer trainee.

"Radiography" means:

1. For radioactive materials: See "Industrial radiography."
2. For x-ray: A technique for generating and recording an x-ray pattern for the purpose of providing the user with an image after termination of the exposure.

"Rating" means the operating limits as specified by the component manufacturer.

"Reasonably maximally exposed individual" means, as used in Part XVI (12VAC5-481-3460 et seq.) of this chapter, a representative of a population who is exposed to TENORM at the maximum TENORM concentration measured in environmental media found at a site along with reasonable maximum case exposure assumptions. The exposure is determined by using maximum values for one or more of the most sensitive parameters affecting exposure, based on cautious but reasonable assumptions, while leaving the others at their mean value.

"Recording" means producing a retrievable form of an image resulting from x-ray photons.

"Redundant beam monitoring system" means a combination of two dose monitoring systems in which each system is designed to terminate irradiation in accordance with a preselected number of dose monitor units.

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

base. A description of the reference man is contained in the International Commission on Radiological Protection report, ICRP Publication 23, "Report of the Task Group on Reference Man."

"Reference plane" means a plane that is displaced from and parallel to the tomographic plane.

"Registrant" means any person who is registered with the agency and is legally obligated to register with the agency pursuant to these regulations and the Act.

"Registration" means registration with the agency in accordance with the regulations adopted by the agency.

"Regulations of the U.S. Department of Transportation" means the regulations in 49 CFR Parts 100 - 189.

"Rem" means the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rems is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 Sv).

"Reportable event" means the administration of either:

1. A diagnostic x-ray exposure where an actual or suspected acute or long-term functional damage to an organ or a physiological system has occurred. Exempt from this reporting requirement is any event when any functional damage to a patient organ or a physiological system that was an expected outcome when the causative procedures were prescribed;
2. A procedure where the patient or operator is injured as a result of a mechanical injury;
3. A teletherapy x-ray or electron dose where the calculated weekly administered dose differs from the weekly prescribed dose by 15% or more; or
4. A brachytherapy x-ray dose where the calculated administered dose differs from the prescribed dose by 10% or more.

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

"Residential location" means any area where structures in which people lodge or live are located, and the grounds on which such structures are located including, but not limited to, houses, apartments, condominiums, and garages.

"Residual radioactive material" means (i) waste (that the U.S. Secretary of Energy determines to be radioactive) in the form of tailings resulting from the processing of ores for the extraction of uranium and other valuable constituents of the ores and (ii) other waste (that the U.S. Secretary of Energy determines to be radioactive) at a processing site that relates to such processing, including any residual stock of unprocessed ores or low-grade materials. This term is used only with respect to materials at sites subject to remediation under Title I of the Uranium Mill Tailings Radiation Control Act of 1978, as amended.

"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 materials at the site and previous burials at the site, even if those burials were made in accordance with the provisions of Part IV (12VAC5-481-600 et seq.) of this chapter.

"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.

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

"Restricted area" means an area, access to which is limited by the licensee or registrant for the purpose of protecting individuals against undue risks from exposure to radiation and radioactive materials. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

"Reviewing official" means the individual who shall make the trustworthiness and reliability determination of an individual to determine whether the individual may have, or continue to have, unescorted access to the Category 1 or Category 2 quantities of radioactive materials that are possessed by the licensee.

"Roentgen" means the special unit of exposure. One roentgen (R) equals  $2.58 \times 10^{-4}$  coulombs per kilogram of air (see "Exposure" and 12VAC5-481-240).

"S-tube" means a tube through which the radioactive source travels when inside a radiographic exposure device.

"Sabotage" means deliberate damage, with malevolent intent, to a Category 1 or Category 2 quantity of radioactive material, a device that contains a Category 1 or Category 2 quantity of radioactive material, or the components of the security system.

"Safe haven" means a readily recognizable and readily accessible site at which security is present or from which, in the event of an emergency, the transport crew can notify and wait for the local law-enforcement authorities.

"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 or registrant.

"Scan" means the complete process of collecting x-ray transmission data for the production of a tomogram. Data can be collected simultaneously during a single scan for the production of one or more tomograms.

"Scan increment" means the amount of relative displacement of the patient with respect to the CT x-ray system between successive scans measured along the direction of such displacement.

"Scan sequence" means a preselected set of two or more scans performed consecutively under preselected CT conditions of operation.

"Scan time" means the period of time between the beginning and end of x-ray transmission data accumulation for a single scan.

"Scattered radiation" means ionizing radiation emitted by interaction of ionizing radiation with matter, the interaction being accompanied by a change in direction of the radiation. Scattered primary radiation means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam.

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

"Secondary dose monitoring system" means a system which will terminate irradiation in the event of failure of the primary dose monitoring system.

"Security zone" means any temporary or permanent area determined and established by the licensee for the physical protection of Category 1 or Category 2 quantities of radioactive material.

"Seismic area" means any area where the probability of a horizontal acceleration in rock of more than 0.3 times the acceleration of gravity in 250 years is greater than 10%, as designated by the United States Geological Survey.

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

"Shadow tray" means a device attached to the radiation head to support auxiliary beam blocking material.

"Shallow dose equivalent" or " $H_s$ ," which applies to the external exposure of the skin or an extremity, means the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm<sup>2</sup>).

"Shielded position" means the location within the radiographic exposure device or storage container which, by manufacturer's design, is the proper location for storage of the sealed source.

"Shielded-room radiography" means industrial radiography conducted in a room shielded so that radiation levels at every location on the exterior meet the limitations specified in 12VAC5-481-640.

"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.

"Shipping paper" means NRC Form 540 and, if required, NRC Form 540A, which includes the information required by the U.S. Department of Transportation in 49 CFR Part 172.

"Shutter" means a device attached to the tube housing assembly which can intercept the entire cross sectional area of the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

"SI" means the abbreviation for the International System of Units.

"SID" (See "Source-image receptor distance").

"Sievert" or "Sv" means the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 Sv = 100 rem).

"Simulator" or "radiation therapy simulation system" means any x-ray system intended for localizing the volume to be exposed during radiation therapy and reproducing the position and size of the therapeutic irradiation field.

"Single tomogram system" means a CT x-ray system that obtains x-ray transmission data during a scan to produce a single tomogram.

"Site area emergency" means events may occur, are in progress, or have occurred that could lead to a significant release of radioactive material and that could require a response by offsite response organizations to protect persons offsite.

"Site boundary" means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee.

"Site closure and stabilization" means those actions that are taken upon completion of operations that prepare the disposal site for custodial care and that assure that the disposal site will remain stable and will not need ongoing active maintenance.

"Source" means the focal spot of the x-ray tube.

"Source assembly" means an assembly that consists of the sealed source and a connector that attaches the source to the control cable. The source assembly may include a ballstop to secure the source in the shielded position.

"Source changer" means a device designed and used for replacement of sealed sources in radiographic exposure devices, including those source changers also used for transporting and storage of sealed sources.

"Source holder" means a housing or assembly into which a radioactive source is placed for the purpose of facilitating the handling and use of the source in well-logging operations.

"Source-image receptor distance" means the distance from the source to the center of the input surface of the image receptor.

"Source material" means:

1. Uranium or thorium, or any combination thereof, in any physical or chemical form; or
2. Ores that contain by weight one-twentieth of 1.0% (0.05%) or more of uranium, thorium or any combination of uranium and thorium. Source material does not include special nuclear material.

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

"Source-skin distance" or "SSD" means the distance from the source to the center of the entrant x-ray field in the plane tangent to the patient's skin surface.

"Source traceability" means the ability to show that a radioactive source has been calibrated either by the national standards laboratory of the National Institute of Standards and Technology, or by a laboratory that participates in a continuing measurement quality assurance program with National Institute of Standards and Technology or other equivalent national or international program.

"Special form radioactive material" means radioactive material that satisfies the following conditions:

1. It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;
2. The piece or capsule has at least one dimension not less than five millimeters (0.2 in.); and
3. It satisfies the requirements of 10 CFR 71.75. A special form encapsulation designed in accordance with the NRC requirements of 10 CFR 71.4 in effect on June 30, 1983 (see 10 CFR Part 71, revised as of January 1, 1983), and constructed before July 1, 1985; a special form encapsulation designed in accordance with the requirements of 10 CFR 71.4 in effect on March 31, 1996 (see 10 CFR Part 71, revised as of January 1, 1996), and constructed before April 1, 1998; and special form material that was successfully tested before September 10, 2015, in accordance with the requirements of 10 CFR 71.75(d) in effect before September 10, 2015, may continue to be used. Any other special form encapsulation must meet requirements of this definition.

"Special nuclear material" means:

1. Plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material the NRC, pursuant to the provisions of § 51 of the Atomic Energy Act of 1954, as amended, (42 USC § 2071) determines to be special nuclear material, but does not include source material; or
2. Any material artificially enriched by any of the foregoing but does not include source material.

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

$$(175 \text{ grams contained U-235}/350) + (50 \text{ grams U-233}/200) + (50 \text{ grams Pu-239}/200) = 1$$

"Specific activity of a radionuclide" means the radioactivity of a radionuclide per unit mass of that nuclide. The specific activity of a material in which the radionuclide is essentially uniformly distributed is the radioactivity per unit mass of the material.

"Spot film" means a radiograph that is made during a fluoroscopic examination to permanently record conditions that exist during that fluoroscopic procedure.

"Spot-film device" means a device intended to transport or position a radiographic image receptor between the x-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.

"Stability" means structural stability.

"State inspector" means an employee of the Virginia Department of Health designated to perform those duties or functions assigned the Radiological Health Program.

"Stationary beam radiation therapy" means radiation therapy without displacement of one or more mechanical axes relative to the patient during irradiation.

"Stationary x-ray equipment" (See "x-ray equipment").

"Stochastic effect" means a health effect that occurs 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. For purposes of this chapter, "probabilistic effect" is an equivalent term.



"Storage" means a condition in which a device or source is not being used for an extended period of time, and has been made inoperable.

"Storage area" means any location, facility, or vehicle that is used to store and secure a radiographic exposure device, a radiation machine, or a storage container when it is not used for radiographic operations. Storage areas are locked or have a physical barrier to prevent accidental exposure, tampering, or unauthorized removal of the device, machine, or container.

"Storage container" means a device in which sealed sources or radiation machines are secured and stored.

"Stray radiation" means the sum of leakage and scattered radiation.

"Subsurface tracer study" means the release of a substance tagged with radioactive material for the purpose of tracing the movement or position of the tagged substance in the well-bore or adjacent formation.

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

"Surface contaminated object" or "SCO" means a solid object that is not itself classed as radioactive material, but that has radioactive material distributed on any of its surfaces. An SCO must be in one of two groups with surface activity not exceeding the following limits:

1. SCO-I: A solid object on which:

a. The nonfixed contamination on the accessible surface averaged over 300 cm<sup>2</sup>, or the area of the surface if less than 300 cm<sup>2</sup>, does not exceed four becquerel per cm<sup>2</sup> (1 E-04 μCi/cm<sup>2</sup>) for beta and gamma and low toxicity alpha emitters, or 0.4 becquerel per cm<sup>2</sup> (1 E-05 μCi/cm<sup>2</sup>) for all other alpha emitters;

b. The fixed contamination on the accessible surface averaged over 300 cm<sup>2</sup>, or the area of the surface if less than 300 cm<sup>2</sup>, does not exceed 4 E+04 becquerel per cm<sup>2</sup> (1.0 μCi/cm<sup>2</sup>) for beta and gamma and low toxicity alpha emitters, or 4 E+03 becquerel per cm<sup>2</sup> (0.1 μCi/cm<sup>2</sup>) for all other alpha emitters; and

c. The nonfixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm<sup>2</sup>, or the area of the surface if less than 300 cm<sup>2</sup>, does not exceed 4 E+04 becquerel per cm<sup>2</sup> (1 μCi/cm<sup>2</sup>) for beta and gamma and low toxicity alpha emitters, or 4 E+03 Becquerel per cm<sup>2</sup> (0.1 μCi/cm<sup>2</sup>) for all other alpha emitters.

2. SCO-II: A solid object on which the limits for SCO-I are exceeded and on which:

a. The nonfixed contamination on the accessible surface averaged over 300 cm<sup>2</sup>, or the area of the surface if less than 300 cm<sup>2</sup>, does not exceed 400 becquerel per cm<sup>2</sup> (1 E-02 μCi/cm<sup>2</sup>) for beta and gamma and low toxicity alpha emitters or 40 becquerel per cm<sup>2</sup> (1 E-03 μCi/cm<sup>2</sup>) for all other alpha emitters;

b. The fixed contamination on the accessible surface averaged over 300 cm<sup>2</sup>, or the area of the surface if less than 300 cm<sup>2</sup>, does not exceed 8 E+05 becquerel per cm<sup>2</sup> (20 μCi/cm<sup>2</sup>) for beta and gamma and low toxicity alpha emitters, or 8 E+04 becquerel per cm<sup>2</sup> (2 μCi/cm<sup>2</sup>) for all other alpha emitters; and

c. The nonfixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm<sup>2</sup>, or the area of the surface if less than 300 cm<sup>2</sup>, does not exceed 8 E+05 becquerel per cm<sup>2</sup> (20 μCi/cm<sup>2</sup>) for beta and gamma and low toxicity alpha emitters, or 8 E+04 becquerel per cm<sup>2</sup> (2 μCi/cm<sup>2</sup>) for all other alpha emitters.

"Surveillance" means monitoring and observation of the disposal site for purposes of visual detection of need for maintenance, custodial care, evidence of intrusion, and compliance with other license and regulatory requirements.

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

"Tabletop, stationary" means a tabletop that, when assembled for use, is incapable of movement with respect to its supporting structure within the plane of the tabletop.

"Target" means that part of an x-ray tube or accelerator onto which a beam of accelerated particles is directed to produce ionizing radiation or other particles.

"Target-skin distance" or "TSD" means the distance measured along the beam axis from the center of the front surface of the x-ray target or electron virtual source, or both, to the surface of the irradiated object or patient.

"Technologically enhanced naturally occurring radioactive material" or "TENORM" means, as used in Part XVI (12VAC5-481-3460 et seq.) of this chapter, naturally occurring radionuclides whose concentrations are increased by or as a result of past or present human practices. TENORM does not include background radiation or the natural radioactivity of rocks or soils. TENORM does not include uranium or thorium in "source material" as defined in the AEA and NRC regulations.

"Technique factors" means the following conditions of operation:

1. For capacitor energy storage equipment, peak tube potential in kilovolts (kV) and quantity of charge in milliampere-seconds (mAs);
2. For field emission equipment rated for pulsed operation, peak tube potential in kilovolts (kV), and number of x-ray pulses;
3. For CT equipment designed for pulsed operation, peak tube potential in kilovolts (kV), scan time in seconds, and either tube current in milliamperes (mA), x-ray pulse width in seconds, and the number of x-ray pulses per scan, or the product of tube current, x-ray pulse width, and the number of x-ray pulses in milliampere-seconds (mAs);
4. For CT equipment not designed for pulsed operation, peak tube potential in kilovolts (kV), and either tube current in milliamperes (mA) and scan time in seconds, or the product of tube current and exposure time in milliampere-seconds (mAs) and the scan time when the scan time and exposure time are equivalent; and
5. For all other equipment, peak tube potential in kilovolts (kV), and either tube current in milliamperes (mA) and exposure time in seconds, or the product of tube current and exposure time in milliampere-seconds (mAs).

"Telemetric position monitoring system" means a data transfer system that captures information by either instrumentation or measuring devices, or both, about the location and status of a transport vehicle or package between the departure and destination locations.

"Teletherapy physicist" means an individual identified as a qualified teletherapy physicist on an agency license.

"Teletherapy" means therapeutic irradiation in which the source of radiation is at a distance from the body.

"Temporary job site" means any location where industrial radiography, wireline service, well-logging, portable gauge or x-ray fluorescence use is performed and where licensed material may be stored other than those locations of use authorized on the license.

"Tenth-value layer" or "TVL" means the thickness of a specified material that attenuates x-radiation or gamma radiation to an extent such that the air kerma rate, exposure rate, or absorbed dose rate is reduced to one-tenth of the value measured without the material at the same point.

"Test" means the process of verifying compliance with an applicable regulation.

"Therapeutic radiation machine" means x-ray or electron-producing equipment designed and used for external beam radiation therapy. For the purpose of this chapter, devices used to administer electronic brachytherapy shall also be considered therapeutic radiation machines.

"These regulations" mean all parts of this chapter.

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

"Tomogram" means the depiction of the x-ray attenuation properties of a section through the body.

"Tomographic plane" means that geometric plane that is identified as corresponding to the output tomogram.

"Tomographic section" means the volume of an object whose x-ray attenuation properties are imaged in a tomogram.

"Total effective dose equivalent" or "TEDE" means the sum of the effective dose equivalent for external exposures and the committed effective dose equivalent for internal exposures.

"Total organ dose equivalent" or "TODE" means the sum of the deep dose equivalent and the committed dose equivalent to the organ receiving the highest dose as described in 12VAC5-481-1040.

"Traceable to a National Standard" (See "Instrument traceability" or "Source traceability").

"Transfer" means, as used in Part XVI (12VAC5-481-3460 et seq.) of this chapter, the physical relocation of NORM containing materials not directly associated with commercial distribution within a business's operation or between general or specific licensees. This term does not include a change in legal title to NORM containing materials that does not involve physical movement of those materials.

"Transport container" means a package that is designed to provide radiation safety and security when sealed sources are transported and that meets all applicable requirements of the U.S. Department of Transportation.

"Transport index" or "TI" means the dimensionless number, rounded up to the next tenth, placed on the label of a package to designate the degree of control to be exercised by the carrier during transportation. The transport index is the number determined by multiplying the maximum radiation level in millisievert (mSv) per hour at one meter (3.3 feet) from the external surface of the package by 100 (equivalent to the maximum radiation level in millirem per hour at one meter (3.3 feet)).

"Treatment site" means the correct anatomical description of the area intended to receive a radiation dose, as described in a written directive.

"Tribal official" means the highest ranking individual that represents tribal leadership, such as the chief, president, or tribal council leadership.

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

"Trustworthiness and reliability" means characteristics of an individual considered dependable in judgment, character, and performance, such that unescorted access to Category 1 or Category 2 quantities of radioactive material by that individual does not constitute an unreasonable risk to the public health and safety or security. A determination of trustworthiness and reliability for this purpose is based upon the results from a background investigation.

"Tube" means an x-ray tube, unless otherwise specified.

"Tube housing assembly" means the tube housing with tube installed. It includes high-voltage or filament transformers and other appropriate elements when such are contained within the tube housing.

"Tube rating chart" means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

"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 Table 1 of 12VAC5-481-3770 F or may be determined by procedures described in 12VAC5-481-3770 A through E.

"Type B quantity" means a quantity of radioactive material greater than a Type A quantity.

"Underwater irradiator" means an irradiator in which the sources always remain shielded under water and humans do not have access to the sealed sources or the space subject to irradiation without entering the pool.

"Underwater radiography" means radiographic operations performed when the radiographic exposure device or radiation machine or related equipment are beneath the surface of the water.

"Unescorted access" means solitary access to an aggregated Category 1 or Category 2 quantity of radioactive material or the devices that contain the material.

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

"Unirradiated uranium" means uranium containing not more than  $2 \times 10^3$  Bq of plutonium per gram of uranium-235, not more than  $9 \times 10^6$  Bq of fission products per gram of uranium-235, and not more than  $5 \times 10^{-3}$  g of uranium-236 per gram of uranium-235.

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

"Unrestricted area" means an area, access to which is neither limited nor controlled by the licensee or registrant. For purposes of these regulations, "uncontrolled area" is an equivalent term.

"Uranium - natural, depleted, enriched"

1. "Natural uranium" means uranium (which may be chemically separated) with the naturally occurring distribution of uranium isotopes, which is approximately 0.711 weight percent uranium-235, and the remainder by weight essentially uranium-238.

2. "Depleted uranium" means uranium containing less uranium-235 than the naturally occurring distribution of uranium isotopes.

3. "Enriched uranium" means uranium containing more uranium-235 than the naturally occurring distribution of uranium isotopes.

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

"Useful beam" means the radiation that passes through the tube housing port and the aperture of the beam-limiting device when the exposure switch or timer is activated.

"User seal check" or "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.

"Variable-aperture beam-limiting device" means a beam-limiting device which has capacity for stepless adjustment of the x-ray field size at a given SID.

"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 five Gy (500 rad) in one hour at one meter from a source of radiation or one meter from any surface that the radiation penetrates.

"Virtual simulator" means a computed tomography (CT) unit used in conjunction with relevant software that recreates the treatment machine and that allows import, manipulation, display, and storage of images from CT or other imaging modalities, or both.

"Virtual source" means a point from which radiation appears to originate.

"Visible area" means that portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image.

"Visiting authorized user" means an authorized user who is not identified on the license of the licensee being visited.

"Waste" means those low-level radioactive wastes containing source, special nuclear, or byproduct material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level radioactive waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in subdivisions 2, 3, and 4 of the definition of byproduct material.

"Waste collector" means an entity, operating under a specific license, 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.

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

"Waste generator" means an entity, operating under a license, that (i) possesses any material or component that contains radioactivity or is radioactively contaminated for which the licensee foresees no further use, and (ii) 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."

"Waste handling licensees" mean persons licensed to receive and store radioactive wastes prior to disposal or persons licensed to dispose of radioactive waste.

"Waste processor" means an entity, operating under a specific license, 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.

"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 sorbed on or solidified in a specifically defined media).

"Wedge filter" means a filter that effects continuous change in transmission over all or a part of the useful beam.

"Week" means seven consecutive days starting on Sunday.

"Weighting factor" or " $w_T$ " for an organ or tissue (T) means 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	0.30 <sup>a/</sup>
Whole Body	1.00 <sup>b/</sup>
<sup>a/</sup> 0.30 results from 0.06 for each of five "remainder" organs, excluding the skin and the lens of the eye, that receive the highest doses.	
<sup>b/</sup> 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.	

"Well-bore" means a drilled hole in which wireline service operations or subsurface tracer studies are performed.

"Well-logging" means all operations involving the lowering and raising of measuring devices or tools that may contain sources of radiation into well-bores or cavities for the purpose of obtaining information about the well or adjacent formations.

"Whole body" means, for purposes of external exposure, head, trunk including male gonads, arms above the elbow, or legs above the knee.

"Wireline" means a cable containing one or more electrical conductors that is used to lower and raise logging tools in the well-bore.

"Wireline service operation" means any evaluation or mechanical service that is performed in the well-bore using devices on a wireline.

"Worker" means an individual engaged in work under a license or registration issued by the agency and controlled by a licensee or registrant but does not include the licensee or registrant.

"Working level" or "WL" means any combination of short-lived radon daughters in one liter of air that will result in the ultimate emission of  $1.3E+5$  MeV of potential alpha particle energy. The short-lived radon daughters of radon-222 are polonium-218, lead-214, bismuth-214, and polonium-214; and those of radon-220 are polonium-216, lead-212, bismuth-212, and polonium-212.

"Working level month" or "WLM" means an exposure to one working level for 170 hours. Two thousand working hours per year divided by 12 months per year is approximately equal to 170 hours per month.

"Written directive" means an authorized user's written order for the administration of radioactive material, radiation from radioactive material, or radiation from a radiation producing machine to a specific patient or human research subject.

"X-ray control" means a device that controls input power to the x-ray high-voltage generator or the x-ray tube. It includes equipment such as timers, phototimers, automatic brightness stabilizers, and similar devices, which control the technique factors of an x-ray exposure.

"X-ray exposure control" means a device, switch, button or other similar means by which an operator initiates or terminates the radiation exposure. The x-ray exposure control may include such associated equipment as timers and back-up timers.

"X-ray equipment" means an x-ray system, subsystem, or component thereof. Types of x-ray equipment are as follows:

1. "Mobile x-ray equipment" means x-ray equipment mounted on a permanent base with wheels or casters for moving while completely assembled.
2. "Portable x-ray equipment" means x-ray equipment designed to be hand-carried.
3. "Stationary x-ray equipment" means x-ray equipment that is installed in a fixed location.

"X-ray field" means that area of the intersection of the useful beam and any one of the sets of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the AKR is one-fourth of the maximum in the intersection.

"X-ray high-voltage generator" means a device that transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tubes, high-voltage switches, electrical protective devices, and other appropriate elements.

"X-ray system" means an assemblage of components for the controlled production of x-rays. It includes minimally an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components that function with the system are considered integral parts of the system.

"X-ray table" means a patient support device with its patient support structure (tabletop) interposed between the patient and the image receptor during radiography or fluoroscopy. This includes, but is not limited to, any stretcher equipped with a radiolucent panel and any table equipped with a cassette tray (or bucky), cassette tunnel, fluoroscopic image receptor, or spot-film device beneath the tabletop.

"X-ray tube" means any electron tube that is designed for the conversion of electrical energy into x-ray energy.

"Year" means the period of time beginning in January used to determine compliance with the provisions of this chapter. The licensee or registrant may change the starting date of the year used to determine compliance by the licensee or registrant provided that the change is made at the beginning of the year. If a licensee or registrant changes in a year, the licensee or registrant shall assure that no day is omitted or duplicated in consecutive years.

#### **12VAC5-481-440. Filing application for specific licenses.**

- A. Applications for specific licenses shall be filed on a form prescribed by the agency.
- B. The agency may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the agency to determine whether the application should be granted or denied or whether a license should be modified or revoked.
- C. Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on his behalf.
- D. An application for a license may include a request for a license authorizing one or more activities.
- E. Applications and documents submitted to the agency may be made available for public inspection in accordance with the Virginia Freedom of Information Act (§ 2.2-3700 et seq. of the Code of Virginia). The agency may withhold records in accordance with specific exemptions in the Virginia Freedom of Information Act or as otherwise specified by law.
- F. An application for a specific license to use radioactive material in the form of a sealed source or in a device that contains the sealed source shall either:
  1. Identify the source or device by manufacturer and model number as registered with the NRC under 10 CFR 32.210 or an Agreement state under equivalent regulations;
  2. Contain the information in 10 CFR 32.210(c);
  3. For sources or devices containing radioactive material manufactured prior to October 23, 2012, that are not registered with the NRC under 10 CFR 32.210 or with an Agreement state, and for which the applicant is unable to provide all categories of information specified in 10 CFR 32.210(c),

the applicant shall provide:

- a. All available information identified in 10 CFR 32.210(c) concerning the source, and, if applicable, the device; and
- b. Sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Such information shall include a description of the source or device, a description of radiation safety features, the intended use and associated operating experience, and the results of a recent leak test;
4. For sealed sources and devices allowed to be distributed without registration of safety information in accordance with 10 CFR 32.210(g)(1), the applicant may supply only the manufacturer, model number, and radionuclide and quantity; or
5. If it is not feasible to identify each sealed source and device individually, the applicant may propose constraints on the number and type of sealed sources and devices to be used and the conditions under which they will be used in lieu of identifying each sealed source and device.
- G. Each application to possess radioactive material in unsealed form, on a foil or plated source, or sealed in glass in excess of the quantities in 12VAC5-481-3740 shall contain one of the following:
  1. An evaluation showing that the projected dose to a person offsite due to a release of radioactive material would not exceed 0.01 Sv (1 rem) total effective dose equivalent or 0.05 Sv (5 rem) to the thyroid; or
  2. An emergency plan, reviewed and commented on by offsite response organizations expected to respond in the event of an accident that contains the following information:
    - a. Facility description. A brief description of the licensee or applicant's facility and surroundings.
    - b. Types of accidents. An identification of each type of radioactive materials accident for which actions by licensee staff or offsite response organizations will be needed to protect members of the public.
    - c. Classification of accidents. A method for classifying and declaring an accident as alert or site area emergency.
    - d. Detection of accidents. Identification of the means for detecting each type of alert or site area emergency in a timely manner.
    - e. Mitigation of consequences. A brief description of the means and equipment that are available for mitigating the consequences of each type of accident, including those provided to protect workers onsite, and a description of the program for maintaining the equipment.
    - f. Assessment of releases. A brief description of the methods and equipment available to assess releases of radioactive material.
    - g. Responsibilities. A brief description of the responsibilities of the licensee or applicant's personnel who will respond if an accident occurs, including identification of personnel responsible for promptly notifying offsite response organizations, including the agency.
    - h. Plan maintenance. A brief description of the positions assigned and methods to develop, maintain and update the plan.
    - i. A list of offsite response organizations, description of their responsibilities and anticipated actions, and copy of formal commitments, if any.
    - j. Notification and coordination. A brief description of the means to promptly notify the offsite response organizations and request offsite assistance including medical assistance for the treatment of contaminated injured onsite workers. The notification and coordination shall include alternate provisions in case key personnel, parts of the facility, or some equipment are unavailable. The licensee shall also commit to notify the agency immediately after notification of the appropriate offsite response organizations and not later than one hour after the licensee declares an emergency.
    - k. Information to be communicated. A brief description of the types of information on facility status, radioactive releases and recommended protective actions, if necessary, to be given to offsite response organizations and the agency. A licensee shall allow the offsite response organizations expected to respond in case of an accident 60 days to comment on the licensee's emergency plan before submitting it to the agency. A licensee shall provide any comments received within the 60 days to the agency with the emergency plan.
    - l. Training. A brief description of the frequency, performance objectives and plan for training that the licensee or applicant will provide workers on how to respond to an emergency, including any special instructions and orientation tours that the licensee or applicant will offer to fire, police, medical and other emergency personnel. The training shall familiarize personnel with site-specific hazards and emergency procedures. The training shall also prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site, including the use of drills, exercises and team training for such scenarios.
    - m. Drills and exercises. Provisions for conducting quarterly communications checks with offsite response organizations and biennial onsite exercises to test response to simulated emergencies. The licensee or applicant shall invite offsite response organizations to participate in biennial exercises. The exercises shall use accident scenarios postulated as the most probable for the specific site and the scenarios may not be known to

most exercise participants. Critiques of exercises shall evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel and overall effectiveness of the response. Deficiencies found by the critiques shall be corrected.

n. Safe condition. A brief description of the means of restoring the facility and surroundings to a safe condition after an accident.

o. Hazardous chemicals. A certification that the applicant has met its responsibilities under the Emergency Planning and Community Right-To-Know Act of 1986, Title III, P.L. 99-499, if applicable to the applicant's activities at the proposed place of use of the radioactive material.

H. An application from a medical facility or educational institution to produce PET radioactive drugs for noncommercial transfer to licensees in its consortium authorized for medical use under Part VII (12VAC5-481-1660 et seq.) of this chapter shall include:

1. A request for authorization for the production of PET radionuclides or evidence of an existing license issued under Part III (12VAC5-481-380 et seq.) of this chapter for a PET radionuclide production facility within its consortium from which it receives PET radionuclides.

2. Evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in 12VAC5-481-480 I.

3. Identification of individual(s) authorized to prepare the PET radioactive drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an ANP as specified in 12VAC5-481-480 I 2.

4. Information identified in 12VAC5-481-480 I 1 c on the PET drugs to be noncommercially transferred to members of its consortium.

I. Manufacture, preparation, or transfer for commercial distribution of drugs containing radioactive material for medical use under Part VII (12VAC5-481-1660 et seq.).

1. An application for a specific license to manufacture, prepare, or transfer for commercial distribution drugs containing radioactive material for use by persons authorized pursuant to Part VII (12VAC5-481-1660 et seq.) will be approved if:

a. The applicant satisfies the general requirements specified in 12VAC5-481-450;

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

(1) Registered or licensed with the U.S. Food and Drug Administration (FDA) as a drug manufacturer;

(2) Registered or licensed with a state agency as a drug manufacturer;

(3) Licensed as a pharmacy by the Virginia Board of Pharmacy;

(4) Operating as a nuclear pharmacy within a federal medical institution; or

(5) A PET drug production facility registered with a state agency.

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

d. The applicant satisfies the following labeling requirements:

(1) A label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The label shall include the radiation symbol as described in 12VAC5-481-850 and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL"; the name of the radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half-life greater than 100 days, the time may be omitted.

(2) A label is affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label shall include the radiation symbol as described in 12VAC5-481-850 and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL" and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

2. A licensee authorized to manufacture, prepare or transfer for commercial distribution radioactive drugs shall ensure that any individual preparing the drugs is one of the following:

a. An authorized nuclear pharmacist (ANP) as defined in 12VAC5-481-10;

b. An individual that meets the requirements specified in 12VAC5-481-1770 and 12VAC5-481-1790, and the licensee has received an approved license amendment identifying this individual as an ANP;

c. A pharmacist, as defined in 12VAC5-481-10, designated as an ANP if:

- (1) The individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material; and
- (2) The individual practiced at a pharmacy at a government agency or federally recognized Indian Tribe before November 30, 2007, or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the NRC; or
- d. An individual under the supervision of an ANP as specified in 12VAC5-481-1710.
3. Shall provide to the agency no later than 30 days after the date that the licensee allows, under subdivision 2 a or c of this subsection, the individual to work as an ANP:
- a. The individual's certification by a specialty board whose certification process has been recognized by the NRC with the written attestation signed by a preceptor as required by 12VAC5-481-1770;
- b. An NRC or another Agreement state license;
- c. NRC master materials licensee permit;
- d. The permit issued by a licensee or NRC master materials permittee of broad scope or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist; or
- e. Documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a government agency or federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC; and
- f. The Virginia Board of Pharmacy's license.
4. A licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha, beta, or photon-emitting radioactive drugs prior to transfer for commercial distribution. In addition, the licensee shall:
- a. Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and
- b. Check each instrument for constancy and proper operation at the beginning of each day of use.
5. Nothing in this subsection relieves the licensee from complying with applicable FDA, other federal, and state requirements governing radioactive drugs.
6. Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination in accordance with 12VAC5-481-1930. The licensee shall record the results of each test and retain each record for three years after the record is made. The licensee shall report the results of any test that exceeds the permissible concentration listed in 12VAC5-481-1930 A at the time of the generator elution in accordance with 12VAC5-481-2080 D.

**12VAC5-481-451. Physical protection of Category 1 and Category 2 quantities of radioactive material.**

A. Any licensee who possesses or uses an aggregated quantity of Category 1 or Category 2 radioactive material equal to or in excess of those in subdivision 1 of this subsection shall establish a physical protection program that meets all requirements detailed in this section.

1. Radionuclides of concern.

Radionuclide	Category 1 (TBq) <sup>1,2</sup>	Category 1 (Ci) <sup>1,2</sup>	Category 2 (TBq) <sup>1,2</sup>	Category 2 (Ci) <sup>1,2</sup>
Am-241	60	1,620	0.6	16.2
Am-241/Be	60	1,620	0.6	16.2
Cf-252	20	540	0.2	5.4
Cm-244	50	1,350	0.5	13.5
Co-60	30	810	0.3	8.1
Cs-137	100	2,700	1	27
Gd-153	1,000	27,000	10	270



Ir-192	80	2,160	0.8	21.6
Pm-147	40,000	1,080,000	400	10,800
Pu-238	60	1,620	0.6	16.2
Pu-239/Be	60	1,620	0.6	16.2
Ra-226	40	1,080	0.4	10.8
Se-75	200	5,400	2	54
Sr-90 (Y-90)	1,000	27,000	10	270
Tm-170	20,000	540,000	200	5,400
Yb-169	300	8,100	3	81
Combinations of radioactive materials listed above <sup>3</sup>			See footnote 4 below	

<sup>1</sup>The aggregate activity of multiple, collocated sources of the same radionuclides should be included when the total activity equals or exceeds the Category 1 or Category 2 threshold.

<sup>2</sup>The primary values used for compliance are TBq. The curie (Ci) values are rounded to two significant figures for informational purposes only.

<sup>3</sup>Radioactive materials are to be considered aggregated or collocated if breaching a common physical barrier (e.g., a locked door at the entrance to a storage room) would allow access to the radioactive material or devices containing the radioactive material.

<sup>4</sup>If several radionuclides are aggregated, the sum of the ratios of the activity of each source,  $i$  of radionuclide,  $n$ ,  $A$  ( $i,n$ ), to the Category 1 or Category 2 threshold for radionuclide  $n$ ,  $Q_n$ , listed for that radionuclide equals or exceeds one.  $[(\text{aggregated source activity for radionuclide A}) / (\text{quantities of concern for radionuclide A})] + [(\text{aggregated source activity for radionuclide B}) / (\text{quantities of concern for radionuclide B})] + \text{etc....} \geq 1$ .

2. A licensee that possesses radioactive waste that contains Category 1 or Category 2 quantities of radioactive material is exempt from the requirements of this section.

3. A licensee that possesses radioactive waste that contains discrete sources, ion-exchange resins, or activated material that weighs less than 2,000 kg (4,409 lbs) is not exempt from the requirements of this section. The licensee shall implement the following requirements to secure the radioactive waste:

- a. Use continuous physical barriers that allow access to the radioactive waste only through established access control points;
- b. Use a locked door or gate with monitored alarm at the access control point;
- c. Assess and respond to each actual or attempted unauthorized access to determine whether an actual or attempted theft, sabotage, or diversion occurred; and
- d. Immediately notify the local law-enforcement agency (LLEA) and request an armed response from the LLEA upon determination that there was an actual or attempted theft, sabotage, or diversion of the radioactive waste.

**B. Background investigations and access authorization program.**

1. Personnel access authorization requirements for Category 1 or Category 2 quantities of radioactive material.

- a. Each licensee that possesses an aggregated quantity of radioactive material that equals or exceeds the Category 2 threshold shall establish, implement, and maintain its access authorization program in accordance with the requirements in this subsection. An applicant for a new license and each licensee that would become newly subject to the requirements in this subsection upon an amendment request of its license shall implement the requirements of this subsection, as appropriate, before taking possession of an aggregated quantity of radioactive material that equals or exceeds the Category 2 threshold. Any licensee that has not previously implemented the increased control requirements of this section

shall implement the provisions of this subsection before aggregating radioactive material to a quantity that equals or exceeds the Category 2 threshold.

b. The licensee's access authorization program shall ensure that the individuals specified in subdivision 1 c of this subsection are trustworthy and reliable.

c. Licensees shall subject the following individuals to an access authorization program:

(1) Any individual whose assigned duties require unescorted access to Category 1 or Category 2 quantities of radioactive material; and

(2) Reviewing officials.

d. Licensees shall approve for unescorted access to Category 1 or Category 2 quantities of radioactive material only those individuals whose assigned job duties require unescorted access to Category 1 or Category 2 quantities of radioactive material.

e. Licensees need not subject the categories of individuals listed in subdivision 5 a of this subsection to the investigation elements of the access authorization program.

2. Access authorization program requirements.

a. Granting unescorted access authorization.

(1) Licensees shall implement the requirements of this subsection for granting initial or reinstated unescorted access authorization.

(2) Individuals who have been determined to be trustworthy and reliable shall also complete the security training required by subdivision C 2 c of this section before being allowed unescorted access to Category 1 or Category 2 quantities of radioactive material.

b. Reviewing officials.

(1) Reviewing officials are the only individuals who may make trustworthiness and reliability determinations that allow individuals to have unescorted access to Category 1 or Category 2 quantities of radioactive materials possessed by the licensee.

(2) Each licensee shall name one or more individuals to be reviewing officials. After completing the background investigation on the reviewing official, the licensee shall provide under oath or affirmation a certification that the reviewing official is deemed trustworthy and reliable by the licensee. Provide oath or affirmation certifications to the agency via an appropriate means listed in 12VAC5-481-150. The fingerprints of the named reviewing official shall be taken by a law-enforcement agency, a federal or state agency that provides fingerprinting services to the public, or a commercial fingerprinting service authorized by a state to take fingerprints. The licensee shall recertify that the reviewing official is deemed trustworthy and reliable every 10 years in accordance with subdivision 3 c of this subsection.

(3) Reviewing officials shall be permitted to have unescorted access to Category 1 or Category 2 quantities of radioactive material.

(4) Reviewing officials cannot approve other individuals to act as reviewing officials.

(5) A reviewing official does not need to undergo a new background investigation before being named by the licensee as the reviewing official if:

(a) The individual has undergone a background investigation that included fingerprinting and an FBI criminal history records check and has been determined to be trustworthy and reliable by the licensee; or

(b) The individual is subject to a category listed in subdivision 5 a of this subsection.

c. Informed consent.

(1) Licensees may not initiate a background investigation without the informed and signed consent of the subject individual. This consent shall include authorization to share personal information with other individuals or organizations as necessary to complete the background investigation. Before a final adverse determination, the licensee shall provide the individual with an opportunity to correct any inaccurate or incomplete information that is developed during the background investigation. Licensees do not need to obtain signed consent from those individuals who meet the requirements of subdivision 3 b of this subsection. A signed consent shall be obtained prior to any reinvestigation.

(2) The subject individual may withdraw his consent at any time. Licensees shall inform the individual that:

(a) If an individual withdraws his consent, the licensee may not initiate elements of the background investigation that were not in progress at the time the individual withdrew his consent; and

(b) The withdrawal of consent for the background investigation is sufficient cause of denial or termination of unescorted access authorization.

d. Any individual who is applying for unescorted access authorization shall disclose the personal history information that is required by the licensee's access authorization program for the reviewing official to make a determination of the individual's trustworthiness and reliability. Refusal to provide, or the falsification of, any personal history information required by this subsection is sufficient cause for denial or termination of unescorted access.

e. Determination basis.

(1) The reviewing official shall determine whether to permit, deny, unfavorably terminate, maintain, or administratively withdraw an individual's unescorted access authorization based on an evaluation of all the information collected to meet the requirements of this subsection.

(2) The reviewing official may not permit any individual to have unescorted access until the reviewing official has evaluated all the information collected to meet the requirements of this subsection and determined that the individual is trustworthy and reliable. The reviewing official may deny unescorted access to any individual based on information obtained at any time during the background investigation.

(3) The licensee shall document the basis for concluding whether or not there is reasonable assurance that an individual is trustworthy and reliable.

(4) The reviewing official may terminate or administratively withdraw an individual's unescorted access authorization based on information obtained after the background investigation has been completed and the individual granted unescorted access information.

(5) Licensees shall maintain a list of persons currently approved for unescorted access authorization. When a licensee determines that a person no longer requires unescorted access or meets the access authorization requirement, the licensee shall remove the person from the approved list as soon as possible, but no later than seven working days, and take prompt measures to ensure that the individual is unable to have unescorted access to the material.

f. Licensees shall develop, implement, and maintain written procedures for implementing the access authorization program. The procedures shall include the provisions for the notification of individuals who are denied unescorted access. The procedures shall include provisions for the review, at the request of the affected individual, of a denial or termination of unescorted access authorization. The procedures shall contain a provision to ensure that the individual is informed of the grounds for the denial or termination of unescorted access authorization and allow the individual an opportunity to provide additional relevant information.

g. Right to correct and complete information.

(1) Prior to any final adverse determination, licensees shall provide each individual subject to this subsection with the right to complete, correct, and explain information obtained as a result of the licensee's background investigation. Confirmation of receipt by the individual of this notification shall be maintained by the licensee for a period of one year from the date of the notification.

(2) If, after reviewing his criminal history record, an individual believes that it is incorrect or incomplete in any respect and wishes to change, correct, update, or explain anything in the record, the individual may initiate challenge procedures. These procedures include direct application by the individual challenging the record to the law-enforcement agency that contributed the questioned information or a direct challenge as to the accuracy or completeness of any entry on the criminal history record to the Federal Bureau of Investigation, Criminal Justice Information Services (CJIS) Division, ATTN: SCU, Mod. D-2, 1000 Custer Hollow Road, Clarksburg, WV 26306 as set forth in 28 CFR 16.30 through 28 CFR 16.34. In the latter case, the Federal Bureau of Investigation (FBI) will forward the challenge to the agency that submitted the data and will request that the agency verify or correct the challenged entry. Upon receipt of an official communication directly from the agency that contributed the original information, the FBI Identification Division will make any change necessary in accordance with the information supplied by that agency. Licensees shall provide at least 10 days for an individual to initiate action to challenge the results of an FBI criminal history records check after the record being made available for his review. The licensee may make a final adverse determination based upon the criminal history records only after receipt of the FBI's confirmation or correction of the record.

h. Records.

(1) The licensee shall retain documentation regarding the trustworthiness and reliability of individual employees for three years from the date the individual no longer requires unescorted access to Category 1 or Category 2 quantities of radioactive material.

(2) The licensee shall retain a copy of the current access authorization program procedures as a record for three years after the procedure is no longer needed. If any portion of the procedure is superseded, the licensee shall retain the superseded material for three years after the record is superseded.

(3) The licensee shall retain the list of individuals approved for unescorted access authorization for three years after the list is superseded or replaced.

3. Background investigations.

a. Before allowing an individual unescorted access to Category 1 or Category 2 quantities of radioactive material or to the devices containing the material, licensees shall complete a background investigation of the individual seeking unescorted access authorization. The scope of the investigation shall encompass at least the seven years preceding the date of the background investigation or since the individual's 18th birthday, whichever is shorter. The background investigation shall include at a minimum:

- (1) Fingerprinting and an FBI identification and criminal history records check in accordance with subdivision 4 of this subsection;
- (2) Verification of true identity of the individual who is applying for unescorted access authorization. A licensee shall review official identification documents (e.g., driver's license; passport; government identification; certificate of birth issued by the state, province, or country of birth) and compare the documents to personal information data provided by the individual to identify any discrepancy in the information. Licensees shall document the type, expiration, and identification number of the identification document or maintain a photocopy of identifying documents on file in accordance with subdivision 6 of this subsection. Licensees shall certify in writing that the identification was properly reviewed and shall maintain the certification and all related documents for review upon inspection;
- (3) Verification of employment history, including military history. Licensees shall verify the individual's employment with each previous employer for the most recent seven years before the date of application;
- (4) Verification that the individual participated in the education process during the claimed period;
- (5) Completion of reference checks to determine the character and reputation of the individual who has applied for unescorted access authorization. Unless other references are not available, reference checks may not be conducted with any person who is known to be a close member of the individual's family, including but not limited to, the individual's spouse, parents, siblings, or children, or any individual who resides in the individual's permanent household. Reference checks under this subsection shall be limited to whether the individual has been and continues to be trustworthy and reliable;
- (6) To the extent possible, obtain independent information to corroborate the information provided by the individual (e.g., seek references not supplied by the individual); and
- (7) If a previous employer, educational institution, or any other entity with which the individual claims to have been engaged fails to provide the information or indicates an inability or unwillingness to provide information within a timeframe deemed appropriate by the licensee but at least after 10 business days of the request or if the licensee is unable to reach the entity, the licensee shall document the refusal, unwillingness, or inability in the record of investigation and attempt to obtain the information from an alternate source.

b. Individuals who have been determined to be trustworthy and reliable for unescorted access to Category 1 or Category 2 quantities of radioactive material in accordance with ~~12VAC5-481-451, "Increased controls and fingerprinting,"~~ fingerprint orders as effective on October 3, 2008, can continue to have unescorted access to Category 1 and Category 2 quantities of radioactive material without further investigation. These individuals shall be subject to the reinvestigation requirement of subdivision 3 c of this subsection.

c. Licensees shall conduct a reinvestigation every 10 years for any individual with unescorted access to Category 1 or Category 2 quantities of radioactive material. The reinvestigation shall consist of fingerprinting and an FBI identification and criminal history records check in accordance with subdivision 4 of this subsection. The reinvestigations shall be completed within 10 years of the date on which these elements were last completed.

4. Requirements for criminal history records checks of individuals granted unescorted access to Category 1 or Category 2 quantities of radioactive material.

a. General performance objective and requirements.

(1) Except for those individuals listed in subdivision 5 a of this subsection and those individuals grandfathered under subdivision 3 b of this subsection, each licensee subject to the provisions of this section shall fingerprint each individual who is to be permitted unescorted access to Category 1 or Category 2 quantities of radioactive material. The licensee shall submit all collected fingerprints to the NRC for transmission to the FBI. The licensee shall use the information received from the FBI as part of the required background investigation to determine whether to grant or deny further unescorted access to Category 1 or Category 2 quantities of radioactive materials for that individual.

(2) The licensee shall notify each affected individual that his fingerprints will be used to secure a review of his criminal history record and shall inform him of the procedures for revising the record or adding explanations to the record.

(3) Fingerprinting is not required if a licensee is reinstating an individual's unescorted access authorization to Category 1 or Category 2 quantities of radioactive material if:

(a) The individual returns to the same facility that granted unescorted access authorization within 365 days of the termination of his unescorted access authorization; and

(b) The previous access was terminated under favorable conditions.

(4) Fingerprints do not need to be taken if an individual who is an employee of a licensee, contractor, manufacturer, or supplier has been granted unescorted access to Category 1 or Category 2 quantities of radioactive material, access to safeguards information, or safeguards information-modified handling by another licensee based upon a background investigation conducted under this subsection, regulations or Fingerprint Orders from another Agreement state, or 10 CFR Part 73. An existing criminal history records check file may be transferred to the licensee asked to grant unescorted access in accordance with the provisions of subdivision 6 c of this subsection.

(5) Licensees shall use the information obtained as part of a criminal history records check solely for the purpose of determining an individual's suitability for unescorted access authorization to Category 1 or Category 2 quantities of radioactive materials, access to safeguards information, or safeguards information-modified handling.

b. Prohibitions.

(1) Licensees may not base a final determination to deny an individual unescorted access authorization to Category 1 or Category 2 quantities of radioactive material solely on the basis of information received from the FBI involving:

(a) An arrest more than one year old for which there is no information of the disposition of the case; or

(b) An arrest that resulted in dismissal of the charge or an acquittal.

(2) Licensees may not use information received from a criminal history records check obtained under this subsection in a manner that would infringe upon the rights of any individual under the First Amendment to the Constitution of the United States, nor shall licensees use the information in any way that would discriminate among individuals on the basis of race, religion, national origin, gender, or age.

c. Procedures for processing of fingerprint checks.

(1) For the purpose of complying with this subsection, licensees shall use an appropriate method listed in 10 CFR 37.7 to submit to the U.S. Nuclear Regulatory Commission, Director, Division of ~~Facilities and Security~~ Physical and Cyber Security Policy, 11545 Rockville Pike, ATTN: Criminal History Program/Mail Stop ~~TWB-05-B32M T-8B20~~, Rockville, MD, 20852, one completed, legible standard fingerprint card (form FD-258, ORIMDNRCOOOZ), electronic fingerprint scan, or, where practicable, other fingerprint record for each individual requiring unescorted access to Category 1 or Category 2 quantities of radioactive material. Copies of these forms may be obtained by ~~writing the Office of Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, by calling (630) 829-9565, or by email to forms.resource@nrc.gov~~ emailing [MAILSVS.Resource@nrc.gov](mailto:MAILSVS.Resource@nrc.gov). Guidance on submitting electronic fingerprints can be found at ~~<http://www.nrc.gov/site-help/e-submittals.html>~~ <https://www.nrc.gov/security/chp.html>.

(2) Fees for processing of fingerprint cards are due upon application. Licensees shall submit payment with the application for the processing of fingerprints through corporate check, certified check, cashier's check, money order, or electronic payment, made payable to the "U.S. NRC." (For guidance on making electronic payments, contact the ~~Security Branch, Division of Facilities and Security at (301) 492-3531~~ Division of Physical and Cyber Security Policy by emailing [crimhist.resource@nrc.gov](mailto:crimhist.resource@nrc.gov).) Combined payment for multiple applications is acceptable. The NRC publishes the amount of the fingerprint check application fee on the NRC public website. To find the current fee amount, go to the ~~Electronic Submittals~~ Licensee Criminal History Records Checks & Firearms Background Check information page at ~~<http://www.nrc.gov/site-help/e-submittals.html>~~ <https://www.nrc.gov/security/chp.html> and see the link for ~~the Criminal History Program under Electronic Submission Systems~~ How do I determine how much to pay for the request?.

(3) The NRC will forward to the submitting licensee all data received from the FBI as a result of the licensee's application for a criminal history records check.

5. Relief.

a. Fingerprinting, identification and criminal history records checks, and other elements of the background investigation required by this subsection are not required for the following individuals prior to granting unescorted access to Category 1 or Category 2 quantities of radioactive material:

(1) An employee of the NRC or of the executive branch of the U.S. government who has undergone fingerprinting for a prior U.S. government criminal history records check;

(2) A member of Congress;

(3) An employee of a member of Congress or congressional committee who has undergone fingerprinting for a prior U.S. government criminal history records check;

(4) The governor of a state or his designated state employee representative;

(5) Federal, state, or local law-enforcement personnel;

- (6) State radiation control program directors and state homeland security advisors or their designated employee representatives;
  - (7) State radiation program employees conducting security inspections on behalf of the NRC under an agreement executed under § 274i of the Atomic Energy Act (42 USC § 2021i);
  - (8) Representatives of the International Atomic Energy Agency (IAEA) engaged in activities associated with the U.S./IAEA Safeguards Agreement who have been certified by the NRC;
  - (9) Emergency response personnel who are responding to an emergency;
  - (10) Commercial vehicle drivers for road shipments of Category 1 and Category 2 quantities of radioactive material;
  - (11) Package handlers at transportation facilities such as freight terminals and railroad yards;
  - (12) Any individual who has an active federal security clearance and provides the appropriate documentation. Written confirmation from the agency or employer that granted the federal security clearance or reviewed the criminal history records check shall be provided to the licensee. The licensee shall retain this documentation for a period of three years from the date the individual no longer requires unescorted access to Category 1 or Category 2 quantities of radioactive material; and
  - (13) Any individual employed by a service provider licensee for whom the service provider licensee has conducted the background investigation for the individual and approved the individual for unescorted access to Category 1 or Category 2 quantities of radioactive material. Written verification from the service provider shall be provided to the licensee. The licensee shall retain the documentation for a period of three years from the date the individual no longer requires unescorted access to Category 1 or Category 2 quantities of radioactive material.
- b. Fingerprinting and identification and criminal history records checks required by this subsection are not required for an individual who has had a favorably adjudicated U.S. Government criminal history records check within the last five years, under a comparable U.S. Government program involving fingerprinting and an FBI identification and criminal history records check, and the individual provides the appropriate documentation. Written confirmation from the agency or employer that reviewed the criminal history records check shall be provided to the licensee. The licensee shall retain this documentation for a period of three years from the date the individual no longer requires unescorted access to Category 1 or Category 2 quantities of radioactive material. These programs include, but are not limited to:
- (1) National Agency Check;
  - (2) Transportation Worker Identification Credentials (TWIC) under 49 CFR Part 1572;
  - (3) Bureau of Alcohol, Tobacco, Firearms, and Explosives background check and clearances under 27 CFR Part 555;
  - (4) Health and Human Services security risk assessments for possession and use of select agents and toxins under 42 CFR Part 73;
  - (5) Hazardous material security threat assessment for hazardous material endorsement to commercial driver's license under 49 CFR Part 1572; and
  - (6) Customs and Border Protection's Free and Secure Trade (FAST) Program.

6. Protection of information.

- a. Each licensee that obtains background information on an individual under this subsection shall establish and maintain a system of files and written procedures for protection of the record and the personal information from unauthorized disclosure.
- b. The licensee may not disclose the record or personal information collected and maintained to persons other than the subject individual, his representative, or to those who have a need to have access to the information in performing assigned duties in the process of granting or denying unescorted access to Category 1 or Category 2 quantities of radioactive material. No individual authorized to have access to the information may disseminate the information to any other individual who does not have a need to know.
- c. The personal information obtained on an individual from a background investigation may be provided to another licensee:
  - (1) Upon the individual's written request to the licensee holding the data to disseminate the information contained in that individual's file; and
  - (2) The recipient licensee verifies information such as name, date of birth, social security number, gender, and other applicable physical characteristics.
- d. The licensee shall make background investigation records obtained under this subsection available for examination by an authorized representative of the agency to determine compliance with the regulations and laws.
- e. The licensee shall retain all fingerprint and criminal history records (including data indicating no record) received from the FBI, or a copy of these records if the individual's file has been transferred, on an individual for three years from the date the individual no longer requires unescorted

access to Category 1 or Category 2 quantities of radioactive material.

7. Access authorization program review.

a. Each licensee shall be responsible for the continuing effectiveness of the access authorization program. Each licensee shall ensure that access authorization programs are reviewed to confirm compliance with the requirements of this subsection and that comprehensive actions are taken to correct any noncompliance that is identified. The review program shall evaluate all program performance objectives and requirements. The review shall be performed at least annually.

b. The results of the reviews, along with all recommendations, shall be documented. Each review report shall identify conditions that are adverse to the proper performance of the access authorization program; the cause of the conditions and, when appropriate, recommend corrective actions; and corrective actions taken. The licensee shall review the findings and take additional corrective actions necessary to preclude repetition of the condition, including reassessment of the deficient areas where indicated.

c. Review records shall be maintained for three years.

C. Physical protection requirements during use.

1. Security program.

a. Each licensee that possesses an aggregated Category 1 or Category 2 quantity of radioactive material shall establish, implement, and maintain a security program in accordance with the requirements of this subsection. An applicant for a new license and each licensee that would become newly subject to the requirements of this subsection upon an amendment request for modification of its license shall implement the requirements of this subsection, as appropriate, before taking possession of an aggregated Category 1 or Category 2 quantity of radioactive material. Any licensee that has not previously implemented the requirements of this subsection shall provide written notification to the agency at least 90 days before aggregating radioactive material to a quantity that equals or exceeds the Category 2 threshold.

b. Each licensee shall establish, implement, and maintain a security program that is designed to monitor and, without delay, detect, assess, and respond to an actual or attempted unauthorized access to Category 1 or Category 2 quantities of radioactive material.

c. Each licensee's security program shall include the program features, as appropriate, described in subdivisions 2 through 8 of this subsection.

2. General security program requirements.

a. Security plan.

(1) Each licensee identified in subdivision 1 a of this subsection shall develop a written security plan specific to its facilities and operations. The purpose of the security plan is to establish the licensee's overall security strategy to ensure the integrated and effective functioning of the security program required by this subsection. The security plan shall, at a minimum, (i) describe the measures and strategies used to implement the requirements of this subsection and (ii) identify the security resources, equipment, and technology used to satisfy the requirements of this subsection.

(2) The security plan shall be reviewed and approved by the individual with overall responsibility for the security program.

(3) A licensee shall revise its security plan as necessary to ensure the effective implementation of agency requirements. The licensee shall ensure that (i) the revision has been reviewed and approved by the individual with overall responsibility for the security program and (ii) the affected individuals are instructed on the revised plan before the changes are implemented.

(4) The licensee shall retain a copy of the current security plan as a record for three years after the security plan is no longer required. If any portion of the plan is superseded, the licensee shall retain the superseded material for three years after the record is superseded.

b. Implementing procedures.

(1) The licensee shall develop and maintain written procedures that document how the requirements of this subsection and the security plan will be met.

(2) The implementing procedures and revisions to these procedures shall be approved in writing by the individual with overall responsibility for the security program.

(3) The licensee shall retain a copy of the current procedure as a record for three years after the procedure is no longer needed. Superseded portions of the procedure shall be retained for three years after the record is superseded.

c. Training.

(1) Each licensee shall conduct training to ensure that those individuals implementing the security program possess and maintain the knowledge, skills, and abilities to carry out their assigned duties and responsibilities effectively. The training shall include at a minimum, instruction on:

(a) The licensee's security program and procedures to secure Category 1 or Category 2 quantities of radioactive material, and the purpose and function of the security measures employed;

(b) The responsibility to report promptly to the licensee any condition that causes or may cause a violation of agency requirements;

(c) The responsibility of the licensee to report promptly to the local law-enforcement agency and the agency any actual or attempted theft, sabotage, or diversion of Category 1 or Category 2 quantities of radioactive material; and

(d) The appropriate response to security alarms.

(2) In determining those individuals who shall be trained on the security program, the licensee shall consider each individual's assigned activities during authorized use and response to potential situations involving actual or attempted theft, diversion, or sabotage of Category 1 or Category 2 quantities of radioactive material. The extent of the training shall be commensurate with the individual's potential involvement in the security of Category 1 or Category 2 quantities of radioactive material.

(3) Refresher training shall be provided at a frequency not to exceed 12 months and when significant changes have been made to the security program. This training shall include (i) review of the training requirements of this subsection and changes made to the security program since the last training; (ii) reports on all relevant security issues, problems, and lessons learned; (iii) relevant results of agency inspections; and (iv) relevant results of the licensee's program review and testing and maintenance.

(4) The licensee shall maintain records of the initial and refresher training for three years from the date of the training. The training records shall include dates of the training, topics covered, a list of licensee personnel in attendance, and related information.

d. Protection of information.

(1) Licensees authorized to possess Category 1 or Category 2 quantities of radioactive material shall limit access to and prevent the unauthorized disclosure of their security plan, implementing procedures, and the list of individuals who have been approved for unescorted access.

(2) Efforts to limit access shall include the development, implementation, and maintenance of written policies and procedures for controlling access to and for proper handling and protection against unauthorized disclosure of the security plan ~~and~~, implementing procedures, and the list of individuals who have been approved for unescorted access.

(3) Before granting an individual access to the security plan ~~or~~, implementing procedures, or the list of individuals who have been approved for unescorted access, licensees shall:

(a) Evaluate an individual's need to know the security plan ~~or~~, implementing procedures, or the list of individuals who have been approved for unescorted access; and

(b) If the individual has not been authorized for unescorted access to Category 1 or Category 2 quantities of radioactive material, the licensee shall complete a background investigation to determine the individual's trustworthiness and reliability. A trustworthiness and reliability determination shall be conducted by the reviewing official and shall include the background investigation elements contained in subdivisions B 3 a (2) through (7) of this section.

(4) Licensees need not subject any individual to background investigation elements for protection of information if that individual is included in the categories of individuals listed in subdivisions B 5 a (1) through (12) of this section or is a security service provider employee, provided written verification that the employee has been determined to be trustworthy and reliable, by the required background investigation in subdivisions B 3 a (2) though (7) of this subsection, has been provided by the security service provider.

(5) The licensee shall document the basis for concluding that an individual is trustworthy and reliable and should be granted access to the security plan ~~or~~, implementing procedures, or the list of individuals who have been approved for unescorted access.

(6) Licensees ~~or~~ shall maintain a list of persons currently approved for access to the security plan implementing procedures, or the list of individuals who have been approved for unescorted access. When a licensee determines that a person no longer needs access to the security plan ~~or~~, implementing procedures, or the list of individuals who have been approved for unescorted access or no longer meets the access authorization requirements for access to the information, the licensee shall remove the person from the approved list as soon as possible, but no later than seven working days after the determination, and take prompt measures to ensure that the individual is unable to obtain the security plan ~~or~~, implementing procedures, or the list of individuals who have been approved for unescorted access.

(7) When not in use, the licensee shall store its security plan ~~and~~, implementing procedures, and the list of individuals who have been approved for unescorted access in a manner to prevent unauthorized access. Information stored in nonremovable electronic form shall be password protected.



(8) The licensee shall retain as a record a copy of the information protection procedures and the list of individuals approved for access to the security plan ~~or~~, implementing procedures, or the list of individuals who have been approved for unescorted access for three years after the document has been superseded.

### 3. Local law-enforcement agency (LLEA) coordination.

a. A licensee subject to this subsection shall coordinate, to the extent practicable, with an LLEA for responding to threats to the licensee's facility, including any necessary armed response. The information provided to the LLEA shall include:

(1) A description of the facilities and the Category 1 and Category 2 quantities of radioactive materials along with a description of the licensee's security measures that have been implemented to comply with this subsection; and

(2) A notification that the licensee will request a timely armed response by the LLEA to any actual or attempted theft, sabotage, or diversion of Category 1 or Category 2 quantities of material.

b. The licensee shall notify the agency within three business days if:

(1) The LLEA has not responded to the request for coordination within 60 days of the coordination request; or

(2) The LLEA notifies the licensee that the LLEA does not plan to participate in coordination activities.

c. The licensee shall document its efforts to coordinate with the LLEA. The documentation shall be kept for three years.

d. The licensee shall coordinate with the LLEA at least every 12 months, or when changes to the facility design or operation adversely affect the potential vulnerability of the licensee's material to theft, sabotage, or diversion.

### 4. Security zones.

a. Licensees shall ensure that all aggregated Category 1 or Category 2 quantities of radioactive material are used or stored within licensee-established security zones. Security zones may be permanent or temporary.

b. Temporary security zones shall be established as necessary to meet the licensee's transitory or intermittent business activities, such as periods of maintenance, source delivery, and source replacement.

c. Security zones shall, at a minimum, allow unescorted access only to approved individuals by:

(1) Isolation of Category 1 and Category 2 quantities of radioactive materials by the use of continuous physical barriers that allow access to the security zone only through established access control points. A physical barrier is a natural or man-made structure or formation sufficient for the isolation of the Category 1 or Category 2 quantities of radioactive material within a security zone;

(2) Direct control of the security zone by approved individuals at all times; or

(3) A combination of continuous physical barriers and direct control.

d. For Category 1 quantities of radioactive material during periods of maintenance, source receipt, preparation for shipment, installation, or source removal or exchange, the licensee shall, at a minimum, provide sufficient individuals approved for unescorted access to maintain continuous surveillance of sources in temporary security zones and in any security zone in which physical barriers or intrusion detection systems have been disabled to allow such activities.

e. Individuals not approved for unescorted access to Category 1 or Category 2 quantities of radioactive material shall be escorted by an approved individual when in a security zone.

### 5. Monitoring, detection, and assessment.

#### a. Monitoring and detection.

(1) Licensees shall establish and maintain the capability to continuously monitor and detect without delay all unauthorized entries into its security zones. Licensees shall provide the means to maintain continuous monitoring and detection capability in the event of a loss of the primary power source, or provide for an alarm and response in the event of a loss of this capability to continuously monitor and detect unauthorized entries.

(2) Monitoring and detection shall be performed by:

(a) A monitored intrusion detection system that is linked to an onsite or offsite central monitoring facility;

(b) Electronic devices for intrusion detection alarms that will alert nearby facility personnel;

(c) A monitored video surveillance system;

(d) Direct visual surveillance by approved individuals located within the security zone; or

(e) Direct visual surveillance by a licensee designed individual located outside the security zone.

(3) A licensee subject to this subsection shall also have a means to detect unauthorized removal of the radioactive material from the security zone. This detection capability shall provide:

(a) For Category 1 quantities of radioactive material, immediate detection of any attempted unauthorized removal of the radioactive material from the security zone. Such immediate detection capability shall be provided by electronic sensors linked to an alarm, continuous monitored video surveillance, or direct visual surveillance; and

(b) For Category 2 quantities of radioactive material, weekly verification through physical checks, tamper indicating devices, use, or other means to ensure that the radioactive material is present.

b. Licensees shall immediately assess each actual or attempted unauthorized entry into the security zone to determine whether the unauthorized access was an actual or attempted theft, sabotage, or diversion.

c. For personnel and automated or electronic systems supporting the licensee's monitoring, detection, and assessments system, licensees shall:

(1) Maintain continuous capability for personnel communication and electronic data transmission and processing among site security systems; and

(2) Provide an alternate communication capability for personnel, and an alternative data transmission and processing capability, in the event of a loss of the primary means of communication or data transmission and processing. Alternative communications and data transmissions systems may not be subject to the same failure modes as the primary systems.

d. Licensees shall immediately respond to any actual or attempted unauthorized access to the security zones, or actual or attempted theft, sabotage, or diversion of Category 1 or Category 2 quantities of radioactive material at licensee facilities or temporary job sites. For any unauthorized access involving an actual or attempted theft, sabotage, or diversion of Category 1 or Category 2 quantities of radioactive material, the licensee's response shall include requesting, without delay, an armed response from the LLEA.

6. Maintenance and testing.

a. Each licensee subject to this subsection shall implement a maintenance and testing program to ensure that intrusion alarms, associated communication systems, and other physical components of the systems used to secure or detect unauthorized access to radioactive material are maintained in operable condition and are capable of performing their intended function when needed. The equipment relied on to meet the security requirements of this subsection shall be inspected and tested for operability and performance at the manufacturer's suggested frequency. If there is no frequency suggested by the manufacturer or the frequency specified is greater than three months, the testing shall be performed at least quarterly, not to exceed three months.

b. The licensee shall maintain records on the maintenance and testing activities for three years.

7. Requirements for mobile devices. Each licensee that possesses mobile devices containing Category 1 or Category 2 quantities of radioactive material shall:

a. Have two independent physical controls that form tangible barriers to secure the material from unauthorized removal when the device is not under direct control and constant surveillance by the licensee; and

b. For devices in or on a vehicle or trailer, unless the health and safety requirements for a site prohibit the disabling of the vehicle, the licensee shall utilize a method to disable the vehicle or trailer when not under direct control and constant surveillance by the licensee. Licensees shall not rely on the removal of an ignition key to meet this requirement.

8. Security program review.

a. Each licensee shall be responsible for the continuing effectiveness of the security program. Each licensee shall ensure that the security program is reviewed to confirm compliance with the requirements of this subsection and that comprehensive actions are taken to correct any noncompliance that is identified. The review shall include the radioactive material security program content and implementation. The review shall be conducted at least annually, not to exceed 12 months.

b. The results of the review, along with all recommendations, shall be documented. Each review report shall identify conditions that are adverse to the proper performance of the security program, the cause of the condition, corrective actions taken, and, when appropriate, recommend corrective actions. The licensee shall review the findings and take any additional corrective actions necessary to preclude repetition of the condition, including reassessment of the deficient areas where indicated.

c. The licensee shall maintain the review documentation for three years.

#### 9. Reporting of events.

a. The licensee shall immediately notify the LLEA after determining that an unauthorized entry resulted in an actual or attempted theft, sabotage, or diversion of Category 1 or Category 2 quantity of radioactive material. As soon as possible after initiating a response, but not at the expense of causing delay or interfering with the LLEA response to the event, the licensee shall notify the agency by telephone at 804-864-8150 during normal business hours and 804-674-2400 after hours. In no case shall the notification to the agency be later than four hours after the discovery of any attempted or actual theft, sabotage, or diversion.

b. The licensee shall assess any suspicious activity related to possible theft, sabotage, or diversion of Category 1 or Category 2 quantities of radioactive material and notify the LLEA as appropriate. As soon as possible but not later than four hours after notifying the LLEA, the licensee shall notify the agency by telephone 804-864-8150 during normal business hours and 804-674-2400 after hours.

c. The initial telephonic notification shall be followed within a period of 30 days by a written report submitted to the agency. The report shall include sufficient information for agency analysis and evaluation, including identification of any necessary corrective actions to prevent future instances.

#### D. Physical protection in transit.

1. Additional requirements for transfer of Category 1 and Category 2 quantities of radioactive material. A licensee transferring a Category 1 or Category 2 quantity of radioactive material to a licensee of the agency, the NRC, or another Agreement state shall meet the license verification provisions listed in this subdivision instead of those listed in 12VAC5-481-570.

a. Any licensee transferring Category 1 quantities of radioactive material to a licensee of the agency, the NRC, or another Agreement state, prior to conducting such transfer, shall verify with the NRC's license verification system or the license issuing authority that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred and that the licensee is authorized to receive radioactive material at the location requested for delivery. If the verification is conducted by contacting the license-issuing authority, the transferor shall document the verification. For transfers within the same organization, the licensee does not need to verify the transfer.

b. Any licensee transferring Category 2 quantities of radioactive material to a licensee of the agency, the NRC, or another Agreement state, prior to conducting such transfer, shall verify with the NRC's license verification system or the license-issuing authority that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred. If the verification is conducted by contacting the license-issuing authority, the transferor shall document the verification. For transfers within the same organization, the licensee does not need to verify the transfer.

c. In an emergency where the licensee cannot reach the license-issuing authority and the license verification system is nonfunctional, the licensee may accept a written certification by the transferee that it is authorized by license to receive the type, form, and quantity of radioactive material to be transferred. The certification shall include the license number, current revision number, issuing agency, expiration date, and for a Category 1 shipment, the authorized address. The licensee shall keep a copy of the certification. The certification shall be confirmed by use of the NRC's license verification system or by contacting the license-issuing authority by the end of the next business day.

d. The transferor shall keep a copy of the verification documentation as a record for three years.

2. Applicability of physical protection of Category 1 and Category 2 quantities of radioactive material during transit.

a. For shipments of category 1 quantities of radioactive material, each shipping licensee shall comply with the requirements for physical protection contained in subdivisions 3 a, 3 e, 4, 5 a (1), 5 b (1), 5 c, 6 a, 6 c, 6 e, 6 g, and 6 h of this subsection.

b. For shipments of Category 2 quantities of radioactive material, each shipping licensee shall comply with the requirements for physical protection contained in subdivisions 3 b through 3 e, 5 a (2), 5 a (3), 5 b (2), 5 c, 6 b, 6 d, 6 f, 6 g, and 6 h of this subsection.

c. The shipping licensee shall be responsible for meeting the requirements of this subsection unless the receiving licensee has agreed in writing to arrange for the in-transit physical protection required under this subsection.

3. Preplanning and coordination of shipment of Category 1 or Category 2 quantities of radioactive material.

a. Each licensee that plans to transport, or deliver to a carrier for transport, licensed material that is a Category 1 quantity of radioactive material outside the confines of the licensee's facility or other place of use or storage shall:

(1) Preplan and coordinate shipment arrival and departure times with the receiving licensee;

(2) Preplan and coordinate shipment information with the governor or the governor's designee of any state through which the shipment will pass to discuss the state's intention to provide law-enforcement escorts and identify safe havens; and

(3) Document the preplanning and coordination activities.

b. Each licensee that plans to transport, or deliver to a carrier for transport, licensed material that is a Category 2 quantity of radioactive material outside the confines of the licensee's facility or other place of use or storage shall coordinate the shipment no-later-than arrival time and the expected shipment arrival with the receiving licensee. The licensee shall document the coordination activities.

c. Each licensee that receives a shipment of a Category 2 quantity of radioactive material shall confirm receipt of the shipment with the originator. If the shipment has not arrived by the no-later-than arrival time, the receiving licensee shall notify the originator.

d. Each licensee that transports or plans to transport a shipment of a Category 2 quantity of radioactive material and determines that the shipment will arrive after the no-later-than arrival time provided pursuant to subdivision 3 b of this subsection, shall promptly notify the receiving licensee of the new no-later-than arrival time.

e. The licensee shall retain a copy of the documentation for preplanning and coordination and any revision thereof as a record for three years.

4. As specified in subdivision 3 of this subsection, each licensee shall provide advance notification to the agency and the governor of a state, or the governor's designee, of the shipment of licensed material in a Category 1 quantity, through or across the boundary of the state, before the transport or delivery to a carrier for transport of the licensed material outside the confines of the licensee's facility or other place of use or storage.

a. Procedures for submitting advance notification:

(1) The notification shall be made to the agency and to the office of each appropriate governor or governor's designee. The contact information, including telephone and mailing addresses, of governors and governor's designees is available on the NRC website at <https://scp.nrc.gov/special/designee.pdf>. The notification to the agency shall be in accordance with 12VAC5-481-150.

(2) A notification delivered by mail shall be postmarked at least seven days before transport of the shipment commences at the shipping facility.

(3) A notification delivered by any means other than mail shall reach the agency at least four days before the transport of the shipment commences and shall reach the office of the governor or the governor's designee at least four days before transport of a shipment within or through the state.

b. Each advance notification of shipment of Category 1 quantities of radioactive material shall contain the following information, if available at the time of the notification:

(1) The name, address, and telephone number of the shipper, carrier, and receiver of the Category 1 radioactive material;

(2) The license numbers of the shipper and receiver;

(3) A description of the radioactive material contained in the shipment, including the radionuclides and quantity;

(4) The point of origin of the shipment and the estimated time and date that shipment will commence;

(5) The estimated time and date that the shipment is expected to enter each state along the route;

(6) The estimated time and date of arrival for the shipment at the destination; and

(7) A point of contact, with a telephone number, for current shipment information.

c. Revision notice.

(1) The licensee shall provide any information not previously available at the time of the initial notification, as soon as the information becomes available but not later than commencement of the shipment, to the agency and the governor of the state or the governor's designee.

(2) A licensee shall promptly notify the agency and governor of the state or the governor's designee of any changes to the information provided in accordance with this subdivision.

d. Each licensee who cancels a shipment for which advance notification has been sent shall send a cancellation notice to the agency and the governor of each state or to the governor's designee previously notified. The licensee shall send the cancellation notice before the shipment would have commenced or as soon thereafter as possible. The licensee shall state in the notice that it is a cancellation and identify the advance notification that is being canceled.

e. The licensee shall retain a copy of the advance notification and any revision and cancellation notices as a record for three years.

f. State officials, state employees, and other individuals, whether or not licensees of the agency, NRC, or another Agreement state, who receive schedule information of the kind specified in subdivision 4 b of this subsection shall protect that information against unauthorized disclosure as specified in subdivision C 2 d of this section.

## 5. Requirements for physical protection of Category 1 and Category 2 quantities of radioactive material during shipment.

## a. Shipments by road.

(1) Each licensee who transports or delivers to a carrier for transport in a single shipment a Category 1 quantity of radioactive material shall:

(a) Ensure that movement control centers are established that maintain position information from a remote location. These control centers shall monitor shipments 24 hours a day, seven days a week and have the ability to communicate immediately, in an emergency, with the appropriate law-enforcement agencies;

(b) Ensure that redundant communications are established that allow the transport to contact the escort vehicle, when an escort vehicle is used, and movement control center at all times. Redundant communications may not be subject to the same interference factors as the primary communication;

(c) Ensure that shipments are continuously and actively monitored by a telemetric position monitoring system or an alternative tracking system reporting to a movement control center. A movement control center shall provide positive confirmation of the location, status, and control over the shipment. The movement control center shall be prepared to promptly implement preplanned procedures in response to deviations from the authorized route or a notification of actual, attempted, or suspicious activities related to the theft, loss, or diversion of a shipment. These procedures will include, but not be limited to, the identification of and contact information for the appropriate LLEA along the shipment route;

(d) Provide an individual to accompany the driver for those highway shipments with a driving time period greater than the maximum number of allowable hours of service in a 24-hour duty day as established by the U.S. Department of Transportation Federal Motor Carrier Safety Administration. The accompanying individual may be another driver; and

(e) Develop written normal and contingency procedures to address (i) notifications to the communication center and law-enforcement agencies; (ii) communication protocols that shall include a strategy for the use of authentication codes and duress codes and provisions for refueling and other stops, detours, and locations where communication is expected to be temporarily lost; (iii) loss of communication; and (iv) responses to an actual or attempted theft or diversion of a shipment.

(f) Each licensee who makes arrangements for the shipment of Category 1 quantities of radioactive material shall ensure that drivers, accompanying personnel, and movement control center personnel have access to the normal and contingency procedures.

(2) Each licensee that transports Category 2 quantities of radioactive material shall maintain constant control and surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance.

(3) Each licensee who delivers to a carrier for transport in a single shipment a Category 2 quantity of radioactive material shall:

(a) Use carriers that have established package tracking systems. An established package tracking system is a documented, proven, and reliable system routinely used to transport objects of value. In order for a package tracking system to maintain constant control and surveillance, the package tracking system shall allow the shipper or transporter to identify when and where the package was last and when it should arrive at the next point of control;

(b) Use carriers that maintain constant control and surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance; and

(c) Use carriers that have established tracking systems that require an authorized signature prior to releasing the package for delivery or return.

## b. Shipments by rail.

(1) Each licensee who transports, or delivers to a carrier for transport, in a single shipment a Category 1 quantity of radioactive material shall:

(a) Ensure that rail shipments are monitored by a telemetric position monitoring system or an alternative tracking system reporting to the licensee, third-party, or railroad communications center. The communications center shall provide positive confirmation of the location of the shipment and its status. The communications center shall implement preplanned procedures in response to deviations from the authorized route or to a notification of actual, attempted, or suspicious activities related to the theft or diversion of a shipment. These procedures will include, but not be limited to, the identification of and contact information for the appropriate LLEA along the shipment route; and

(b) Ensure that periodic reports to the communications center are made at preset intervals.

(2) Each licensee who transports, or delivers to a carrier for transport, in a single shipment a Category 2 quantity of radioactive material shall:

(a) Use carriers that have established package tracking systems. An established package tracking system is a documented, proven, and reliable system routinely used to transport objects of value. In order for a package tracking system to maintain constant control and surveillance, the

package tracking system shall allow the shipper or transporter to identify when and where the package was last and when it should arrive at the next point of control;

(b) Use carriers that maintain constant control and surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance; and

(c) Use carriers that have established tracking systems that require an authorized signature prior to releasing the package for delivery or return.

c. Each licensee who makes arrangements for the shipment of Category 1 quantities of radioactive material shall immediately conduct an investigation upon discovery that a Category 1 shipment is lost or missing. Each licensee who makes arrangements for the shipment of Category 2 quantities of radioactive material shall immediately conduct an investigation, in coordination with the receiving licensee, of any shipment that has not arrived by the designated no-later-than arrival time.

#### 6. Reporting of events.

a. The shipping licensee shall notify the appropriate LLEA and the agency within one hour of its determination that a shipment of Category 1 quantities of radioactive material is lost or missing. The appropriate LLEA would be the law-enforcement agency in the area of the shipment's last confirmed location. During the investigation required by this subsection, the shipping licensee will provide agreed upon updates to the agency on the status of the investigation.

b. The shipping licensee shall notify the agency within four hours of its determination that a shipment of Category 2 quantities of radioactive material is lost or missing. If, after 24 hours of its determination that the shipment is lost or missing, the radioactive material has not been located and secure, the licensee shall immediately notify the agency.

c. The shipping licensee shall notify the designated LLEA along the shipment route as soon as possible upon discovery of any actual or attempted theft or diversion of a shipment or suspicious activities related to the theft or diversion of a shipment of a Category 1 quantity of radioactive material. As soon as possible after notifying the LLEA, the licensee shall notify the agency upon discovery of any actual or attempted theft or diversion of a shipment, or any suspicious activity related to the shipment, of Category 1 radioactive material.

d. The shipping licensee shall notify the agency as soon as possible upon discovery of any actual or attempted theft or diversion of a shipment, or any suspicious activity related to the shipment, of a Category 2 quantity of radioactive material.

e. The shipping licensee shall notify the agency and the LLEA as soon as possible upon recovery of any lost or missing Category 1 quantities of radioactive material.

f. The shipping licensee shall notify the agency as soon as possible upon recovery of any lost or missing Category 2 quantities of radioactive material.

g. The initial telephonic notification required by subdivisions 6 a through 6 d of this subsection shall be followed within a period of 30 days by a written report submitted to the agency. A written report is not required for notifications on suspicious activities required by subdivisions 6 c and 6 d of this subsection. The report shall include the following information:

(1) A description of the licensed material involved, including kind, quantity, and chemical and physical form;

(2) A description of the circumstances under which the loss or theft occurred;

(3) A statement of disposition, or probable disposition, of the licensed material involved;

(4) Actions that have been taken, or will be taken, to recover the material; and

(5) Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed material.

h. Subsequent to filing the written report, the licensee shall also report any additional substantive information on the loss or theft within 30 days after the licensee learns of such information.

#### E. Records.

1. Each record required by this section shall be legible throughout the retention period specified. The record may be the original or a reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications shall include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

2. Licensees shall maintain the records that are required by this section for the period specified. If a retention period is not otherwise specified, these records shall be retained until the agency terminates the facility's license. All records related to this section may be destroyed upon agency termination of the facility license.

**12VAC5-481-480. Special requirements for a specific license to manufacture, assemble, repair, or distribute commodities, products, or devices that contain radioactive material.**

A. Reserved.

B. Licensing the distribution of radioactive material in exempt quantities. (Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing radioactive material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the Nuclear Regulatory Commission, Washington, DC 20555-0001.)

C. Licensing the manufacture or initial transfer of devices to persons generally licensed under 12VAC5-481-430 B.

1. An application for a specific license to manufacture or initially transfer devices containing radioactive material, excluding special nuclear material, to persons generally licensed under 12VAC5-481-430 B or equivalent regulations of the NRC, or another Agreement state will be approved if:

a. The applicant satisfies the general requirements of 12VAC5-481-450;

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

(1) The device can be safely operated by persons not having training in radiological protection;

(2) Under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in any period of one calendar quarter a dose in excess of 10% of the limits specified in 12VAC5-481-640; and

(3) Under accident conditions such as fire and explosion associated with handling, storage, and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in 12VAC5-481-3580, Column IV;

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

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

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

(3) The information called for in one of the following statements, as appropriate, in the same or substantially similar form:

(a) The receipt, possession, use, and transfer of this device, Model \_\_\_\_\_, Serial No. \_\_\_\_\_, are subject to a general license or the equivalent and the regulations of the Nuclear Regulatory Commission or a state with which the Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

**CAUTION—RADIOACTIVE MATERIAL**

\_\_\_\_\_Name of manufacturer or initial transferor

(b) The receipt, possession, use, and transfer of this device, Model \_\_\_\_\_, Serial No. \_\_\_\_\_, are subject to a general license or the equivalent, and the regulations of a licensing state. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited. (The model, serial number, and name of the manufacturer or distributor may be omitted from this label provided the information is elsewhere specified in labeling affixed to the device.)

**CAUTION—RADIOACTIVE MATERIAL**

\_\_\_\_\_Name of manufacturer or initial transferor;

d. 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, and the words, "Caution Radioactive Material," the

radiation symbol described in 12VAC5-481-850, and the name of the manufacturer or initial distributor;

e. Each device meeting the criteria of 12VAC5-481-430 B 4 m bears a permanent (e.g., embossed, etched, stamped, or engraved) label affixed to the source housing if separate, 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 12VAC5-481-850; and

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

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

a. Primary containment or source capsule;

b. Protection of primary containment;

c. Method of sealing containment;

d. Containment construction materials;

e. Form of contained radioactive material;

f. Maximum temperature withstood during prototype tests;

g. Maximum pressure withstood during prototype tests;

h. Maximum quantity of contained radioactive material;

i. Radiotoxicity of contained radioactive material; and

j. Operating experience with identical devices or similarly designed and constructed devices.

3. In the event the applicant desires that the general licensee under 12VAC5-481-430 B, or under equivalent regulations of the NRC, or another Agreement state, be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the "on-off" mechanism and indicator, or remove the device from installation, the applicant shall include in the application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and basis for such estimates. The submitted information shall demonstrate that performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a calendar quarter dose in excess of 10% of the limits specified in 12VAC5-481-640.

4. Each person licensed under this subsection to distribute devices to generally licensed persons shall:

a. Furnish a copy of the general license contained in 12VAC5-481-430 B to each person to whom he directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license contained in 12VAC5-481-430 B;

b. Furnish a copy of the general license contained in the NRC's, or another Agreement state's, regulation equivalent to 12VAC5-481-430 B, or alternatively, furnish a copy of the general license contained in 12VAC5-481-430 B to each person to whom he directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license of the NRC, or another Agreement state. If a copy of the general license in 12VAC5-481-430 B is furnished to such a person, it shall be accompanied by a note explaining that the use of the device is regulated by the NRC, or another Agreement state, under requirements substantially the same as those in 12VAC5-481-430 B;

c. Report to the agency all transfers of such devices to persons for use under the general license in 12VAC5-481-430 B. Such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the agency and the general licensee, the type and model number of device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user. If no transfers have been made to persons generally licensed under 12VAC5-481-430 B during the reporting period, the report shall so indicate. The report shall cover each calendar quarter and shall be filed within 30 days thereafter;

d. Furnish reports to other agencies.

(1) Report to the NRC all transfers of such devices to persons for use under the NRC's general license in 10 CFR 31.5.



(2) Report to the responsible state agency all transfers of devices manufactured and distributed pursuant to this subsection for use under a general license in that state's regulations equivalent to 12VAC5-481-430 B.

(3) Such reports shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the agency and the general licensee, the type and model of the device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user. The report shall be submitted within 30 days after the end of each calendar quarter in which such a device is transferred to the generally licensed person.

(4) If no transfers have been made to NRC general licensees during the reporting period, this information shall be reported to the NRC.

(5) If no transfers have been made to general licensees within a particular state during the reporting period, this information shall be reported to the responsible state agency upon request of that agency; and

e. Keep records showing the name, address, and the point of contact for each general licensee to whom he directly or through an intermediate person transfers radioactive material in devices for use pursuant to the general license provided in 12VAC5-481-430 B, or equivalent regulations of the NRC or another Agreement state. The records shall show the date of each transfer, the radionuclide and the quantity of radioactivity in each device transferred, the identity of any intermediate person, and compliance with the report requirements of subdivision 4 of this subsection.

f. If a notification of bankruptcy has been made under 12VAC5-481-500 E or the license is to be terminated, each person licensed under this section shall provide, upon request, to the agency, the NRC and to any appropriate Agreement state, records of final disposition required under subdivision 4 e of this subsection.

g. The licensee shall maintain all information concerning transfers and receipts of devices that supports the reports required by this section. Records required by this section shall be maintained for a period of three years following the date of the recorded event.

D. Special requirements for the manufacture, initial transfer, assembly, or repair of luminous safety devices for use in aircraft. An application for a specific license to manufacture, assemble, or repair luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed under 12VAC5-481-430 D will be approved if:

1. The applicant satisfies the general requirements specified in 12VAC5-481-450.

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

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

b. Details of construction and design;

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

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

e. Quality assurance procedures to be followed that are sufficient to ensure compliance with subdivision 8 of this subsection; and

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

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

4. The agency determines that:

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

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

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

d. Prototypes of the device have been subjected to and have satisfactorily passed the tests required by subdivision 5 of this subsection.

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

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

b. The devices are inspected for evidence of physical damage and for loss of tritium or promethium-147 after each stage of testing using methods of inspection adequate for determining compliance with the criteria in subdivision 5 c of this subsection.

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

(1) A leak resulting in a loss of 0.1% or more of the original amount of tritium or promethium-147 from the device;

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

(3) Any other evidence of physical damage.

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

7. Labeling.

a. A person licensed to manufacture, assemble, or initially transfer devices containing tritium or promethium-147 for distribution to persons generally licensed under 12VAC5-481-430 D, except as provided in subdivision 7 b of this subsection, shall affix to each device a label containing the radiation symbol prescribed by 12VAC5-481-850, such other information as may be required by the agency including disposal instructions when appropriate, and the following or a substantially similar statement that contains the information in the following statement:

The receipt, possession, use, and transfer of this device, Model\* \_\_\_\_\_, Serial No.\* \_\_\_\_\_, 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 or of a state with which the NRC has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION--RADIOACTIVE MATERIAL

\_\_\_\_\_  
(Name of manufacturer, assembler, or initial transferor.)\*

\*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.

b. If the agency determines that it is not feasible to affix a label to the device containing all the information called for in subdivision 7 a of this subsection, it may waive those requirements and require the following:

(1) A label is affixed to the device identifying:

(i) The manufacturer, assembler, or initial transferor; and

(ii) The type of radioactive material; and

(2) A leaflet bearing the following information be enclosed in or accompany the container in which the device is shipped:

(i) The name of the manufacturer, assembler, or initial transferor;

(ii) The type and quantity of radioactive material;

(iii) The model number;

(iv) A statement that the receipt, possession, use, and transfer of the device are subject to a general license or the equivalent and the regulations of the NRC or of an Agreement state; and

(v) Such other information as may be required by the agency, including disposal instructions when appropriate.

8. Quality assurance; prohibition of transfer.

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

b. Each person licensed under this subsection shall:

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

(2) Subject inspection lots to acceptance sampling procedures, by procedures specified in subdivision 8 c of this subsection and in the license issued under this subsection, to provide at least 95% confidence that the lot tolerance percent defective of 5.0% will not be exceeded.

c. The licensee shall subject each inspection lot to the following:

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

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

(i) A leak resulting in a loss of 0.1% or more of the original amount of tritium or promethium-147 from the device;

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

(iii) Any other criteria specified in the license issued under this subsection.

d. No person licensed under this subsection shall transfer to persons generally licensed under 12VAC5-481-430 D or under an equivalent general license of the NRC or other Agreement state:

(1) Any luminous safety device tested and found defective under any condition of a license issued under subdivisions 1 through 6 or this subdivision 8 of this subsection, unless the defective luminous safety device has been repaired or reworked, retested, and determined by an independent inspector to meet the applicable acceptance criteria; or

(2) Any luminous safety device contained within any lot that has been sampled and rejected as a result of the procedures in subdivision 8 b (2) of this subsection, unless:

(i) A procedure for defining sub-lot size, independence, and additional testing procedures is contained in the license issued under this subsection; and

(ii) Each individual sub-lot is sampled, tested, and accepted in accordance with subdivisions 8 b (2) and d (2) (i) of this subsection and any other criteria that may be required as a condition of the license issued under this subsection.

9. Transfer reports.

a. Each person licensed under this subsection shall file an annual report with the agency, which shall state the total quantity of tritium or promethium-147 transferred to persons generally licensed under 12VAC5-481-430 D. The report shall identify each general licensee by name, state the kinds and numbers of luminous devices transferred, and specify the quantity of tritium or promethium-147 in each kind of device. Each report shall cover the year ending June 30 and shall be filed within 30 days thereafter. If no transfers have been made to persons generally licensed under 12VAC5-481-430 D during the reporting period, the report shall indicate so.

b. Each person licensed under this subsection shall report annually all transfers of devices to persons for use under a general license in the NRC or another Agreement state's regulations that are equivalent to 12VAC5-481-430 D to (i) the NRC at Director, Office of Nuclear Material Safety and Safeguards, ATTN: Document Control Desk/GLTS, by an appropriate method listed in 10 CFR 30.6(a) and (ii) the responsible Agreement state agency. The report shall state the total quantity of tritium or promethium-147 transferred, identify each general licensee by name, state the kinds and numbers of luminous devices transferred, and specify the quantity of tritium or promethium-147 in each kind of device. If no transfers have been made to the NRC or particular Agreement state during the reporting period, this information shall be reported to the NRC and responsible Agreement state agency.

E. Special requirements for license to manufacture or initially transfer calibration sources containing americium-241, plutonium or radium-226 for distribution to persons generally licensed under 12VAC5-481-430 F. An application for a specific license to manufacture calibration and reference sources containing americium-241, plutonium or radium-226 to persons generally licensed under 12VAC5-481-430 F will be approved if:

1. The applicant satisfies the general requirement of 12VAC5-481-450.

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

a. Chemical and physical form and maximum quantity of americium 241 or radium-226 in the source;

b. Details of construction and design;

- c. Details of the method of incorporation and binding of the americium-241 or radium-226 in the source;
- d. Procedures for and results of prototype testing of sources, which are designed to contain more than 0.005 microcurie (0.185 kilobecquerel) of americium-241 or radium-226, to demonstrate that the americium-241 or radium-226 contained in each source will not be released or be removed from the source under normal conditions of use;
- e. Details of quality control procedures to be followed in manufacture of the source;
- f. Description of labeling to be affixed to the source or the storage container for the source; and
- g. Any additional information, including experimental studies and tests, required by the NRC to facilitate a determination of the safety of the source.

3. Each source will contain no more than 5 microcuries of americium-241 or radium-226.

4. The agency determines, with respect to any type of source containing more than 0.005 microcurie (0.185 kilobecquerel) of americium-241 or radium-226, that:

- a. The method of incorporation and binding of the americium-241 or radium-226 in the source is such that the americium-241 will not be released or be removed from the source under normal conditions of use and handling of the source; and
- b. The source has been subjected to and has satisfactorily passed appropriate tests required by subdivision 5 of this subsection.

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

- a. The initial quantity of radioactive material deposited on each source is measured by direct counting of the source.
- b. The sources are subjected to tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment or binding of americium-241 or radium-226, such as physical handling, moisture, and water immersion.
- c. The sources are inspected for evidence of physical damage and for loss of americium-241 or radium-226 after each stage of testing using methods of inspection adequate for determining compliance with the criteria in subdivision 5 d of this subsection.
- d. Source designs are rejected for which the following has been detected for any unit (i) removal of more than 0.005 microcurie (0.185 kilobecquerel) of americium-241 or radium-226 from the source or (ii) any other evidence of physical damage.

6. Labeling of devices. Each person licensed under this subsection shall affix to each source or storage container for the source a label that shall contain sufficient information relative to safe use and storage of the source and shall include the following statement or a substantially similar statement which contains the information in the following statement:

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

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

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(Name of manufacturer or initial transferor)"

7. Leak testing of each source. Each person licensed under this subsection shall perform a dry wipe test upon each source containing more than 0.1 microcurie (3.7 kilobecquerel) of americium-241 or radium-226 before transferring the source to a general licensee under 12VAC5-481-430 F or under equivalent regulations of the NRC or another Agreement state. This test shall be performed by wiping the entire radioactive surface of the source with a filter paper with the application of moderate finger pressure. The radioactivity on the filter paper shall be measured using methods capable of detecting 0.005 microcurie (0.185 kilobecquerel) of americium-241 or radium-226. If a source has been shown to be leaking or losing more than 0.005 microcurie (0.185 kilobecquerel) of americium-241 or radium-226 by the methods described in this section, the source shall be rejected and shall not be transferred to a general licensee under 12VAC5-481-430 F, or equivalent regulations of the NRC or another Agreement state.

F. Reserved.

G. Manufacture and distribution of radioactive material for certain in vitro clinical or laboratory testing under general license. An application for a specific license to manufacture or distribute radioactive material for use under the general license of 12VAC5-481-430 G will be approved if:

1. The applicant satisfies the general requirements specified in 12VAC5-481-450.
2. The radioactive material is to be prepared for distribution in prepackaged units of:
  - a. Carbon-14 in units not exceeding 370 kBq (10  $\mu$ Ci) each.
  - b. Cobalt-57 in units not exceeding 370 kBq (10  $\mu$ Ci) each.
  - c. Hydrogen-3 (tritium) in units not exceeding 1.85 MBq (50  $\mu$ Ci) each.
  - d. Iodine-125 in units not exceeding 370 kBq (10  $\mu$ Ci) each.
  - e. Mock iodine-125 in units not exceeding 1.85 kBq (0.05  $\mu$ Ci) of iodine-129 and 185 Bq (0.005  $\mu$ Ci) of americium-241 each.
  - f. Iodine-131 in units not exceeding 370 kBq (10  $\mu$ Ci) each.
  - g. Iron-59 in units not exceeding 740 kBq (20  $\mu$ Ci) each.
  - h. Selenium-75 in units not exceeding 370 kBq (10  $\mu$ Ci) each.
3. Each prepackaged unit bears a durable, clearly visible label:
  - a. Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 370 kBq (10  $\mu$ Ci) of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; 1.85 MBq (50  $\mu$ Ci) of hydrogen-3 (tritium); 740 kBq (20  $\mu$ Ci) of iron-59; or mock iodine-125 in units not exceeding 1.85 kBq (0.05  $\mu$ Ci) of iodine-129 and 185 Bq (0.005  $\mu$ Ci) of americium-241 each; and
  - b. Displaying the radiation caution symbol described in 12VAC5-481-850 and the words, "CAUTION, RADIOACTIVE MATERIAL," and "Not for Internal or External Use in Humans or Animals."
4. One of the following statements, as appropriate, or a substantially similar statement that contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure that accompanies the package:
  - a. This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the Nuclear Regulatory Commission or of a state with which the Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority.  
 \_\_\_\_\_ Name of manufacturer
  - b. This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of a licensing state.  
 \_\_\_\_\_ Name of manufacturer
5. The label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such radioactive material. In the case of the Mock Iodine-125 reference or calibration source, the information accompanying the source shall also contain directions to the licensee regarding the waste disposal requirements set out in 12VAC5-481-910.
- H. Licensing the manufacture and distribution of ice detection devices. An application for a specific license to manufacture and distribute ice detection devices to persons generally licensed under 12VAC5-481-430 H will be approved if:
  1. The applicant satisfies the general requirements of 12VAC5-481-450;
  2. The applicant submits sufficient information regarding each type of device pertinent to evaluation of the potential radiation exposure, including:
    - a. Chemical and physical form and maximum quantity of strontium-90 in the device;
    - b. Details of construction and design of the source of radiation and its shielding;
    - c. Radiation profile of a prototype device;
    - d. Procedures for and results of prototype testing of devices to demonstrate that the strontium-90 contained in each device will not be released or be removed from the device under the most severe conditions likely to be encountered in normal handling and use;
    - e. Details of quality control procedures to be followed in manufacture of the device;

- f. Description of labeling to be affixed to the device;
  - g. Instructions for handling and installation of the device;
  - h. Any additional information, including experimental studies and tests, required by the agency to facilitate a determination of the safety of the device;
3. Each device will contain no more than 50 microcuries of strontium-90 in an insoluble form;
4. Each device will bear durable, legible labeling that includes the radiation caution symbol prescribed by 12VAC5-481-850, a statement that the device contains strontium-90 and the quantity thereof, instructions for disposal and statements that the device may be possessed pursuant to a general license, that the manufacturer or civil authorities should be notified if the device is found, that removal of the labeling is prohibited, and that disassembly and repair of the device may be performed only by a person holding a specific license to manufacture or service such devices;
5. The agency determines that:
- a. The method of incorporation and binding of the strontium-90 in the device is such that the strontium-90 will not be released from the device under the most severe conditions that are likely to be encountered in normal use and handling of the device;
  - b. The strontium-90 is incorporated or enclosed so as to preclude direct physical contact by any individual with it and is shielded so that no individual will receive a radiation exposure to a major portion of his body in excess of 0.5 rem in a year under ordinary circumstances of use;
  - c. The device is so designed that it cannot be easily disassembled;
  - d. Prototypes of the device have been subjected to and have satisfactorily passed the tests required by subdivision 6 of this subsection;
  - e. Quality control procedures have been established to satisfy the requirements of subdivision 8 of this subsection;
6. The applicant shall subject at least five prototypes of the device to tests as follows:
- a. The devices are subjected to tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment of strontium-90, such as temperature, moisture, absolute pressure, water immersion, vibration, shock, and weathering.
  - b. The devices are inspected for evidence of physical damage and for loss of strontium-90 after each stage of testing, using methods of inspection adequate for determining compliance with the criteria in subdivision 6 c of this subsection.
  - c. Device designs are rejected for which the following has been detected for any unit:
    - (1) A leak resulting in a loss of 0.1% or more of the original amount of strontium-90 from the device;
    - (2) Surface contamination of strontium-90 on the device of more than 2,200 disintegrations per minute per 100 square centimeters of surface area; or
    - (3) Any other evidence of physical damage;
7. The device has been registered in the Sealed Source and Device Registry; and
8. Quality assurance; prohibition of transfer.
- a. Each person licensed under this subsection shall visually inspect each device and shall reject any that has an observable physical defect that could affect containment of the strontium-90.
  - b. Each person licensed under this subsection shall test each device for possible loss of strontium-90 or for contamination by wiping with filter paper an area of at least 100 square centimeters on the outside surface of the device, or by wiping the entire surface area if it is less than 100 square centimeters. The detection on the filter paper of more than 2,200 disintegrations per minute of radioactive material per 100 square centimeters of surface wiped shall be cause for rejection of the tested device.
  - c. Each person licensed under this subsection shall:
    - (1) Maintain quality assurance systems in the manufacture of the ice detection device containing strontium-90 in a manner sufficient to provide reasonable assurance that the safety-related components of the distributed devices are capable of performing their intended functions; and
    - (2) Subject inspection lots to acceptance sampling procedures by procedures specified in subdivision 8 d of this subsection and in the license issued under this subsection, to provide at least 95% confidence that the lot tolerance percent defective of 5.0% will not be exceeded.

d. Each person licensed under this subsection shall subject each inspection lot to:

(1) Tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could possibly affect the effective containment of strontium-90, such as absolute pressure and water immersion.

(2) Inspection for evidence of physical damage, containment failure, or for loss of strontium-90 after each stage of testing using methods of inspection adequate to determine compliance with the following criteria for defective (i) a leak resulting in a loss of 0.1% or more of the original amount of strontium-90 from the device and (ii) any other criteria specified in the license issued under this subsection.

e. No person licensed under this subsection shall transfer to persons generally licensed under 12VAC5-481-430 H, or under an equivalent general license of the NRC or another Agreement state:

(1) Any ice detection device containing strontium-90 tested and found defective under the criteria specified in a license issued under this subsection unless the defective ice detection device has been repaired or reworked, retested, and determined by an independent inspector to meet the applicable acceptance criteria; or

(2) Any ice detection device containing strontium-90 contained within any lot that has been sampled and rejected as a result of the procedures in subdivision 8 c (2) of this subsection, unless:

(i) A procedure for defining sub-lot size, independence, and additional testing procedures is contained in the license issued under this subsection; and

(ii) Each individual sub-lot is sampled, tested, and accepted in accordance with subdivisions 8 c (2) and 8 e (2) (i) of this subsection and any other criteria as may be required as a condition of the license issued under this subsection.

I. Manufacture, preparation, or transfer for commercial distribution of drugs containing radioactive material for medical use under Part VII (12VAC5-481-1660 et seq.) of this chapter.

1. An application for a specific license to manufacture, prepare, or transfer for commercial distribution drugs containing radioactive material for use by persons authorized pursuant to Part VII (12VAC5-481-1660 et seq.) of this chapter will be approved if:

a. The applicant satisfies the general requirements specified in 12VAC5-481-450;

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

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

(2) Registered or licensed with a state agency as a drug manufacturer;

(3) Licensed as a pharmacy by the Virginia Board of Pharmacy;

(4) Operating as a nuclear pharmacy within a federal medical institution; or

(5) A PET drug production facility registered with a state agency;

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

d. The applicant ~~satisfies~~ commits to the following labeling requirements:

(1) A label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The label shall include the radiation symbol as described in 12VAC5-481-850 and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL"; the name of the radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half-life greater than 100 days, the time may be omitted.

(2) A label is affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label shall include the radiation symbol as described in 12VAC5-481-850 and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL" and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

2. A licensee authorized to manufacture, prepare or transfer for commercial distribution radioactive drugs shall ensure that any individual preparing the drugs is one of the following:

a. An authorized nuclear pharmacist (ANP) as defined in 12VAC5-481-10;

b. An individual who meets the requirements specified in 12VAC5-481-1770 and 12VAC5-481-1790, and the licensee has received an approved license amendment identifying this individual as an ANP;

c. A pharmacist, as defined in 12VAC5-481-10, designated as an ANP if:

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

(2) The individual practiced at a pharmacy at a government agency or federally recognized Indian Tribe before November 30, 2007, or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the NRC; or

d. An individual under the supervision of an ANP as specified in 12VAC5-481-1710.

3. Shall provide to the agency no later than 30 days after the date that the licensee allows, under subdivision 2 a or c of this subsection, the individual to work as an ANP:

a. The individual's certification by a specialty board whose certification process has been recognized by the NRC ~~with the written attestation signed by a preceptor as required by 12VAC5-481-1770~~ as specified in 12VAC5-481-1770;

b. An NRC or another Agreement state license;

c. NRC master materials licensee permit;

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

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

f. The Virginia Board of Pharmacy's license.

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

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

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

5. A licensee shall satisfy the labeling requirements in subsection 11 d of this section.

6. Nothing in this subsection relieves the licensee from complying with applicable FDA, other federal, and state requirements governing radioactive drugs.

~~7.~~ 7. Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination in accordance with 12VAC5-481-1930. The licensee shall record the results of each test and retain each record for three years after the record is made.

J. Manufacture and distribution of sources or devices containing radioactive material for medical use. An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to Part VII (12VAC5-481-1660 et seq.) of this chapter for the medical use of radioactive material or use as a calibration, transmission or reference source will be approved if:

1. The applicant satisfies the general requirements in 12VAC5-481-450;

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

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

b. Details of design and construction of the source or device;

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



- d. For devices containing radioactive material, the radiation profile of a prototype device;
  - e. Details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests;
  - f. Procedures and standards for calibrating sources and devices;
  - g. Legend and methods for labeling sources and devices as to their radioactive content; and
  - h. Instructions for handling and storing the source or device from the radiation safety standpoint; these instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device provided, that instructions that are too lengthy for such label may be summarized on the label and printed in detail on a brochure that is referenced on the label;
3. The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity, and date of assay, and a statement that the source or device is licensed by the agency for distribution to persons licensed pursuant to Part VII (12VAC5-481-1660 et seq.) of this chapter for the medical use of radioactive material or under equivalent licenses of the NRC, or another Agreement state, provided that such labeling for sources that do not require long-term storage may be on a leaflet or brochure that accompanies the source;
4. In the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than six months, the applicant shall include sufficient information to demonstrate that such longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source;
5. In determining the acceptable interval for test of leakage of radioactive material, the agency will consider information that includes, but is not limited to:
- a. Primary containment or source capsule;
  - b. Protection of primary containment;
  - c. Method of sealing containment;
  - d. Containment construction materials;
  - e. Form of contained radioactive material;
  - f. Maximum temperature withstood during prototype tests;
  - g. Maximum pressure withstood during prototype tests;
  - h. Maximum quantity of contained radioactive material;
  - i. Radiotoxicity of contained radioactive material; and
  - j. Operating experience with identical sources or devices or similarly designed and constructed sources or devices; and
6. The device has been registered in the Sealed Source and Device Registry.
- K. Requirements for license to manufacture and distribute industrial products containing depleted uranium for mass-volume applications.
1. An application for a specific license to manufacture industrial products and devices containing depleted uranium for use pursuant to 12VAC5-481-420 C or equivalent regulations of the NRC or another Agreement state will be approved if:
- a. The applicant satisfies the general requirements specified in 12VAC5-481-450;
  - b. The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses, and potential hazards of the industrial product or device to provide reasonable assurance that possession, use, or transfer of the depleted uranium in the product or device is not likely to cause any individual to receive in any period of one calendar quarter a radiation dose in excess of 10% of the limits specified in 12VAC5-481-640; and
  - c. The applicant submits sufficient information regarding the industrial product or device and the presence of depleted uranium for a mass-volume application in the product or device to provide reasonable assurance that unique benefits will accrue to the public because of the usefulness of the product or device.
2. In the case of an industrial product or device whose unique benefits are questionable, the agency will approve an application for a specific license under this subsection only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal

and dispersal of significant quantities of depleted uranium into the environment.

3. The agency may deny any application for a specific license under this subsection if the end use or uses of the industrial product or device cannot be reasonably foreseen.

4. Each person licensed pursuant to subdivision 1 of this subsection shall:

a. Maintain the level of quality control required by the license in the manufacture of the industrial product or device, and in the installation of the depleted uranium into the product or device;

b. Label or mark each unit to:

(1) Identify the manufacturer or initial transferor of the product or device and the number of the license under which the product or device was manufactured or initially transferred, the fact that the product or device contains depleted uranium, and the quantity of depleted uranium in each product or device; and

(2) State that the receipt, possession, use, and transfer of the product or device are subject to a general license or the equivalent and the regulations of the NRC or another Agreement state;

c. Assure that the depleted uranium before being installed in each product or device has been impressed with the following legend clearly legible through any plating or other covering: "Depleted Uranium";

d. Do the following:

(1) Furnish a copy of the general license contained in 12VAC5-481-420 C and a copy of agency form "Certificate - Use of Depleted Uranium under a General License" to each person to whom depleted uranium in a product or device for use pursuant to the general license contained in 12VAC5-481-420 C is transferred; or

(2) Furnish a copy of the general license contained in the NRC's or another Agreement state's regulation equivalent to 12VAC5-481-420 B and a copy of the NRC's or another Agreement state's certificate, or alternatively, furnish a copy of the general license contained in 12VAC5-481-420 C and a copy of agency form "Certificate - Use of Depleted Uranium under a General License" to each person to whom depleted uranium in a product or device for use pursuant to the general license of the NRC or another Agreement state is transferred, with a note explaining that use of the product or device is regulated by the NRC or another Agreement state under requirements substantially the same as those in 12VAC5-481-420 C;

e. Report to the agency all transfers of industrial products or devices to persons for use under the general license in 12VAC5-481-420 C. Such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the agency and the general licensee, the type and model number of device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such a product or device is transferred to the generally licensed person. If no transfers have been made to persons generally licensed under 12VAC5-481-420 C during the reporting period, the report shall so indicate;

f. Do the following:

(1) Report to the NRC all transfers of industrial products or devices to persons for use under the NRC general license in 10 CFR 40.25;

(2) For devices transferred to another Agreement state, report to the responsible state agency all transfers of devices manufactured and distributed pursuant to this subsection for use under a general license in that state's regulations equivalent to 12VAC5-481-420 C;

(3) Such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the agency and the general licensee, the type and model number of the device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such product or device is transferred to the generally licensed person;

(4) If no transfers have been made to NRC licensees during the reporting period, this information shall be reported to the NRC; and

(5) If no transfers have been made to general licensees within another Agreement state during the reporting period, this information shall be reported to the responsible state agency upon the request of that agency; and keep records showing the name, address, and point of contact for each general licensee to whom he transfers depleted uranium in industrial products or devices for use pursuant to the general license provided in 12VAC5-481-420 C or equivalent regulations of the NRC or another Agreement state. The records shall be maintained for a period of two years and shall show the date of each transfer, the quantity of depleted uranium in each product or device transferred, and compliance with the report requirements of this section.

L. Serialization of nationally tracked sources. Each licensee who manufactures a nationally tracked source shall assign a unique serial number to each nationally tracked source. Serial numbers shall be composed only of alpha-numeric characters.

**12VAC5-481-590. Reciprocal recognition of licenses.**

Licenses of radioactive, source, and special nuclear material in quantities not sufficient to form a critical mass.

1. Subject to these regulations, any person who holds a specific license from the NRC or another Agreement state, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within the Commonwealth for a period not in excess of 180 days during the one-year reciprocal approval period, provided that:

a. The licensing document does not limit the activity authorized by such document to specified installations or locations;

b. The out-of-state licensee notifies the agency ~~in writing~~ using Applications for Reciprocal Recognition of Out-of-State Radioactive Materials License and Reciprocity Notification forms at least three days prior to engaging in such activity. Such notification shall indicate the location, period, and type of proposed possession and use within the state, and shall be accompanied by a copy of the pertinent licensing document. If, for a specific case, the three-day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the agency, obtain permission to proceed sooner. The agency may waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities under the general license provided in this subdivision;

c. The out-of-state licensee complies with all applicable regulations of the agency and with all the terms and conditions of the licensing document, except any such terms and conditions that may be inconsistent with applicable regulations of the agency;

d. The out-of-state licensee supplies such other information as the agency may request;

e. The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in this subdivision except by transfer to a person:

(1) Specifically licensed by the agency, the NRC or another Agreement state to receive such material, or

(2) Exempt from the requirements for a license for such material under 12VAC5-481-400 A; and

f. The out-of-state licensee submits the payment required by 12VAC5-490-40 to the agency.

2. Notwithstanding the provisions of subdivision 1 of this section, any person who holds a specific license issued by the NRC or another Agreement state authorizing the holder to manufacture, transfer, install, or service a device described in 12VAC5-481-430 B within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate, or service such a device in this state provided that:

a. Such person shall file a report with the agency within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this state. Each such report shall identify each general licensee to whom such device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;

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

c. Such person shall assure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that "Removal of this label is prohibited"; and

d. The holder of the specific license shall furnish to each general licensee to whom he transfers such device or on whose premises he installs such device a copy of the general license contained in 12VAC5-481-430 B or in equivalent regulations of the agency having jurisdiction over the manufacture and distribution of the device.

3. The agency may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by the NRC or another Agreement state, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.

**12VAC5-481-1350. Personnel monitoring.**

A. The licensee or registrant 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 ~~combination of direct reading dosimeter, an operating alarming ratemeter, and either a film badge, an optically stimulated luminescence (OSL) dosimeter or a thermoluminescent dosimeter (TLD)~~ a personnel dosimeter. At permanent radiographic installations where other appropriate alarming or warning devices are in routine use, or during radiographic operations using radiation machines, the ~~use~~ wearing of an alarming ratemeter is not required.

1. Pocket dosimeters must have a range from 0 to 2 mSv (200 mrem) and must be recharged at the start of each shift. Electronic personal dosimeters may only be used in place of ion-chamber pocket dosimeters.
  2. Each ~~film badge, OSL or TLD~~ personnel dosimeter must be assigned to and worn by only one individual.
  3. Film badges must be exchanged monthly ~~OSLs or TLDs must be exchanged, and all other dosimeters that require replacement must be exchanged~~ at periods not to exceed three months. All personnel dosimeters must be evaluated at periods not to exceed three months or promptly after replacement, whichever is more frequent.
  4. ~~After replacement, each film badge, OSL or TLD must be returned to the supplier for processing within 14 calendar days of the end of the monitoring period, or as soon as practicable. In circumstances that make it impossible to return each film badge, OSL or TLD in 14 calendar days, such circumstances must be documented and available for review by the agency.~~
- B. Direct reading dosimeters, such as pocket dosimeters or electronic personal dosimeters, must be read and the exposures recorded at the beginning and end of each shift, and records must be maintained in accordance with 12VAC5-481-1490.
- C. Pocket dosimeters, or electronic personal dosimeters, must be checked at periods not to exceed 12 months for correct response to radiation, and records must be maintained in accordance with 12VAC5-481-1490. Acceptable dosimeters must read within plus or minus 20% of the true radiation exposure.
- D. If an individual's pocket dosimeter is found to be off-scale, or the electronic personal dosimeter reads greater than 2 mSv (200 mrem), the individual's ~~film badge, OSL or TLD~~ personnel dosimeter must be sent for processing within 24 hours. For personnel dosimeters that do not require processing, evaluation of the dosimeter must be started within 24 hours. In addition, the individual may not resume work associated with the use of sources of radiation until a determination of the individual's radiation exposure has been made. This determination must be made by the radiation safety officer or the radiation safety officer's designee. The results of this determination must be included in the records maintained in accordance with 12VAC5-481-1490.
- E. ~~If a film badge, OSL or TLD~~ the personnel dosimeter is lost or damaged, the worker shall cease work immediately until a replacement ~~film badge, OSL or TLD~~ personnel dosimeter meeting the requirements of subsection A of this section is provided and the exposure is calculated for the time period from issuance to loss or damage of the ~~film badge, OSL or TLD~~ personnel dosimeter. The results of the calculated exposure and the time period for which the ~~film badge, OSL or TLD~~ personnel dosimeter was lost or damaged must be included in the records maintained in accordance with 12VAC5-481-1490.
- F. ~~Reports received from the film badge, OSL or TLD processor~~ Dosimetry results must be retained in accordance with 12VAC5-481-1490.
- G. Each alarming ratemeter must:
1. Be checked to ensure that the alarm functions properly before using at the start of each shift;
  2. Be set to give an alarm signal at a preset dose rate of 5 mSv (500 mrem) per hour with an accuracy of plus or minus 20% of the true radiation dose rate;
  3. Require special means to change the preset alarm function; and
  4. Be calibrated at periods not to exceed 12 months for correct response to radiation. The licensee shall maintain records of alarming ratemeter calibrations in accordance with 12VAC5-481-1490.

#### **12VAC5-481-1490. Records of personnel monitoring.**

Each licensee or registrant shall maintain the following exposure records specified in 12VAC5-481-1350:

1. Direct reading dosimeter readings and yearly operability checks required by 12VAC5-481-1350 B and 12VAC5-481-1350 C for three years after the record is made;
2. Records of alarming ratemeter calibrations for three years after the record is made;
3. ~~Reports received from the film badge, OSL or TLD processor~~ Personnel dosimeter results until the agency terminates the license or registration; and
4. Records of estimates of exposures as a result of off-scale personal direct reading dosimeters; or lost or damaged ~~film badges, OSL or TLD's,~~ personnel dosimeters until the agency terminates the license or registration.

#### **12VAC5-481-1690. Notifications.**

A. Licensees shall provide the agency the following information for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user, an authorized nuclear pharmacist, an ophthalmic physicist, or an authorized medical physicist:

1. A copy of (i) the board certification, (ii) the written attestation signed by a preceptor, and (iii) the NRC or another Agreement state license;
2. The permit issued by a NRC master material licensee;

3. The permit issued by a broad scope licensee;
  4. The permit issued by a NRC master material broad scope permittee; or
  5. Documentation that only accelerator-produced radioactive materials, discrete sources of radium-226, or both, were used for medical use or in the practice of nuclear pharmacy at a government agency or federally recognized Indian tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC.
  6. For individuals permitted to work within the 30-day time frame, the licensee shall also provide, as appropriate, verification of completion of:
    - a. Any additional case experience required in 12VAC5-481-1980 2 b (7) for an authorized user under 12VAC5-481-1950;
    - b. Any additional training required in 12VAC5-481-2040 A 4 for an authorized user under 12VAC5-481-2040 A; or
    - c. Any additional training required in 12VAC5-481-1760 A 3 for an authorized medical physicist.
- B. A licensee shall notify the agency no later than 30 days after:
1. An authorized user, an authorized nuclear pharmacist, a radiation safety officer, an associate radiation safety officer, an ophthalmic physicist, or an authorized medical physicist permanently discontinues performance of duties under the license or has a name change;
  2. The licensee permits an authorized user or an individual qualified to be a radiation safety officer, under 12VAC5-481-1750 and 12VAC5-481-1790, to function as a temporary radiation safety officer and to perform the functions of a radiation safety officer in accordance with 12VAC5-481-1700 C;
  3. The licensee's mailing address changes;
  4. The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in 12VAC5-481-500 B; or
  5. The licensee has added to or changed the areas of use identified in the application or on the license where radioactive material is used in accordance with either 12VAC5-481-1900 or 12VAC5-481-1920 if the change does not include addition or relocation of either an area where PET radionuclides are produced or a PET radioactive drug delivery line from the PET radionuclide/PET radioactive drug production area.
- C. The licensee shall send the documents required in this section to the appropriate address identified in 12VAC5-481-150.

**12VAC5-481-1700. Authority and responsibilities for the radiation protection programs and changes.**

- A. In addition to the radiation protection program requirements of 12VAC5-481-630, the licensee's management or designee shall approve, in writing:
1. Requests for a license application, renewal, or amendment before submittal to the agency;
  2. Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist, or an authorized medical physicist; and
  3. Radiation protection program changes that do not require a license amendment and are permitted under subsection F of this section.
- B. The licensee's management shall appoint a radiation safety officer (RSO) who agrees, in writing, to be responsible for implementing the radiation protection program. ~~This written document shall establish the authority, duties, and responsibilities of the RSO. Licensees, through the RSO, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements. Licensees shall provide the RSO sufficient authority, organization freedom, time, resources, and management prerogative to:~~
- ~~1. Identify radiation safety problems;~~
  - ~~2. Initiate, recommend, or provide corrective actions;~~
  - ~~3. Stop unsafe operations; and~~
  - ~~4. Verify implementation of corrective actions.~~

The licensee, through the RSO, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements. A licensee's management may appoint, in writing, one or more associate radiation safety officers to support the RSO. The RSO, with written agreement of the licensee's management, must assign the specific duties and tasks to each associate RSO. These duties and tasks are restricted to the types of use for which the associate radiation safety officer is listed on a license. The RSO may delegate duties and tasks to the associate radiation safety officer but shall not delegate the authority or responsibilities for implementing the radiation protection program.

- C. For up to 60 days each year, licensees may permit an authorized user or an individual qualified to be a RSO, under 12VAC5-481-1750 and 12VAC5-481-1790, to function as a temporary radiation safety officer, as provided in subsection G if the licensee takes the actions required in subsections B, E, G, and H of this section and notifies the agency in accordance with 12VAC5-481-1690 B.

D. Licensees may simultaneously appoint more than one temporary RSO in accordance with subsection C of this section, if needed to ensure that the temporary RSO satisfies the requirements to be a RSO for each of the different types of uses of radioactive material permitted by the licensee.

E. Licensees that are authorized for two or more different types of uses of radioactive material under Articles 6, 7, and 9 of this part, or two or more types of units under 12VAC5-481-2040 B, shall establish a Radiation Safety Committee (RSC) to oversee all uses of radioactive material permitted by the license. The RSC shall include an authorized user for each type of use permitted by the license, the RSO, a representative of the nursing service, and a representative of management who is neither an authorized user nor a RSO. The RSC may include other members the licensee considers appropriate.

F. A licensee may revise its radiation protection program without agency approval if:

1. The revision does not require a license amendment under 12VAC5-481-450 or 12VAC5-481-1680;
2. The revision is in compliance with this chapter and the license;
3. The revision has been reviewed and approved by the RSO and licensee management; and
4. The affected individuals are instructed on the revised program before the changes are implemented.

#### **12VAC5-481-1720. Written directives.**

A. A written directive shall be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 30 microcuries ( $\mu\text{Ci}$ ) (1.11 megabecquerels (MBq)), any therapeutic dose of unsealed radioactive material, or any therapeutic dose of radiation from radioactive material.

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive shall be documented as soon as possible in writing in the patient's record. A written directive shall be prepared within 48 hours of the oral directive.

B. The written directive shall contain the patient or human research subject's name and the following information:

1. For any administration of quantities greater than 30  $\mu\text{Ci}$  (1.11 MBq) of sodium iodide (I-131): the dosage;
2. For an administration of a therapeutic dosage of unsealed radioactive material other than sodium iodide (I-131): the radioactive drug, dosage, and route of administration;
3. For gamma stereotactic radiosurgery: the total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site;
4. For teletherapy: the total dose, dose per fraction, number of fractions, and treatment site;
5. For high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or
6. For permanent implant brachytherapy:

a. Before implantation: treatment site, the radionuclide, and the total source strength; and

b. After implantation but before the patient leaves the post-treatment recovery area: treatment site, number of sources implanted, total source strength implanted, and the date; or

7. For all other brachytherapy, including low, medium and pulsed dose rate remote afterloaders:

- a. Before implantation: treatment site, the radionuclide, and dose; and
- b. After implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose) and date.

C. A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of radioactive drug containing radioactive material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision shall be documented as soon as possible in the patient's record. A revised written directive shall be signed by the authorized user within 48 hours of the oral revision.

#### **12VAC5-481-1730. Procedures for administrations requiring a written directive.**

For any administration requiring a written directive, licensees shall develop, implement, and maintain written directive procedures to provide high confidence that the patient's or human research subject's identity is verified before each administration and each administration is in accordance with the written directive. A licensee shall retain a copy of the procedures required by this section in accordance with 12VAC5-481-2070. At a minimum, the procedures required by this section shall address the following items that are applicable to the licensee's use of radioactive material:

1. Verifying the identity of the patient or human research subject;
2. Verifying that the specific details of the administration are in accordance with the treatment plan, if applicable, and the written directive;
3. Checking both manual and computer-generated dose calculations; ~~and~~
4. Verifying that all computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by 12VAC5-481-2040 B; and C and 12VAC5-481-2060;

5. Determining if a medical event, as defined in 12VAC5-481-2080, has occurred; and

6. Determining, for permanent implant brachytherapy, within 60 calendar days from the date the implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation portion of the written directive unless a written justification of patient unavailability is documented.

**12VAC5-481-1750. Training for radiation safety officer and associate radiation safety officer.**

Except as provided in 12VAC5-481-1780, licensees shall require an individual fulfilling the responsibilities of the radiation safety officer (RSO) or an individual assigned duties and tasks as an associate radiation safety officer as provided in 12VAC5-481-1700 to be an individual who:

1. Is certified by a specialty board who has been recognized by the agency, the NRC, or an agreement state and who meets the requirements of subdivision 5 of this section. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit Web page. To have its certification process recognized, a specialty board shall require all candidates for certification to (i) hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science; (ii) have five or more years of professional experience in health physics (graduate training may be substituted for no more than two years of the required experience) including at least three years in applied health physics; and (iii) pass an examination administered by diplomates of the specialty board that evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or

2. Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; has two years of full-time practical training or supervised experience in medical physics (i) under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the agency, NRC, or an agreement state or (ii) in clinical nuclear medicine facilities providing diagnostic or therapeutic services under the direction of physicians who meet the requirements for authorized users in 12VAC5-481-1780, 12VAC5-481-1940, or 12VAC5-481-1980; and has passed an examination administered by diplomates of the specialty board that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or

3. Has completed a structured educational program consisting of provisions, as follows:

a. 200 hours of classroom and laboratory training in the following areas:

- (1) Radiation physics and instrumentation;
- (2) Radiation protection;
- (3) Mathematics pertaining to the use and measurement of radioactivity;
- (4) Radiation biology; and
- (5) Radiation dosimetry; and

b. One year of full-time radiation safety experience under the supervision of the individual identified as the RSO on an agency, NRC, or another agreement state license or permit issued by ~~a~~ an NRC master material licensee that authorizes similar types of uses of radioactive material involving. An associate radiation safety officer may provide supervision for those areas for which the associate radiation safety officer is authorized on an agency, NRC, or another agreement state license or permit issued by an NRC master material licensee. The full-time radiation safety experience must involve the following:

- (1) Shipping, receiving, and performing related radiation surveys;
- (2) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;
- (3) Securing and controlling radioactive material;
- (4) Using administrative controls to avoid mistakes in the administration of radioactive material;

(5) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

(6) Using emergency procedures to control radioactive material; and

(7) Disposing of radioactive material; ~~or and~~

c. This individual must obtain a written attestation signed by a preceptor radiation safety officer or associate radiation safety officer who has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual is seeking approval as a radiation safety officer or an associate radiation safety officer. The written attestation must state that the individual has satisfactorily completed the requirements in subdivisions 3 a, 3 b, and 5 of this section and is able to independently fulfill the radiation safety-related duties as a radiation safety officer or has an associate radiation safety officer for a medical use licensee; or

~~3. 4.~~ Meets the following qualifications:

a. Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the agency, NRC, or an agreement state under subdivision 1 of 12VAC5-481-1760 ~~4~~ and has experience in radiation safety for similar types of use of radioactive material for which the licensee is seeking the approval of the individual as RSO or an associate radiation safety officer and who meets the requirements in subdivisions 4 and subdivision 5 of this section; or

b. Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist (i) identified on the an agency, NRC, or another agreement state license and; a permit issued by a NRC master material licensee; a permit issued by an agency, NRC, or another agreement state board scope licensee; or a permit issued by a NRC master material license board scope permittee; (ii) has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual has RSO or associate radiation safety officer responsibilities; and (iii) meets subdivisions 4 and subdivision 5 of this section; ~~and or~~

c. Has experience with the radiation safety aspects of the types of use of radioactive material for which the individual is seeking simultaneous approval both as a radiation safety officer and the authorized user on the same new medical use license or new medical use permit issued by a NRC master material license. The individual must also meet the requirements in subdivision 5 of this section.

~~4. 5.~~ Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a RSO, an associate radiation safety officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the types of use for which the licensee is seeking approval; ~~and~~

~~5. Has obtained written attestation, signed by a preceptor RSO, that the individual has satisfactorily completed the requirements in subdivisions 1, 2, or 3; and 4 of this section, and has achieved a level of radiation safety knowledge sufficient to function independently as a RSO for a medical use licensee.~~

#### **12VAC5-481-1760. Training for an authorized medical physicist.**

Except as provided in 12VAC5-481-1780, licensees shall require the authorized medical physicist (AMP) to be an individual who:

1. Is certified by a specialty board whose certification process has been recognized by the agency, NRC, or an agreement state and who meets the requirements of subdivision 4 of this section. The name of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

a. Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

b. Have two years of full-time practical training or supervised experience in medical physics (i) under the supervision of a medical physicist who is certified in medical physics by a specialty board whose certification process has been recognized under this section by the agency, the NRC, or an agreement state; or (ii) in clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements in 12VAC5-481-1780, 12VAC5-481-2018, or 12VAC5-481-2040; and

c. Pass an examination, administered by diplomates of the specialty board that assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery; or

2. Meets the following requirements:

a. Holds a master's or doctor's degree in physics, biophysics, radiological physics, medical physics, health physics, other physical science, engineering, or applied mathematics from an accredited college or university or an equivalent training program approved by the agency, the NRC, or another Agreement state and has completed one year of full-time training in medical physics and an additional year of full-time practical



experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the types of use for which the individual is seeking authorization. This training and work experience shall be conducted in clinical radiation facilities that provide high-energy, external beam therapy (photons and electrons with energies greater than or equal to one million electron volts) and brachytherapy services and shall include:

- (1) Performing sealed source leak tests and inventories;
- (2) Performing decay corrections;
- (3) Performing full calibration and periodic spot-checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and
- (4) Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

3. Has training for the types of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the types of use for which the individual is seeking authorization; and

4. Has obtained written attestation that the individual has satisfactorily completed the requirements of subdivisions ~~1 or 2~~ and 3 of this section; ~~and has achieved a level of competency sufficient to function independently as an authorized medical physicist~~ is able to independently fulfill the radiation safety-related duties as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation shall be signed by a preceptor authorized medical physicist who meets the requirements in 12VAC5-481-1760, 12VAC5-481-1780, or equivalent NRC or agreement state requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status.

#### **12VAC5-481-1770. Training for an authorized nuclear pharmacist.**

Except as provided in 12VAC5-481-1780, licensees shall require the authorized nuclear pharmacist (ANP) to be a pharmacist who:

1. Is certified by a specialty board whose certification process has been recognized by the NRC; ~~or, the agency, or an agreement state. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit web page.~~ To have its certification process recognized, a specialty board shall require all candidates for certification to:

a. Have graduated from a pharmacy program accredited by the American Council on Pharmaceutical Education (ACPE) or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;

b. Hold a current, active license to practice pharmacy;

c. Provide evidence of having acquired at least 4000 hours of training or experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2000 hours of the required training and experience; and

d. Pass an examination in nuclear pharmacy administered by diplomates of the specialty board that assesses knowledge and competency in procurement, compounding, quality assurance, dispensing, distribution, health and safety, radiation safety, provision of information and consultation, monitoring patient outcomes, research, and development; or

2. Meets the following requirements:

a. Has completed 700 hours in a structured educational program consisting:

(1) 200 hours of classroom and laboratory training in the following areas:

- (a) Radiation physics and instrumentation;
- (b) Radiation protection;
- (c) Mathematics pertaining to the use and measurement of radioactivity;
- (d) Chemistry of byproduct material for medical use; and
- (e) Radiation biology; and

(2) Supervised practical experience in a nuclear pharmacy involving:

- (a) Shipping, receiving, and performing related radiation surveys;

- (b) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha-emitting or beta-emitting radionuclides;
- (c) Calculating, assaying, and safely preparing dosages for patients or human research subjects;
- (d) Using administrative controls to avoid medical events in the administration of radioactive material; and
- (e) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

3. Has obtained written attestation, signed by a preceptor ANP, that the individual has satisfactorily completed the requirements in subdivision 4 or 2 of this section and ~~has achieved a level of competency sufficient to function independently as an ANP~~ is able to independently fulfill the radiation safety-related duties as an authorized nuclear pharmacist.

**12VAC5-481-1780. Training for experienced radiation safety officer, teletherapy or medical physicist, authorized medical physicist, nuclear pharmacist, authorized nuclear pharmacist, and authorized user.**

A. The following applies to individuals with experience as a radiation safety officer (RSO), teletherapy or medical physicist, ~~authorized medical physicist (AMP), nuclear pharmacist,~~ or authorized nuclear pharmacist (ANP):

1. An individual identified ~~as an RSO, AMP, or ANP on a specific an agency, NRC, or agreement state~~ license or a permit issued by the agency, the NRC, or another agreement state; broad scope licensee or master material license permit; or by a master material license permittee of broad scope ~~that authorizes medical use or the practice of nuclear pharmacy as a RSO, a teletherapy or medical physicist, AMP, a nuclear pharmacist, or an ANP~~ on or before October 24, 2002 January 14, 2019, need not comply with the training requirements of 12VAC5-481-1750, 12VAC5-481-1760, or 12VAC5-481-1770, respectively, ~~except the RSO and AMP identified in this subdivision must meet the training requirements in subdivision 5 of 12VAC5-481-1750 or subdivision 3 of 12VAC5-481-1760, as appropriate, for any material or uses for which they were not authorized prior to this date.~~

2. An individual identified ~~as an RSO, AMP, or ANP on a license or a permit issued by a the agency, NRC, or another agreement state broad scope licensee or master material license permit or by a master material license permittee of broad scope between October 24, 2002, and April 29, 2005,~~ need not comply with the training requirements of 12VAC5-481-1750, 12VAC5-481-1760, or 12VAC5-481-1770, respectively: certified by the American Board of Health Physics in Comprehensive Health Physics, American Board of Radiology, American Board of Nuclear Medicine, American Board of Science in Nuclear Medicine, Board of Pharmaceutical Specialties in Nuclear Pharmacy, American Board of Medical Physics in Radiation Oncology Physics, Royal College of Physicians and Surgeons of Canada in Nuclear Medicine, American Osteopathic Board of Radiology, or American Osteopathic Board of Nuclear Medicine on or before October 24, 2005, need not comply with the training requirements of 12VAC5-481-1750 to be identified as an RSO or as an associate RSO on an agency, NRC, or another agreement state license or NRC master material permit for those materials and uses that these individuals performed on or before October 24, 2005. Any individual certified by the American Board of Radiology in therapeutic radiological physics, Roentgen ray and gamma ray physics, x-ray and radium physics, or radiological physics, or certified by the American Board of Medical Physics in radiation oncology physics, on or before October 24, 2005, need not comply with the training requirements for an authorized medical physicist described in 12VAC5-481-1760 for those materials and uses that these individuals performed on or before October 24, 2005.

3. An RSO, AMP, or ANP, who used only accelerator-produced radioactive materials or discrete sources of radium-226, or both, for medical uses or in the practice of nuclear pharmacy at a government agency or federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of 12VAC5-481-1750, 12VAC5-481-1760, or 12VAC5-481-1770, respectively, when performing the same uses. A nuclear pharmacist, who prepared only radioactive drugs containing accelerator-produced radioactive materials, or a medical physicist, who used only accelerator-produced radioactive materials, at the locations and time period identified in this subdivision, qualifies as an authorized nuclear pharmacist or an authorized medical physicist, respectively, for those materials and uses performed before these dates, for purposes of this part.

B. The following applies to experienced authorized users (AU):

1. Physicians, dentists, or podiatrists identified as AUs for the medical use of radioactive material on a license issued by the agency, the NRC, or another Agreement state; a permit issued by an NRC master material licensee; a permit issued by an agency, NRC, or other Agreement state broad scope licensee; or a permit issued by an NRC master material license broad scope permittee ~~on or before October 24, 2002~~ January 14, 2019, who perform only those medical uses for which they were authorized ~~on or before~~ on or before that date need not comply with the training requirements of Articles 5 (12VAC5-481-1900 et seq.) through 9 (12VAC5-481-2040 et seq.) of this part.

2. Physicians, dentists, or podiatrists identified as AUs for the medical use of radioactive material on a license issued by the agency, the NRC, or another Agreement state; a permit issued by an NRC master material licensee; a permit issued by an agency, NRC, or other Agreement state broad scope licensee; or a permit issued by an NRC master material license broad scope permittee ~~who perform only those medical uses for which they were authorized between~~ on or before October 24, 2002, and ~~April 29, 2005~~ 2005, need not comply with the training requirements of Articles 5

(12VAC5-481-1900 et seq.) through 9 (12VAC5-481-2040 et seq.) of this part for those materials and uses that these individuals performed on or before October 24, 2005, as follows:

a. For uses authorized under 12VAC5-481-1900 or 12VAC5-481-1920, or oral administration of sodium iodide I-131 requiring a written directive for imaging and localization purposes, a physician who was certified on or before October 24, 2005, in nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology by the American Board of Radiology; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or American Osteopathic Board of Nuclear Medicine in nuclear medicine;

b. For uses authorized under 12VAC5-481-1950, a physician who was certified on or before October 24, 2005, by the American Board of Nuclear Medicine; the American Board of Radiology in radiology, therapeutic radiology, or radiation oncology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or the American Osteopathic Board of Radiology after 1984;

c. For uses authorized under 12VAC5-481-2010 or 12VAC5-481-2040, a physician who was certified on or before October 24, 2005, in radiology, therapeutic radiology or radiation oncology by the American Board of Radiology; radiation oncology by the American Osteopathic Board of Radiology; radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; and

d. For uses authorized under 12VAC5-481-2020, a physician who was certified on or before October 24, 2005, in radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or nuclear medicine by the Royal College of Physicians and Surgeons of Canada.

3. Physicians, dentists, or podiatrists who used only accelerator-produced radioactive materials or discrete sources of radium-226, or both, for medical uses performed at a government agency or federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of Articles 5 (12VAC5-481-1900 et seq.) through 9 (12VAC5-481-2040 et seq.) of this part when performing the same medical uses. A physician, dentist, or podiatrist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both for medical uses at the locations and time period identified in this subdivision, qualifies as an AU for those materials and uses performed before these dates for purposes of this chapter.

C. Individuals who need not comply with training requirements as described in this section may serve as preceptors for, and supervisors of, applicants seeking authorization on NRC licenses for the same uses for which these individuals are authorized.

#### **12VAC5-481-1910. Training for uptake, dilution, and excretion studies.**

Except as provided in 12VAC5-481-1780, licensees shall require an authorized user of unsealed radioactive material for the uses authorized under 12VAC5-481-1900 to be a physician:

1. Who is certified by a medical specialty board whose certification process has been recognized by the NRC ~~and who meets the requirements in subdivision 3 b of this section,~~ the agency, or an agreement state. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit Web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

a. Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies as described in subdivisions 3 a (1) through 3 a (2) (f) of this section; and

b. Pass an examination administered by diplomates of the specialty board that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

2. Who is an authorized user under 12VAC5-481-1940, 12VAC5-481-1980, or equivalent NRC or other Agreement state requirements; or

3. Who has:

a. Completed 60 hours of training and experience, including a minimum of eight hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies. The training and experience shall include the following:

(1) Classroom and laboratory training in the following areas:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

(c) Mathematics pertaining to the use and measurement of radioactivity;

(d) Chemistry of radioactive material for medical use; and

(e) Radiation biology; and

(2) Work experience under the supervision of an authorized user who meets the requirements in this section, 12VAC5-481-1780, 12VAC5-481-1940, 12VAC5-481-1980, or equivalent NRC or other Agreement state requirements, involving:

(a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(b) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(c) Calculating, measuring, and safely preparing patient or human research subject dosages;

(d) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

(e) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

(f) Administering dosages of radioactive drugs to patients or human research subjects; and

b. ~~Obtained written attestation, signed by a preceptor authorized user who meets the requirements in this section, 12VAC5-481-1780, 12VAC5-481-1940, or 12VAC5-481-1980, or equivalent NRC or other agreement state requirements,~~ that the individual has satisfactorily completed the requirements in ~~subdivisions 1 a or~~ subdivision 3 a of this section and ~~has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 12VAC5-481-1900: is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under 12VAC-481-1900.~~ The attestation must be obtained from either:

(1) A preceptor authorized user who meets the requirements in this section, 12VAC5-481-1780, 12VAC5-481-1940, or 12VAC5-481-1980 or equivalent NRC or other agreement state requirements; or

(2) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in this section, 12VAC5-481-1780, 12VAC5-481-1940, or 12VAC5-481-1980 or equivalent NRC or other agreement state requirements and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subdivision 3 a of this section.

#### **12VAC5-481-1930. Permissible molybdenum-99, strontium-82, and strontium-85 concentrations.**

A. Licensees may not administer to humans a radiopharmaceutical that contains:

1. More than 0.15  $\mu\text{Ci}$  of molybdenum-99 per mCi of technetium-99m (0.15 kBq of molybdenum-99 per MBq of technetium-99m); or
2. More than 0.02  $\mu\text{Ci}$  of strontium-82 per mCi of rubidium-82 chloride (0.02 kBq of strontium-82 per MBq of rubidium-82 chloride injection) or more than 0.2  $\mu\text{Ci}$  of strontium-85 per mCi of rubidium-82 (0.2 kBq of strontium-85 per MBq of rubidium-82 chloride injection).

~~B. To demonstrate compliance with subsection A of this section, the licensee preparing the radioactive drug from the radionuclide generator shall:~~

- ~~1. Measure the concentration of radionuclide contaminant in the first eluate after receipt of a molybdenum-99/technetium-99m generator;~~
- ~~2. Measure the concentration of radionuclide contaminant in each eluate or extract, as appropriate for other generator systems, not to exceed before the first patient use of the day for a strontium/rubidium-82 generator.~~

B. A licensee that uses molybdenum-99/technetium-99m for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration in each eluate from a generator to demonstrate compliance with subsection A of this section.

C. A licensee that uses a strontium-82/rubidium-82 generator for preparing a rubidium-82 radiopharmaceutical shall, before the first patient use of the day, measure the concentration of radionuclides strontium-82 and strontium-82 to demonstrate compliance with subsection A of this section.

D. If a licensee is required to measure the molybdenum-99 concentration or strontium-82 and strontium-82 concentrations, the licensee shall retain a record of each measurement in accordance with 12VAC5-481-2070 K.

E. The licensee shall report any measurement that exceeds the limits in subsection A of this section at the time of generator elution in accordance with 12VAC5-481-2080 D.

#### **12VAC5-481-1940. Training for imaging and localization studies.**

Except as provided in 12VAC5-481-1780, licensees shall require an authorized user (AU) of unsealed radioactive material for the uses authorized under 12VAC5-481-1920 to be a physician:

1. Who is certified by a medical specialty board whose certification process has been recognized by the NRC ~~and who meets the requirements in subdivision 3 b of this section, the agency, or an agreement state. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit Web page; or~~

2. Who is an AU under 12VAC5-481-1980 and meets the requirements in subdivision 3 a (2) (g) of this section, or equivalent NRC or other Agreement state requirements; or

3. Who has:

a. Completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies. The training and experience shall include at a minimum:

(1) Classroom and laboratory training in the following areas:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

(c) Mathematics pertaining to the use and measurement of radioactivity;

(d) Chemistry of radioactive material for medical use; and

(e) Radiation biology; and

(2) Work experience, under the supervision of an authorized user who meets the requirements in this section, 12VAC5-481-1780, or 12VAC5-481-1980 and subdivision 3 a (2) (g) of this section, or equivalent NRC or other Agreement state requirements. ~~An authorized nuclear pharmacist who meets the requirements of 12VAC5-481-1770 or 12VAC5-481-1780 may provide the supervised work experience in subdivision 3 a (2) (g) of this section. Work experience must involve; involving:~~

(a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(b) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(c) Calculating, measuring, and safely preparing patient or human research subject dosages;

(d) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

(e) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;

(f) Administering dosages of radioactive drugs to patients or human research subjects; and

(g) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclide purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

b. ~~Obtained written attestation, signed by a preceptor authorized user who meets the requirements in this section, 12VAC5-481-1780, or 12VAC5-481-1980 and subdivision 3 a (2) (g), or equivalent NRC or other agreement state requirements, that the individual has satisfactorily completed the requirements in subdivisions 1 a or subdivision 3 a of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 12VAC5-481-1900 and 12VAC5-481-1920. is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under 12VAC5-481-1900 and 12VAC5-481-1920. The attestation must be obtained from either:~~

(1) ~~A preceptor authorized user who meets the requirements in this section, 12VAC5-481-1780, or 12VAC5-481-1980 and subdivision 3 a (2) (g) of this section, or equivalent NRC or other agreement state requirements; or~~

(2) ~~A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in this section, 12VAC5-481-1780, or 12VAC5-481-1980 and subdivision 3 a (2) (g), or equivalent NRC or other agreement state requirements and concurs with the attestation provided by the residency program director. The residency training must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specific in subdivision 3 a of this section.~~

**12VAC5-481-1950. Use of unsealed radioactive material for which a written directive is required.**

Licensees may use any unsealed radioactive material identified in subdivision 2 b (7) of 12VAC5-481-1980 prepared for medical use and for which a written directive is required that is:

1. Obtained from a manufacturer or preparer licensed under 12VAC5-481-480 I or equivalent NRC or other Agreement state requirements or a PET radioactive drug producer licensed under 12VAC5-481-440 H or equivalent NRC or another agreement state requirements;
2. Excluding production of PET radionuclides, prepared by an ANP; a physician who is an authorized user (AU) and who meets the requirements specified in 12VAC5-481-1940 or 12VAC5-481-1980; or an individual under the supervision, as specified in 12VAC5-481-1710, of an ANP or the physician who is an AU;
3. Obtained from and prepared by an agency, NRC, or another agreement state licensee for use in research in accordance with an investigational new drug (IND) protocol accepted by U.S. Food and Drug Administration (FDA); or
4. Prepared by the licensee for use in research in accordance with an IND protocol accepted by FDA.

**12VAC5-481-1980. Training for use of unsealed radioactive material for which a written directive is required.**

Except as provided in 12VAC5-481-1780, licensees shall require an authorized user (AU) of unsealed radioactive material for the uses authorized under 12VAC5-481-1950 to be a physician:

1. Who is certified by a medical specialty board whose certification process has been recognized by the NRC, the agency, or an agreement state and who meets the requirements in subdivisions 2 b (7) and 3 of this section. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit Web page; or

2. Who has completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive. The training and experience shall include:

a. Classroom and laboratory training in the following areas:

- (1) Radiation physics and instrumentation;
- (2) Radiation protection;
- (3) Mathematics pertaining to the use and measurement of radioactivity;
- (4) Chemistry of radioactive material for medical use; and
- (5) Radiation biology; and

b. Work experience under the supervision of an AU who meets the requirements in this section, 12VAC5-481-1780, or equivalent NRC or another agreement state requirements. A supervising AU, who meets the requirements of this subdivision 2 shall also have experience in administering dosages in the same dosage category or categories (i.e., subdivision 2 b (7) of this section) as the individual requesting authorized user status. The work experience shall involve:

- (1) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- (2) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;
- (3) Calculating, measuring, and safely preparing patient or human research subject dosages;
- (4) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
- (5) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;
- (6) (Reserved.)

(7) Administering dosages of radioactive drugs to patients or human research subjects ~~involving a minimum of three cases in each~~ from the three categories in this subdivision 2 b (7). Radioactive drugs containing radionuclides in categories not included in this subdivision are regulated under 12VAC5-481-2060. This work experience must involve a minimum of three cases in each of the following categories (experience with at least three cases in subdivision 2 b (7)(b) of this section also satisfies the requirements of subdivision 2 b (7)(a) of this section), for which the individual is requesting authorized user status.

~~These categories are oral~~ (a) Oral administration of less than or equal to 33 mCi (1.22 GBq) of sodium iodide I-131, for which a written directive is required;

~~oral (b) Oral~~ administration of greater than 33 mCi (1.22 GBq) of sodium iodide I-131;

~~parenteral~~

~~(c) Parenteral~~ administration of any ~~beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV, for which a written directive is required; or parenteral administration of any other radionuclide, for which a written directive is required:~~ radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha characteristics, or photon energy of less than 150 keV, for which a written directive is required; and

3. Who has obtained written attestation that the individual has satisfactorily completed the requirements in ~~either subdivisions 1 and subdivision 2 b (7) of this section or subdivision 2 of this section and has achieved a level of competency sufficient to function independently as an AU for the medical uses authorized under 12VAC5-481-1950:~~ is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 for medical uses authorized under 12VAC5-481-1950. The written attestation shall be obtained from either:

~~signed by a~~ a. A preceptor AU who meets the requirements in this section, 12VAC5-481-1780, or equivalent NRC or other agreement state requirements. The preceptor AU, who meets the requirements in subdivision 2 of this section shall have and has experience in administering dosages in the same dosage category or categories (i.e., subdivision 2 b (7) of this section) as the individual requesting authorized user status; or

b. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements of this section, 12VAC5-481-1780, or equivalent NRC or other agreement state requirements; has experience in administering dosages in the same dosage category as the individual requesting the authorized user status; and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include the training and experience specified in subdivision 2 b of this section.

**12VAC5-481-1990. Training for the oral administration of sodium iodide (I-131) requiring a written directive in quantities less than or equal to 33 mCi (1.22 GBq).**

Except as provided in 12VAC5-481-1780, licensees shall require an authorized user (AU) for the oral administration of sodium iodide (I-131) requiring a written directive in quantities less than or equal to 33 mCi (1.22 GBq) to be a physician:

1. Who is certified by a medical specialty board whose certification process includes all of the requirements of subdivision 3 of this section and has been recognized by the NRC, the agency, or an agreement state. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Licensee Toolkit Web page; or

2. Who is an AU under 12VAC5-481-1980 for uses listed in subdivision 2 b (7) ~~(a) and (b)~~ of 12VAC5-481-1980, 12VAC5-481-2000, or equivalent NRC or other agreement state requirements; or

3. Who has:

a. Completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide (I-131) for procedures requiring a written directive. The training shall include:

- (1) Radiation physics and instrumentation;
- (2) Radiation protection;
- (3) Mathematics pertaining to the use and measurement of radioactivity;
- (4) Chemistry of byproduct material for medical use; and
- (5) Radiation biology; and

b. Work experience under the supervision of an AU who meets the requirements in this section, 12VAC5-481-1780, 12VAC5-481-1980, 12VAC5-481-2000, or equivalent NRC or another agreement state requirements. A supervising AU who meets the requirements in subdivision 2 of 12VAC5-481-1980 shall also have experience in administering dosages as specified in subdivision 2 b (7) ~~(a) or subdivision 2 b (7)(b)~~ of 12VAC5-481-1980. The work experience shall involve:

- (1) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- (2) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

- (3) Calculating, measuring, and safely preparing patient or human research subject dosages;
- (4) Using administrative controls to prevent a medical event involving the use of byproduct material;
- (5) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and
- (6) Administering dosages to patients or human research subjects, that includes at least three cases involving the oral administration of less than or equal to 33 mCi (1.22 GBq) of sodium iodide (I-131); and

4. Obtained written attestation that the individual has satisfactorily completed the requirements in ~~subdivisions 1 and 3 b of this section or~~ subdivision 3 of this section and ~~has achieved a level of competency sufficient to function independently as an AU for oral administration of less than or equal to 33 millicuries (1.22 gigabecquerels of sodium iodide I-131 for medical uses authorized under 12VAC5-481-1950~~ is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 for medical uses authorized under 12VAC5-481-1950. The attestation must be obtained from either:

~~The written attestation shall be signed by a preceptor AU who~~ a. A preceptor authorized user who meets the requirements in this section, 12VAC5-481-1780, 12VAC5-481-1980, 12VAC5-481-2000, or equivalent NRC or other agreement state requirements. ~~A preceptor AU who meets the requirement in subdivision 2 of 12VAC5-481-1980 shall also have~~ and has experience in administering dosages as specified in subdivision 2 b (7) (a) ~~or (b) of 12VAC5-481-1980; or~~

b. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in this section, 12VAC5-481-1780, 12VAC5-481-1980, 12VAC5-481-2000, or equivalent NRC or other agreement state requirements, has experience in administering dosages as specified in 12VAC5-481-1980 2 b (7) (a) or (b), and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subdivision 3 of this section.

**12VAC5-481-2000. Training for the oral administration of sodium iodide (I-131) requiring a written directive in quantities greater than 33 mCi (1.22 GBq).**

Except as provided in 12VAC5-481-1780, licensees shall require an authorized user (AU) for the oral administration of sodium iodide (I-131) requiring a written directive in quantities greater than 33 mCi (1.22 GBq) to be a physician:

1. Who is certified by a medical specialty board whose certification process includes all of the requirements in subdivision 3 of this section and has been recognized by the NRC, the agency, or an agreement state. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit Web page; or

2. Who is an AU under 12VAC5-481-1980 for uses listed in subdivision 2 b (7) (b) of 12VAC5-481-1980 or equivalent NRC or other agreement state requirements; or

3. Who has:

a. Completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide (I-131) for procedures requiring a written directive. The training shall include:

- (1) Radiation physics and instrumentation;
- (2) Radiation protection;
- (3) Mathematics pertaining to the use and measurement of radioactivity;
- (4) Chemistry of radioactive material for medical use; and
- (5) Radiation biology; and

b. Work experience, under the supervision of an AU who meets the requirements in this section, 12VAC5-481-1780, 12VAC5-481-1980, ~~12VAC5-481-1990~~, or equivalent NRC or other agreement state requirements. A supervising AU who meets the requirements in subdivision 2 of 12VAC5-481-1980 shall also have experience in administering dosages as specified in subdivision 2 b (7) (b) of 12VAC5-481-1980. The work experience shall involve:

- (1) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- (2) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;



- (3) Calculating, measuring, and safely preparing patient or human research subject dosages;
- (4) Using administrative controls to prevent a medical event involving the use of radioactive material;
- (5) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
- (6) Administering dosages to patients or human research subjects that includes at least three cases involving the oral administration of greater than 33 mCi (1.22 GBq) of sodium iodide (I-131); and

c. Obtained written attestation that the individual has satisfactorily completed the requirements in ~~subdivisions 1 and 3 b of this section or subdivision 3 of this section and has achieved a level of competency sufficient to function independently as an AU for medical uses authorized under 12VAC5-481-1950.~~ is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 for medical uses authorized under 12VAC5-481-1950. The written attestation must be obtained by either:

~~shall be signed by a preceptor AU who (1) A preceptor authorized user who meets the requirements in this section, 12VAC5-481-1780, 12VAC5-481-1980, 12VAC5-481-1990, or equivalent NRC or other Agreement state requirements. A preceptor AU who meets the requirements in subdivision 2 of 12VAC5-481-1980 shall also have~~ and has experience in administering dosages as specified in subdivision 2 b (7) (b) of 12VAC5-481-1980; or

~~(2) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements of this section, 12VAC5-481-1780, 12VAC5-481-1980, or equivalent NRC or other agreement state requirements; has experience in administering dosages as specified in 12VAC5-481-1980 2 b (7) (b); and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience as specified in this subdivision 3.~~

#### **12VAC5-481-2001. Training for the parenteral administration of unsealed radioactive material requiring a written directive.**

Except as provided in 12VAC5-481-1780, licensees shall require an authorized user (AU) for the parenteral administration requiring a written directive to be a physician:

1. Who is an AU under 12VAC5-481-1980 for uses listed in subdivision 2 b (7) (c) of 12VAC5-481-1980 or equivalent NRC or other Agreement state requirements; or
2. Who is an AU under ~~12VAC5-481-2010~~ 12VAC5-481-2018, 12VAC5-481-2040, or equivalent NRC or other agreement state requirements and who meets the requirements in subdivision 4 of this section; or
3. Who is certified by a medical specialty board whose certification process has been recognized by the NRC, the agency, or an agreement state under 12VAC5-481-2018 or 12VAC5-481-2040 and who meets the requirements in subdivision 4 of this section; and
4. Who has:
  - a. Completed 80 hours of classroom and laboratory training applicable to parenteral administrations ~~for which a written directive is required of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV or parenteral administration of any other radionuclide for which a written directive is required.~~ The training shall include:
    - (1) Radiation physics and instrumentation;
    - (2) Radiation protection;
    - (3) Mathematics pertaining to the use and measurement of radioactivity;
    - (4) Chemistry of radioactive material for medical use; and
    - (5) Radiation biology; and
  - b. Work experience under the supervision of an AU who meets the requirements in this section, 12VAC5-481-1780, 12VAC5-481-1980, or equivalent NRC or other Agreement state requirements in the parenteral administration ~~for which a written directive is required of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV or parenteral administration of any other radionuclide for which a written directive is required~~ listed in 12VAC5-481-1980 2 b (7) (c). A supervising AU who meets the requirements in this section, 12VAC5-481-1980, or equivalent NRC or other agreement state requirements shall have experience in administering dosages as specified in subdivision 2 b (7) of 12VAC5-481-1980 in the same category as the individual requesting authorized user status. The work experience shall involve:
    - (1) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(2) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(3) Calculating, measuring, and safely preparing patient or human research subject dosages;

(4) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

(5) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

(6) Administering dosages to patients or human research subjects that include at least three cases ~~involving of~~ the parenteral administration for which a written directive is required of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV or at least three cases involving the parenteral administration of any other radionuclide for which a written directive is required as specified in 12VAC5-481-1980 2 b (7)(c); and

5. Obtained a written attestation that the individual has satisfactorily completed the requirements in subdivision 2 or 3; and subdivision 4 b of this section or subdivision 4 of this section, and ~~has achieved a level of competency sufficient to function independently as an AU for the parenteral administration of unsealed radioactive material requiring a written directive~~ is able to independently fulfill the radiation safety-related duties as an authorized user for the parenteral administration of unsealed byproduct material requiring a written directive. The written attestation shall be obtained from either:

~~signed by a~~ a. A preceptor AU who meets the requirements in this section, 12VAC5-481-1780, 12VAC5-481-1980, or equivalent NRC or other agreement state requirements. A preceptor AU who meets the requirements in this section, 12VAC5-481-1980, or equivalent NRC or other agreement state requirements shall have experience in administering dosages as specified in subdivision 2 b (7) of 12VAC5-481-1980 in the same category as the individual requesting authorized user status; or

b. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements of this section, 12VAC5-481-1780, 12VAC5-481-1980, or equivalent NRC or other agreement state requirements; has experience in administering dosages in the same dosage category as the individual requesting authorized user status; and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council of Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subdivision 4 of this section.

#### **12VAC5-481-2010. Use of sources for manual brachytherapy.**

Licensees shall use only brachytherapy sources ~~for therapeutic medical uses:~~

1. As approved in the Sealed Source and Device Registry for manual brachytherapy medical use. The manual brachytherapy sources may be used for manual brachytherapy uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry; or

2. In research to deliver therapeutic doses for medical use in accordance with an active Investigational Device Exemption application accepted by the U.S. Food and Drug Administration provided the requirements of 12VAC5-481-1740 are met.

#### **12VAC5-481-2016. ~~Decay of strontium-90~~ Strontium-90 sources for ophthalmic treatments.**

~~Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay shall be based on the activity determined under 12VAC5-481-2015:~~

A. Licensees who use strontium-90 for ophthalmic treatments must ensure that certain activities as specified in subsection B of this section are performed by either:

1. An authorized medical physicist; or

2. An individual who:

a. Is identified as an ophthalmic physicist on a specific medical use license issued the agency, NRC, or another agreement state; permit issued by an agency, NRC, or another agreement state broad scope licensee; medical use permit issued by a NRC master material licensee; or permit issued by a NRC master material broad scope medical use permittee;

b. Holds a master's or doctor's degree in physics, medical physics, other physical sciences, engineering, or applied mathematics from an accredited college or university;

c. Has successfully completed one year of full-time training in medical physics and an additional year of full-time work experience under the supervision of a medical physicist; and

d. Has documented training in the following:

- (1) The creation, modification, and completion of written directives;
- (2) Procedures for administrations requiring a written directive; and
- (3) Performing the calibration measurements of brachytherapy sources as detailed in 12VAC5-481-2015.

**B. The individuals who are identified in subsection A of this section must:**

1. Calculate the activity of each strontium-90 sources that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under 12VAC5-481-2015; and
2. Assist the licensee in developing, implementing, and maintaining written procedures to provide a high confidence that the administration is in accordance with the written directive. These procedures must include the frequencies that the individual meeting the requirements in subsection A of this section will observe treatments, review the treatment methodology, calculate treatment time for prescribed dose, and review records to verify that the administrations were in accordance with the written directive.

**C. Licensees must return a record of the activity of each strontium-90 source in accordance with 12VAC5-481-2070 P.**

**12VAC5-481-2018. Training for use of manual brachytherapy sources.**

Except as provided in 12VAC5-481-1780, licensees shall require an authorized user of a manual brachytherapy source for uses authorized under 12VAC5-481-2010 to be a physician:

1. Who is certified by a medical specialty board whose certification process has been recognized by the NRC, the agency, or an agreement state. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit Web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

a. Successfully complete a minimum of three years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

b. Pass an examination administered by diplomates of the specialty board that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy; or

2. Who has:

a. Completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes:

(1) 200 hours of classroom and laboratory training in the following areas:

- (a) Radiation physics and instrumentation;
- (b) Radiation protection;
- (c) Mathematics pertaining to the use and measurement of radioactivity; and
- (d) Radiation biology; and

(2) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in this subsection, 12VAC5-481-1780, or equivalent NRC or another agreement state requirements at a medical institution facility authorized to use radioactive material under 12VAC5-481-2010, involving:

- (a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- (b) Checking survey meters for proper operation;
- (c) Preparing, implanting, and removing brachytherapy sources;
- (d) Maintaining running inventories of material on hand;
- (e) Using administrative controls to prevent a medical event involving the use of radioactive material;
- (f) Using emergency procedures to control radioactive material; and

b. Completed three years of supervised clinical experience in radiation oncology, under an AU who meets the requirements in this section, 12VAC5-481-1780, or equivalent NRC or another Agreement state requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by subdivision 2 a (2) of this section.

3. Who has obtained written attestation, ~~signed by a preceptor AU who meets the requirements in this section, 12VAC5-481-1780, or equivalent NRC or other agreement state requirements,~~ that the individual has satisfactorily completed the requirements in this subdivision 2 of this section and has achieved a level of competency sufficient to function independently as an AU of manual brachytherapy sources for the medical uses authorized in 12VAC5-481-2010. This attestation must be obtained from either:

a. A preceptor authorized user who meets the requirements in this section, 12VAC5-481-1780, or equivalent NRC or other agreement state requirements; or

b. A residency program director who affirms in writing that the attestation represents the residency program faculty where at least one faculty member is an authorized user who meets the requirement in this section, 12VAC5-481-1780, or equivalent NRC or other agreement state requirements and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specific in subsection 2 of this section.

#### **12VAC5-481-2019. Training for ophthalmic use of strontium-90.**

Except as provided in 12VAC5-481-1780, licensees shall require the AU of strontium-90 for ophthalmic radiotherapy to be a physician:

1. Who is an authorized user (AU) under 12VAC5-481-2018 or equivalent NRC or other Agreement state requirements; or

2. Who has:

a. Completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training shall include:

- (1) Radiation physics and instrumentation;
- (2) Radiation protection;
- (3) Mathematics pertaining to the use and measurement of radioactivity; and
- (4) Radiation biology; and

b. Clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution, clinic, or private practice that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training shall involve:

- (1) Examination of each individual to be treated;
- (2) Calculation of the dose to be administered;
- (3) Administration of the dose; and
- (4) Follow up and review of each individual's case history; and

c. Obtained written attestation, signed by a preceptor AU who meets the requirements in 12VAC5-481-1780, 12VAC5-481-2018, this section, or equivalent NRC or other Agreement state requirements, that the individual has satisfactorily completed the requirements in this subdivision 2 and has achieved a level of competency sufficient to function independently as an AU of strontium-90 for ophthalmic use is able to independently fulfill the radiation safety-related duties as an authorized user of strontium-90 for ophthalmic use.

#### **12VAC5-481-2020. Use of sealed sources for diagnosis.**

A. Licensees shall use only sealed sources that are not in medical devices for diagnostic medical uses as if the sealed sources are approved in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

B. A licensee must only use medical devices containing sealed sources for diagnostic medical uses if both the sealed sources and medical devices are approved in the Sealed Source and Device Registry for diagnostic medical uses. The diagnostic medical devices may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

C. Sealed sources and devices for diagnostic medical uses may be used in research in accordance with an active Investigational Device Exemption application accepted by the U.S. Food and Drug Administration provided the requirements of 12VAC5-481-1740 are met.

**12VAC5-481-2030. Training for use of sealed sources for diagnosis.**

Except as provided by 12VAC5-481-1780, licensees shall require the authorized user of a diagnostic sealed source for use in a device authorized under 12VAC5-481-2020 to be a physician, dentist, or podiatrist who:

1. Is certified by a specialty board that whose certification process includes all of the requirements in subdivisions 3 and 4 of this section and whose certification has been recognized by the NRC, the agency, or an agreement state. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit Web page; or

2. Is an authorized user for uses listed under 12VAC5-481-1920 or equivalent NRC or other agreement state requirements; or

3. Has completed eight hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training shall include:

- a. Radiation physics and instrumentation;
- b. Radiation protection;
- c. Mathematics pertaining to the use and measurement of radioactivity; and
- d. Radiation biology; and

~~3.~~ 4. Has completed training in the use of the device for the uses requested.

**12VAC5-481-2040. Training requirements and use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit.**

A. Except as provided in 12VAC5-481-1780, licensees shall require an authorized user (AU) of a sealed source in remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units to be a physician:

1. Who is certified by a medical specialty board whose certification process has been recognized by the NRC, the agency, or an agreement state and who meets the requirements in subdivision 3 of this section. The names of board certifications that have been recognized by the agency, NRC, or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit Web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

a. Successfully complete a minimum of three years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

b. Pass an examination administered by diplomates of the specialty board that tests knowledge and competence radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders and external beam therapy; or

2. Who has:

a. Completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes:

(1) 200 hours of classroom and laboratory training in the following areas: radiation physics and instrumentation; radiation protection; mathematics pertaining to the use and measurement of radioactivity; and radiation biology; and

(2) 500 hours of work experience, under the supervision of an AU who meets the requirements in this section, 12VAC5-481-1780, or equivalent NRC or another agreement state requirements at a medical institution that is authorized for subsections B and C of this section, involving: reviewing full calibration measurements and periodic spot-checks; preparing treatment plans and calculating treatment doses and times; using administrative controls to prevent a medical event involving the use of radioactive material; implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console; checking and using survey meters; and selecting the proper dose and knowing how it is to be administered; and

b. Completed three years of supervised clinical experience in radiation therapy under an AU who meets the requirements in this section, 12VAC5-481-1780, or equivalent NRC or another Agreement state requirements as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by this subdivision.

3. Who has obtained written attestation that the individual has satisfactorily completed the requirements in ~~(i) subdivision 1 or 2 of this subsection subdivisions 2 a, 2 b,~~ and ~~(ii) subdivisions 3 and 4 of this subsection~~ and has achieved a level of competency sufficient to function independently as an AU of each type of therapeutic medical unit for which the individual is requesting AU status. The written attestation shall be signed by either:

a. A preceptor AU who meets the requirements in this subsection, 12VAC5-481-1780, or equivalent NRC or another agreement state requirements for an AU for each type of therapeutic medical unit for which the individual is requesting AU status; or

b. A residency program director who affirms in writing that the attestation of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in this subsection, 12VAC5-481-1780, or equivalent NRC or other agreement state requirements for the type of therapeutic medical unit for which the individual is requesting authorized user status and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subdivisions 2 a and 2 b of this subsection.

4. Who has received training in device operation, safety procedures, and clinical use for the types of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an AU or authorized medical physicist, as appropriate, who is authorized for the types of use for which the individual is seeking authorization.

B. Licensees shall use sealed sources in photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units for therapeutic medical uses:

1. As approved in the Sealed Source and Device Registry; or

2. In research in accordance with an active Investigational Device Exemption application accepted by the U.S. Food and Drug Administration provided the requirements of 12VAC5-481-1740 are met.

C. Licensees shall use photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units:

1. As approved in the Sealed Source and Device Registry to deliver a therapeutic dose for medical use. These devices may be used for therapeutic medical treatments that are not explicitly provided for in the Sealed Source and Device Registry but must be used in accordance with radiation safety conditions and limitations described in the Sealed Source and Device Registry; or

2. In research in accordance with an active Investigational Device Exemption application accepted by the U.S. Food and Drug Administration provided the requirements of 12VAC5-481-1740 are met.

**12VAC5-481-2043. Safety procedures and instructions, and precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.**

A. Safety procedures and instructions.

1. Licensees shall:

a. Secure the unit, the console, the console keys, and the treatment room when not in use or unattended;

b. Permit only individuals approved by the authorized user (AU), the authorized medical physicist (AMP), or the RSO to be present in the treatment room during treatment with sources;

c. Prevent dual operation of more than one radiation producing device in a treatment room if applicable; and

d. Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source in the shielded position, or remove the patient or human research subject from the radiation field with controls from the outside the treatment room. These procedures shall include:

(1) Instructions for responding to equipment failure and the names of the individuals responsible for implementing corrective actions;

(2) The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

(3) The names and telephone numbers of the authorized user (AU), the authorized medical physicist (AMP), and the RSO to be contacted if the unit or the console operates abnormally.

2. A copy of the procedures required by subdivision 1 d of this subsection shall be physically located at the unit console.

3. Licensees shall post instructions at the unit console to inform the operator of:

a. The location of the procedures required by subdivision 1 d of this subsection; and

b. The names and telephone numbers of the AU, the AMP, and the RSO to be contacted if the unit or console operates abnormally.

4. Safety instruction and training.

a. Prior to the first use of patient treatment of a new unit or an existing unit with a manufacturer upgrade that affects the operation and safety of the unit, a licensee shall ensure that vendor operational and safety training is provided to all individuals who will operate the unit. The vendor operational and safety training must be provided by the device manufacturer or by an individual certified by the device manufacturer to provide the operational and safety training.

b. Licensees shall provide instruction and document initially and at least annually to all individuals who operate the unit, as appropriate to the individual's assigned duties, in:  
~~a. The the procedures identified in subdivision 1 d of this subsection;~~ and ~~b. The the operating procedures for the unit.~~

5. Licensees shall ensure that operators, authorized users, and authorized medical physicists participate in drills of the emergency procedures initially and at least annually and document the exercise.

6. Licensees shall retain a record of individuals receiving instruction required by subdivision 4 of this subsection in accordance with 12VAC5-481-2070 L.

7. Licensees shall retain a copy of the procedures required by subdivisions 1 d and 4 b of this subsection in accordance with 12VAC5-481-2070 R.

B. Safety procedures for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

1. Licensees shall control access to the treatment room by a door at each entrance.

2. Licensees shall equip each entrance to the treatment room with an electrical interlock system that will:

a. Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;

b. Cause the source to be shielded when an entrance door is opened; and

c. Prevent the source from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source on-off console is reset at the console.

3. Licensees shall require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels.

4. Except for low-dose remote afterloader units, licensees shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation.

5. For licensed activities where sources are placed within the patient's or human research subject's body, licensees shall only conduct treatments that allow for expeditious removal of a decoupled or jammed source.

6. In addition to the requirements specified in subdivisions 1 through 5 of this subsection, licensees shall:

a. For medium dose-rate and pulsed dose-rate remote afterloader units, require:

(1) An AMP and either an AU or a physician under the supervision of an AU who has been trained to the operation and emergency response for the unit to be physically present during the initiation of all patient treatments involving the units; and

(2) An AMP and either an AU or an individual under the supervision of an AU who has been trained to remove the source applicators in the event of an emergency involving the unit to be immediately available during the continuation of all patient treatments involving the unit.

b. For high dose-rate remote afterloader units, require:

(1) An AU and an AMP to be physically present during the initiation of all patient treatments involving the unit; and

(2) An AMP and either an AU or a physician under the supervision of an AU who has been trained in the operation and emergency response for the unit to be physically present during continuation of all patient treatments involving the unit.

c. For gamma stereotactic radiosurgery units, require an AU and an AMP to be physically present throughout all patient treatments involving the unit.

d. Notify the RSO, or his designee, and the authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

7. Licensees shall have applicable emergency response equipment available near each treatment room to respond to a source that:

- a. Remains in the unshielded position; or
- b. Lodges within the patient following completion of the treatment.

**12VAC5-481-2048. ~~Five-year inspection~~ Full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units.**

A. Licensees shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during each source replacement ~~or at intervals not to exceed five years, whichever comes first~~, to assure proper functioning of the source exposure mechanism and other safety components. The interval between each full-inspection servicing shall not exceed five years for each teletherapy unit and shall not exceed seven years for each gamma stereotactic radiosurgery unit.

B. This inspection and servicing may only be performed by person specifically licensed to do so by the agency, the NRC, or another Agreement state.

C. Licensees shall keep a record of the inspection and servicing in accordance with 12VAC5-481-2070 X.

**12VAC5-481-2070. Records.**

A. Records of authority and responsibilities for radiation protection programs.

1. Licensees shall retain a record of actions taken by the licensee's management in accordance with 12VAC5-481-1700 for five years. The record shall include a summary of the actions taken and a signature of licensee management.

2. Licensees shall retain a copy of both authority, duties, and responsibilities of the RSO as required by 12VAC5-481-1700 and a signed copy of each RSO's agreement to be responsible for implementing the radiation safety program, as required by 12VAC5-481-1700, for the duration of the license. The records shall include the signature of the RSO and licensee management.

3. For each associate radiation safety officer, the licensee shall retain for five years after the associate radiation safety officer is removed from the license, a copy of the written document appointing the associate radiation safety officer signed by licensee's management.

B. Records of radiation protection program changes. Licensees shall retain a record of each radiation protection program change made in accordance with 12VAC5-481-1700 F for five years. The record shall include a copy of the old and new procedures, the effective date of the change, and the signature of the licensee management that reviewed and approved the change.

C. Records of written directives. Licensees shall retain a copy of each written directive as required by 12VAC5-481-1720 for three years.

D. Records for procedures for administrations requiring written directive. Licensees shall retain a copy of the procedures required by 12VAC5-481-1730 for the duration of the license.

E. Records of dosages of unsealed radioactive material for medical use. Licensees shall maintain a record of dosage determinations required by 12VAC5-481-1820 for three years. The record shall contain the radiopharmaceutical; the patient's or human research subject's name or identification number if one has been assigned; the prescribed dosage, the determined dosage, or a notation that the total activity is less than 30  $\mu\text{Ci}$  (1.1 MBq); the date and time of dosage determination; and the name of the individual who determined the dosage.

F. Records of leak tests and inventory of sealed sources and brachytherapy sources.

1. Licensees shall retain records of leak tests required by 12VAC5-481-1840 for three years. The records shall include the model number, and the serial number, if one has been assigned, of each source tested; the identity of each source by radionuclide and its estimated activity; the results of the test; the date of the test; and the name of the individual who performed the test.

2. Licensees shall retain records of the semi-annual physical inventory of sealed sources and brachytherapy sources required by 12VAC5-481-1840 for three years. The inventory records shall contain the model number of each source, and serial number of each source if one has been assigned, the identity of each source by radionuclide and its nominal activity, the location of each source, and the name of the individual who performed the inventory.

G. Records of surveys for ambient radiation exposure rate. Licensees shall retain a record of each survey required by 12VAC5-481-1860 for three years. The record shall include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

H. Records of the release of individuals containing unsealed radioactive material or implants containing radioactive material.

1. Licensees shall retain a record signed by the authorized user of the basis for authorizing the release of an individual in accordance with 12VAC5-481-1870 for three years after the date of release if the total effective dose equivalent is calculated by:

- a. Using the retained activity rather than the activity administered;
- b. Using an occupancy factor less than 0.25 at 1 meter;
- c. Using the biological or effective half-life; or
- d. Considering the shielding by tissue.



2. Licensees shall retain a record for three years after the date of release of the instruction required by 12VAC5-481-1870 that were provided to a breast-feeding female if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 500 mrem (5 mSv).

I. Records of mobile medical services.

1. Licensees shall retain a copy of each letter that permits the use of radioactive material at the client's address, as required by 12VAC5-481-1880. Each letter shall clearly delineate the authority and responsibility of the licensee and the client and shall be retained for three years after the last provision of service.

2. Licensees shall retain the record of each survey required by 12VAC5-481-1880 for three years. The record shall include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

J. Records of decay-in-storage. Licensees shall maintain records of the disposal of licensed materials, as required by 12VAC5-481-1890 for three years. The record shall include the date of the disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the survey.

K. Records of molybdenum-99, strontium-82 and strontium-85 concentrations. Licensee shall maintain a record of molybdenum-99 concentration or strontium-82 and strontium-85 concentration tests required by 12VAC5-481-1930 for three years. The record shall include:

1. For each measured elution of technetium-99m, the ratio of measures expressed as microcuries of molybdenum-99 per millicurie of technetium-99m or kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m, the time and date of the measurement, and the name of the individual who made the measurement; or

2. For each measured elution of rubidium-82, the ratio of the measures expressed as microcurie of strontium-82 per millicurie of rubidium-82 or kilobecquerel of strontium-82 per megabecquerel of rubidium-82, microcurie of strontium-85 per millicurie of rubidium-82 or kilobecquerel of strontium-85 per megabecquerel of rubidium-82, the time and date of the measurement, and the name of the individual who made the measurement.

L. Records of safety instruction. Licensees shall maintain a record of safety instructions and training required by 12VAC5-481-1960 and 12VAC5-481-1970 and the operational and safety instructions required by 12VAC5-481-2013 for three years. Each record shall include a list of topics covered, the date of the instruction or training, the names of the attendees, and the names of the individuals who provided the instruction.

M. Records of surveys after source implant and removal. Licensees shall maintain a record of the surveys required by 12VAC5-481-2011 and 12VAC5-481-2041 for three years. Each record shall include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey.

N. Records of brachytherapy source accountability.

1. Licensee shall maintain a record of brachytherapy source accountability required by 12VAC5-481-2012 for three years.

2. For temporary implants, the record shall include the number and activity of sources removed from storage, the time and date they were removed from storage, the name of the individual who removed them from storage, and the location of use and the number and activity of sources returned to storage, the time and date they were returned to storage, and the name of the individual who returned them to storage.

3. For permanent implants, the record shall include the number and activity of sources removed from storage, the date they were removed from storage, the name of the individual who removed them from storage, the number and activity of sources not implanted, the date they were returned to storage, the name of the individual who returned them to storage, and the number and activity of sources permanently implanted in the patient or human research subject.

O. Records of calibration measurements of brachytherapy sources. Licensees shall maintain a record of the calibrations of brachytherapy sources required by 12VAC5-481-2015 for three years after the last use of the source. The record shall include the date of the calibration; the manufacturer's name, model number and serial number for the source and the instruments used to calibrate the source; the source output or activity; the source positioning accuracy within the applicators; and the name of the individual, the source manufacturer, or the calibration laboratory that performed the calibration.

P. Records of decay of strontium-90 sources for ophthalmic treatments. Licensees shall maintain a record of the activity of a strontium-90 source required by 12VAC5-481-2016 for the life of the source. The record shall include the date and initial activity of the source as determined under 12VAC5-481-2016, and for each decay calculation, the date and the source activity as determined under 12VAC5-481-2016 and the signature of the authorized medical physicist.

Q. Records of installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. Licensees shall retain a record of the installation, adjustment, maintenance, and repair of remote afterloaders units, teletherapy units, and gamma stereotactic radiosurgery units as required by 12VAC5-481-2042 for three years. For each installation, adjustment, maintenance, and repair, the record shall include the date, description of the service, and names of the individuals who performed the work.

R. Records of safety procedures. Licensees shall retain a copy of the procedures required by 12VAC5-481-2043 until the licensee no longer possesses the remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit.

S. Records of dosimetry equipment used with remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. Licensees shall retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment done in accordance with 12VAC5-481-2044 for the duration of the license. For each calibration, intercomparison, or comparison, the record shall include the date; the manufacturer's name, model numbers, and serial numbers of the instruments that were calibrated, intercompared, or compared as required by 12VAC5-481-2044; the correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison; and the names of the individuals who performed the calibration, intercomparison, or comparison.

T. Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations. Licensees shall maintain a record of the teletherapy unit, remote afterloader unit, and gamma stereotactic radiosurgery unit full calibrations required by 12VAC5-481-2045 for three years. The record shall include the date of calibration; the manufacturer's name, model number, and serial number of the teletherapy, remote afterloader, and gamma stereotactic radiosurgery unit, the source, and the instruments used to calibrate the unit; the results and an assessment of the full calibrations; the results of the autoradiograph required for low dose-rate remote afterloader units; and the signature of the authorized medical physicist who performed the full calibration.

U. Records of periodic spot-checks for teletherapy units, remote afterloader units, and gamma stereotactic radiosurgery units.

1. Licensees shall retain a record of each periodic spot-check for teletherapy units, remote afterloader units, and gamma stereotactic radiosurgery units required by 12VAC5-481-2046 for three years. The record shall include:

a. For each teletherapy unit; the date of the spot-check, the manufacturer's name, model number, and serial number, source, and 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 determined accuracy of each distance measuring and 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 source exposure indicator light, and the viewing and intercom system and doors; the name of the individual who performed the periodic spot-check; and the signature of the authorized medical physicist who reviewed the record of the spot-check.

b. For each remote afterloader unit: the date of the spot-check, the manufacturer's name, model and serial number for the remote afterloader unit and source; an assessment of timer accuracy; notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, and clock and decayed source activity in the unit's computer; the name of the individual who performed the periodic spot-check; and the signature of the authorized medical physicist who reviewed the record of the spot-check.

c. For each gamma stereotactic radiosurgery unit: the date of the spot-check, the manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit; an assessment of timer linearity and accuracy; the calculated on-off error; a determination of trunnion centricity; the difference between the anticipated output and the measured output; an assessment of source output against computer calculations; notations indicating the operability of radiation monitors; helmet microswitches, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems; timer termination, treatment table retraction mechanism, and stereotactic frames and localizing device (trunnions); the name of the individual who performed the periodic spot-check; and the signature of the authorized medical physicist who reviewed the record of the spot-check.

2. Licensees shall retain a copy of the procedures required by 12VAC5-481-2046 A 2, 12VAC5-481-2046 B, and 12VAC5-481-2046 C 2 until the licensee no longer possesses the teletherapy unit, remote afterloader unit, or gamma stereotactic radiosurgery unit.

V. Records of additional technical requirements for mobile remote afterloader units. Licensees shall retain a record of each check for mobile remote afterloader units required by 12VAC5-481-2047 for three years. The record shall include the date of the check, the manufacturer's name, model number, and serial number of the remote afterloader unit; notations accounting for all sources before the licensee departs from a facility; notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators, source transfer tubes, and transfer tube applicator interfaces; source positioning accuracy; and the signature of the individual who performed the check.

W. Records of surveys of therapeutic treatment units. Licensees shall maintain a record of radiation surveys of treatment units made in accordance with 12VAC5-481-2041 for the duration of use of the unit. The record shall include the date of the measurements, the manufacturer's name, model number, and serial number of the treatment unit; source and instrument used to measure radiation levels; each dose rate measured around the source while the unit is in the off position and the average of all measurements; and the signature of the individual who performed the test.

X. Records of five-year inspection for teletherapy and gamma stereotactic radiosurgery units. Licensees shall maintain a record of the ~~five-year inspections~~ full-inspection servicing for teletherapy and gamma stereotactic radiosurgery required by 12VAC5-481-2048 for the duration of use of the unit. The record shall include the inspector's radioactive materials license number, the date of inspection, the manufacturer's name, model number, and serial number of both the treatment unit and source, a list of components inspected and serviced, the type of service, and the signature of the inspector.

#### **12VAC5-481-2080. Reports.**

A. Report and notification of a medical event.

1. Licensees shall report any event as a medical event, except for an event that results from patient intervention, in which the administration of radioactive material or radiation from radioactive material, except permanent implant brachytherapy, results in:

a. A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 5 rem (0.05 Sv) effective dose equivalent, 50 rem (0.5 Sv) to an organ or tissue, or 50 rem (0.5 Sv) shallow dose equivalent to the skin; and

- (1) The total dose delivered differs from the prescribed dose by 20% or more;
- (2) The total dosage delivered differs from the prescribed dosage by 20% or more or falls outside the prescribed dosage range; or
- (3) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50% or more.

b. A dose that exceeds 5 rem (0.05 Sv) effective dose equivalent, 50 rem (0.5 Sv) to an organ or tissue, or 50 rem (0.5 Sv) shallow dose equivalent to the skin from any of the following:

- (1) An administration of a wrong radioactive drug containing radioactive material or the wrong radionuclide for a brachytherapy procedure;
- (2) An administration of a radioactive drug containing radioactive material by the wrong route of administration;
- (3) An administration of a dose or dosage to the wrong individual or human research subject;
- (4) An administration of a dose or dosage delivered by the wrong mode of treatment; or
- (5) A leaking sealed source.

c. A dose to the skin or an organ or tissue other than the treatment site that exceeds by 50 rem (0.5 Sv) ~~to an organ or tissue and 50% or more of the dose expected from to that site if the administration defined in had been given in accordance with the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site) prepared or revised before administration and 50% or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration.~~

2. For permanent implant brachytherapy, the administration of radioactive material or radiation from radioactive material, excluding sources that were implanted in the correct site but migrated outside the treatment site, that result in the total source strength administered differing by 20% or more from the total source strength documented in the post-implantation portion of the written directive or the total source strength administered outside of the treatment site exceeding 20% of the total source strength documented in the post-implantation of the written directive or an administration involving any of the following: wrong radionuclide, the wrong individual or human research subject, sealed sources implanted directly into a location discontinuous from the treatment site as documented in the post-implantation portion of the written directive, or a leaking sealed source resulting in a dose that exceeds 50 rem (0.5 Sv) to an organ or tissue.

3. Licensees shall report any event resulting from intervention of a patient or human research subject in which the administration of radioactive material or radiation from radioactive material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

~~3.~~ 4. Licensees shall notify the agency by telephone no later than the next calendar day after discovery of the medical event.

~~4.~~ 5. By an appropriate method listed in 12VAC5-481-150, licensees shall submit a written report to the agency within 15 days after discovery of the medical event.

a. The written report shall include:

- (1) The licensee's name;
- (2) The name of the prescribing physician;
- (3) A brief description of the event;
- (4) Why the event occurred;
- (5) The effect, if any, on the individuals who received the administration;
- (6) What actions, if any, have been taken or are planned to prevent recurrence; and
- (7) Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

b. The report may not contain the individual's name or any other information that could lead to identification of the individual.

5. 6. Licensees shall provide notification of the event to the referring physician and also notify the individual who is the subject of the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he will inform the individual or that, based on medical judgment, telling the individual would be harmful. Licensees are not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, licensees shall notify the individual as soon as possible thereafter. Licensees may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of this subdivision, the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, licensees shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. Licensees shall provide such a written description if requested.

6. Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event, or to that individual's responsible relatives or guardians.

7. Licensees shall:

a. Annotate a copy of the report provided to the agency with the:

(1) Name of the individual who is the subject of the event; and

(2) ~~Social security number or other identification~~ identification number, ~~or if one has been assigned no other identification number is available, the social security number;~~ of the individual who is the subject of the event; and

b. Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

B. Report and notification of a dose to an embryo/fetus or a nursing child.

1. Licensees shall report any dose to an embryo/fetus that is greater than 500 mrem (5 mSv) dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.

2. Licensees shall report any dose to a nursing child that is a result of an administration of radioactive material to a breast-feeding individual that:

a. Is greater than 5 mSv (500 rem) total effective dose equivalent; or

b. Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

3. Licensees shall notify the agency by telephone no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in accordance with subdivision 1 or 2 in this subsection.

4. By an appropriate method listed in 12VAC5-481-150, licensees shall submit a written report to the agency within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in subdivision 1 or 2 of this subsection.

a. The written report shall include

(1) The licensee's name;

(2) The name of the prescribing physician;

(3) A brief description of the event;

(4) Why the event occurred;

(5) The effect, if any, on the embryo/fetus or the nursing child;

(6) What actions, if any, have been taken or are planned to prevent recurrence; and

(7) Certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.

b. The report shall not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

5. Licensees shall provide notification of the event to the referring physician and also notify the pregnant individual or mother, both hereafter referred to as "mother," no later than 24 hours after discovery of an event that would require reporting under subdivisions 1 or 2 of this subsection, unless the referring physician personally informs the licensee either that the mother will be informed or that, based on medical judgment, telling the mother would be harmful. Licensees are not required to notify the mother without first consulting with the referring

physician. If the referring physician or mother cannot be reached within 24 hours, licensees shall make the appropriate notifications as soon as possible thereafter. Licensees may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this subdivision, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother, when appropriate. If a verbal notification is made, licensees shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. Licensees shall provide such a written description if requested.

6. Licensees shall:

a. Annotate a copy of the report provided to the agency with the:

(1) Name of the pregnant individual or the nursing child who is the subject of the event; and

(2) ~~Social security number or other identification~~ identification number, ~~or if one has been assigned, no other identification number is available, the social security number~~ of the pregnant individual or the nursing child who is the subject of the event; and

b. Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

C. Report of a leaking source.

1. Licensees shall file a report within five days if a leak test required by 12VAC5-481-1840 reveals the presence of 0.005  $\mu\text{Ci}$  (185 Bq) or more of removable contamination.

2. The report shall be filed with the agency by an appropriate method listed in 12VAC5-481-150. The written report shall include:

a. The model number and serial number, if assigned, of the leaking source;

b. The radionuclide and its estimated activity;

c. The results of the test;

d. The date of the test; and

e. The action taken.

D. Report and notification for an eluate exceeding permissible molybdenum-99, strontium-82, and strontium-85 concentrations.

1. Licensees shall notify the agency and the distributor of the generator by telephone within seven calendar days after discovery that an eluate exceeded the permissible concentration listed in 12VAC5-481-1930 A at the time of generator elution. The telephone report to the agency must include the manufacturer, model number, and serial number (or lot number) of the generator; the results of the measurement; the date of the measurement; whether dosages were administered to patients or human research subjects; when the distributor was notified; and the action taken.

2. By an appropriate method listed in 12VAC5-481-150, the licensee shall submit a written report to the agency within 30 calendar days after discovery of an eluate exceeding the permissible concentration at the time of generator elution. The written report shall include the action taken by the licensee; the patient dose assessment; the methodology used to make this dose assessment if the eluate was administered to patients or human research subjects; the probable cause and assessment of failure in the licensee's equipment, procedure, or training that contributed to the excessive readings if an error occurred in the licensee's breakthrough determination; and the information in the telephone report as required by subdivision 1 of this subsection.

#### **12VAC5-481-2850. Personnel monitoring.**

A. Irradiator operators shall wear a personnel dosimeter ~~that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor~~ while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator. The personnel dosimeter processor ~~shall be accredited for the~~ must be capable of detecting high energy photons in the normal and accident dose ranges (see 12VAC5-481-750). Each personnel dosimeter shall be assigned to and worn by only one individual. Film badges shall be processed at least monthly, and other personnel dosimeters that require replacement shall be ~~processed~~ evaluated at least quarterly or promptly after replacement, whichever is more frequent.

B. Other individuals who enter the radiation room of a panoramic irradiator shall wear a dosimeter, which may be a pocket dosimeter. For groups of visitors, only two people who enter the radiation room are required to wear dosimeters. If pocket dosimeters are used to meet the requirements of this subsection, a check of their response to radiation shall be done at least annually. Acceptable dosimeters shall read within plus or minus 30% of the true radiation dose.

#### **12VAC5-481-3000. General license: NRC-approved packages.**

A. A general license is hereby issued to any licensee to transport, or to deliver to a carrier for transport, licensed material in a package for which a license, certificate of compliance (CoC), or other approval has been issued by the NRC. This general license applies only to a licensee who has a quality assurance program approved by the agency as satisfying the provisions of 12VAC5-481-3130.

B. This general license applies only to a licensee who:

1. Has a copy of the license, CoC, or other approval by the NRC of the package and has the drawings and other documents referenced in the approval relating to the use and maintenance of the packaging and to the actions to be taken prior to shipment;
2. Complies with the terms and conditions of the license, certificate, or other approval by the NRC, as applicable, and the applicable requirements of Part XIII (12VAC5-481-2950 et seq.) of this chapter;
3. Prior to the licensee's first use of the package, submits in writing to the NRC: ATTN: Document Control Desk, Director, Division of ~~Spent Fuel Storage and Transportation~~ Fuel Management, Office of Nuclear Material Safety and Safeguards, using an appropriate method listed in 10 CFR 71.1(a), the licensee's name and license number and the package identification number specified in the package approval; and
4. Has a quality assurance program that complies with 12VAC5-481-3130.

C. The general license in subsection A of this section applies only when the package approval authorizes use of the package under this general license.

D. For a Type B or fissile material package, the design of which was approved by the NRC before April 1, 1996, the general license is subject to the additional restrictions of 12VAC5-481-3010.

#### **12VAC5-481-3120. Advance notification of transport of nuclear waste.**

A. Prior to the transport of any nuclear waste outside of the confines of the licensee's facility or other place of use or storage, or prior to the delivery of any nuclear waste to a carrier for transport, each licensee shall provide advance notification of such transport.

B. Advance notification for transport of licensed material is required when:

1. The licensed material is required to be in Type B packaging for transportation;
2. The licensed material is being transported to or across state boundary en route to a disposal facility or to a collection point for transport to a disposal facility; and
3. The quantity of licensed material in a single package exceeds:
  - a. 3000 times the  $A_1$  value of the radionuclides as specified in 12VAC5-481-3770;
  - b. 3000 times the  $A_2$  value of the radionuclides as specified in 12VAC5-481-3770; or
  - c. 1000 terabecquerel (27,000 curies).

C. Each advance notification required by subsections A and B of this section shall contain the following information:

1. The name, address, and telephone number of the shipper, carrier, and receiver of the shipment;
2. A description of the nuclear waste contained in the shipment as required by 49 CFR 172.202 and 172.203(d);
3. The point of origin of the shipment and the seven-day period during which departure of the shipment is estimated to occur;
4. The seven-day period during which arrival of the shipment at state boundaries or tribal reservation boundaries is estimated to occur;
5. The destination of the shipment, and the seven-day period during which arrival of the shipment is estimated to occur; and
6. A point of contact with a telephone number for current shipment information.

D. The notification required by subsections A and B of this section shall be made in writing to each office of the governor or governor's designee, the office of each appropriate tribal official or tribal official's designee, and to the agency. A notification delivered by mail shall be postmarked at least seven days before the beginning of the seven-day period during which departure of the shipment is estimated to occur. A notification delivered by any other means than mail shall reach each office of the governor or governor's designee, the office of each appropriate tribal official or tribal official's designee, and the agency, at least four days before the beginning of the seven-day period during which departure of the shipment is estimated to occur. A copy of the notification shall be retained by the licensee for three years.

1. A list of names and mailing addresses of the governors' designees receiving advance notification of transportation of nuclear waste was published in the Federal Register on June 30, 1995 (60 FR 34306).

2. Contact information for each state, including telephone and mailing addresses of governors and governors' designees, and participating tribes, including telephone and mailing addresses of tribal officials and tribal officials' designees, is available on the NRC website at:

<https://scp.nrc.gov/special/designee.pdf>.

3. A list of the names and mailing addresses of the governors' designees and tribal officials' designees of participating tribes is available on request from the Director, Division of ~~Material~~ Materials Safety, Security, State, and Tribal and Rulemaking Program Programs, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

E. The licensee shall notify the governor or governor's designee, the office of each appropriate tribal official or tribal official's designee, and the agency of any changes to schedule information provided pursuant to subsections A and B of this section. Such notification shall be by telephone to a responsible individual in the office of the governor or governor's designee, the office of each appropriate tribal official or tribal official's designee, and the agency. The licensee shall maintain for three years a record of the name of the individual contacted.

F. Each licensee who cancels a nuclear waste shipment, for which advance notification has been sent, shall send a cancellation notice, identifying the advance notification that is being canceled, to the governor or governor's designee, the office of each appropriate tribal official or tribal official's designee, and to the agency. A copy of the notice shall be retained by the licensee for three years.

#### **12VAC5-481-3290. Personnel monitoring.**

A. No licensee shall permit any individual to act as a logging supervisor or a logging assistant unless each such individual wears ~~either a film badge, OSL or TLD personnel dosimeter at all times during the handling of licensed radioactive materials.~~ Each ~~film badge, OSL or TLD personnel dosimeter~~ shall be assigned to and worn by only one individual. Film badges must be replaced at least monthly and ~~OSLs or TLDs~~ all other personnel dosimeters that require replacement must be replaced at least quarterly. After replacement, each film badge, OSL or TLD must be promptly processed. All personnel dosimeters must be evaluated at least quarterly or promptly after replacement, whichever is more frequent.

B. Personnel monitoring records shall be maintained for inspection until the agency authorizes disposition.

NOTICE: The following forms used in administering the regulation have been filed by the agency. Amended or added forms are reflected in the listing and are published following the listing. Online users of this issue of the Virginia Register of Regulations may also click on the name to access a form. The forms are also available from the agency contact or may be viewed at the Office of Registrar of Regulations, 900 East Main Street, 11th Floor, Richmond, Virginia 23219.

#### FORMS (12VAC5-481)

##### Applications for a New Radioactive Material License

[Academic, Research and Development, and Other Licenses of Limited Scope, Revision 4 \(6/2018\)](#)

[Broad Scope, Revision 3 \(1/2016\)](#)

[Fixed Gauge Devices, Revision 4 \(6/2018\)](#)

[Industrial Radiography, Revision 4 \(6/2018\)](#)

[Irradiators – Part XII, Revision 2 \(6/2018\)](#)

[Medical Use, Revision 3 \(6/2018\)](#)

[Portable Gauges, Revision 3 \(6/2018\)](#)

[Radiopharmacy, Revision 2 \(6/2018\)](#)

[Sealed Sources, Revision 4 \(6/2018\)](#)

[Self-Shielded Irradiators, Revision 4 \(6/2018\)](#)

[Material in Well Logging, Tracer, and Field Flood Study, Revision 3 \(1/2016\)](#)

[XRF Devices, Revision 3 \(6/2018\)](#)

[Manufacturing and Distribution, Revision 3 \(6/2018\)](#)

##### Applications for Renewal of a Radioactive Material License

[Academic, Research and Development and Other Licenses of Limited Scope, Revision 4 \(6/2018\)](#)

[Broad Scope, Revision 3 \(1/2016\)](#)

[Fixed Gauge Devices, Revision 4 \(6/2018\)](#)

[Industrial Radiography, Revision 4 \(6/2018\)](#)

[Irradiators – Part XII, Revision 1 \(6/2018\)](#)

[Medical Use, Revision 3 \(6/2018\)](#)

[Portable Gauges, Revision 5 \(6/2018\)](#)

[Radiopharmacy, Revision 2 \(6/2018\)](#)

[Sealed Sources, Revision 4 \(6/2018\)](#)

[Self-Shielded Irradiators, Revision 4 \(6/2018\)](#)

[Material in Well Logging, Tracer, and Field Flood Study, Revision 3 \(1/2016\)](#)

[XRF Devices, Revision 5 \(6/2018\)](#)

[Manufacturing and Distribution, Revision 3 \(6/2018\)](#)

[Training, Experience, and Preceptor Attestations](#)

[A: Radiation Safety Officer for Medical Use, Revision 0 \(7/2016\)](#)

[B: Authorized User - Written Directive Not Required, Revision 0 \(7/2016\)](#)

[C: Unsealed Radioactive Material Requiring Written Directive, Revision 2, \(6/2014\)](#)

[D: Authorized User for Manual Brachytherapy Sources, Revision 0 \(7/2016\)](#)

[E: Authorized User of Remote Afterloader, Teletherapy, or Gamma Stereotactic Radiosurgery Units, Revision 0 \(7/2016\)](#)

[F: Authorized Medical Physicist, Revision 0 \(7/2016\)](#)

[G: Authorized Nuclear Pharmacist, Revision 0 \(7/2016\)](#)

[Other Forms](#)

[Certificate of Disposition of Materials, Revision 0 \(7/2016\)](#)

[Certificate - Use of Depleted Uranium under General License, Revision 0 \(7/2016\)](#)

[Cumulative Occupational Exposure History, Revision 1 \(1/2015\)](#)

[Fingerprint Record, Federal Bureau of Investigation, FD-258, \(rev. 9/2013\)](#)

[Notice to Employees, RH-F-12 \(1/2011\)](#)

[Occupational Exposure Record per Monitoring Period, Revision 1 \(1/2015\)](#)

[Registration Certificate - In Vitro Testing with Radioactive Material under General License, Revision 0 \(7/2016\)](#)

[Reciprocity Privileges Checklist, Revision 0 \(7/2016\)](#)

[Application for Reciprocal Recognition of Out-of-State Radioactive Materials License, Revision 0 \(2/2021\)](#)

[Reciprocity Notification, Revision 0 \(2/2021\)](#)

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