CHAPTER 481

VIRGINIA RADIATION PROTECTION REGULATIONS

PART I.

GENERAL PROVISIONS.

ARTICLE 1.

GENERAL PROVISIONS.

12 VAC 5-481-10. Definitions.

As used in these regulations, these terms have the definitions set forth below.

"A_1" means the maximum activity of special form radioactive material permitted in a Type A package.

"A_2" means the maximum activity of radioactive material, other than special form radioactive material, permitted in a Type A package. These values are either listed in Appendix L of these regulations, Table I, or may be derived in accordance with the procedure prescribed in Appendix L of these regulations.

"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.

"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 Code of Virginia Sections 32.1-227 through 238.

"Active maintenance" means any significant activity needed during the period of institutional control to maintain a reasonable assurance that the performance objectives in 12 VAC 5-481-2820 and 12 VAC 5-481-2830 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).

"Added filtration" means any filtration which is in addition to the inherent filtration.

"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.

"Agreement State" means any state with which the Nuclear Regulatory Commission or the Atomic Energy Commission has entered into an effective agreement under subsection 274b. of the Atomic Energy Act of 1954, as amended (73 Stat. 689).

"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 exist in concentrations:

1. In excess of the derived air concentrations (DACs) specified in Appendix F, Table I of these regulations; 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 (K)" means the kinetic energy released in air by ionizing radiation. Kerma is determined as the quotient of De by Dm, where De is the sum of the initial kinetic energies of all the charged ionizing particles liberated by uncharged ionizing particles in air of mass Dm. The SI unit of air kerma is joule per kilogram and the special name for the unit of kerma is the gray (Gy).

"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- or gamma-rays to determine the elemental composition or to examine the microstructure of materials.

"Annual limit on intake" (ALI) means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent of 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 Table I, Columns 1 and 2, of Appendix F.

"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.

"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.

"As low as is reasonably achievable" (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 or her employee or agent who assembles components into an X-ray system that is subsequently used to provide professional or commercial services.

"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.

"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 user" means a practitioner of the healing arts who is identified as an authorized user on an Agency, Agreement State, Licensing State or the Nuclear Regulatory Commission license that authorizes the medical use of radioactive material.

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

"Background radiation" means radiation from cosmic sources; naturally occurring radioactive materials, including radon, except as a decay product of source or special nuclear material, and including global fallout as it exists in the environment from the testing of nuclear explosive devices. "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 which provides a means to restrict the dimensions of the X-ray field.

"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" (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, 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.

"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 utilizing special nuclear material; and

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 or thorium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition.

"C-arm X-ray system" 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 12 VAC 5-481-720 of these regulations.

"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 which 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.

"Cephalometric device" means a device intended for the radiographic visualization and measurement of the dimensions of the human head.

"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.

"Certified cabinet X-ray system" means an X-ray system which 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 which are subject to regulations promulgated under Public Law 90-602, the Radiation Control for Health and Safety Act of 1968 of the Food and Drug Administration.

"Certified system" means any X-ray system which has one or more certified component(s).

"Certifying entity" means an independent certifying organization meeting the requirements in Appendix K or a state regulatory program meeting the requirements in Appendix K.

"CFR" means Code of Federal Regulations.

"Changeable filters" means any filter, exclusive of inherent filtration, which can be removed from the useful beam through any electronic, mechanical, or physical process.

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

"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.

"Coefficient of variation (C)" means the ratio of the standard deviation to the mean value of a set 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.

"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.

"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.

"Commencement of construction" means any clearing of land, excavation, or other substantial action that would adversely affect the environment of a land disposal facility. The term does not mean disposal site exploration, necessary roads for disposal site exploration, borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the suitability of the disposal site or the protection of environmental values.

"Committed dose equivalent" ($H_{T,50}$) 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" ($H_{E, 50}$) is 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.

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

"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:

μ_x = Linear attenuation coefficient of the material of interest;

μ_w = Linear attenuation coefficient of water;

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

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

"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 cable" 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 tube" means a protective sheath for guiding the control cable. The control tube connects the

control drive mechanism to the radiographic exposure device.

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

"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 Houndsfield scale of CTN is used;

μ_x = Linear attenuation coefficient of the material of interest;

μ_w = Linear attenuation coefficient of water.

"Curie" means a unit of quantity of activity. One curie (Ci) is that quantity of radioactive material which decays at the rate of 3.7E+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.

"Dead-man switch" means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

"Declared pregnant woman" means a woman who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception.

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

"Department of Energy" means the Department of Energy established by Public Law 95-91, August 4, 1977, 91 Stat. 565, 42 U.S.C. 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 sections 104(b), (c) and (d) of the Energy Reorganization Act of 1974 (Public Law 93-438, October 11, 1974, 88 Stat. 1233 at 1237, 42 U.S.C. 5814, effective January 19, 1975) and retransferred to the Secretary of Energy pursuant to section 301(a) of the Department of Energy Organization Act (Public Law 95-91, August 4, 1977, 91 Stat. 565 at 577-578, 42 U.S.C. 7151, effective October 1, 1977.)

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

"Derived air concentration" (DAC) means the concentration of a given radionuclide in air which, if breathed by the reference man for a working year of 2,000 hours under conditions of light work, 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 Table I, Column 3, of Appendix F.

"Derived air concentration-hour" (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").

"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.

"Diagnostic X-ray imaging system" means an assemblage of components for the generation, emission and reception of X-rays and the transformation, storage and visual display of the resultant X-ray image.

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

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

"Disposal site" means that portion of a land disposal facility which 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.

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

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

"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 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 (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 ($H_E = \sum(w_T H_T)$.

"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.

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

"Entrance exposure rate" means the exposure free in air per unit time at the point where the center of the useful beam enters the patient.

"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.

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

"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 which 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" means the quotient of Dq by dm where "Dq" is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in

a volume element of air having mass "dm" are completely stopped in air. The SI unit of exposure is the coulomb per kilogram (C/kg). See 12 VAC 5-481-250 Units of Exposure and Dose for the special unit.

"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.

"Eye dose equivalent" means the external dose equivalent to the lens of the eye at a tissue depth of 0.3 centimeter (300 mg/cm^2).

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

"Fail-safe characteristics" mean a design feature which 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 which 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 12 VAC 5-481-3750.

"Fissile material" means any special nuclear material consisting of or containing one or more fissile radionuclides. Fissile radionuclides are plutonium-238, plutonium-239, plutonium-241, uranium-233, and uranium-235. Neither natural nor depleted uranium is fissile material. Agency jurisdiction extends only to special nuclear material if quantities are not sufficient to form a critical mass as defined in Part I (12 VAC 5-481-10 et seq.) of these regulations.

A. Fissile Class I: A package which may be transported in unlimited numbers and in any arrangement, and which 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.

B. Fissile Class II: A package which may be transported together with other packages in any arrangement but, for criticality control, in numbers which 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.

"Fluoroscopic imaging assembly" means a subsystem in which X-ray photons produce a visible image. It includes the image receptor(s) such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

"Focal spot (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 Nuclear Regulatory Commission licensed facilities" means nuclear reactors, nuclear fuel reprocessing plants, uranium enrichment plants, or critical mass experimental facilities where Atomic Energy Commission or Nuclear Regulatory Commission 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 Environmental Protection Agency under the authority of the Atomic Energy Act of 1954, as amended, that impose limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.

"General environment" means, as used in Part XVI, 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 which, by design, is not limited to radiographic examination of specific anatomical regions.

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

"Gray (Gy)" means the SI unit of absorbed dose, kerma, and specific energy imparted equal to one joule per kilogram. The previous unit of absorbed dose (rad) is being replaced by the gray. (1 Gy=100 rad).

"Guide tube" 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 (HVL)" means the thickness of a specified material which 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-half of the value measured without the material at the same point.

"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 2000 hours of hands-on experience required for a radiation safety officer in 12 VAC 5-481-1310 A 2 or the hands-on experience for a radiographer as required by 12 VAC 5-481-1320 A.

"Hazardous waste" means those wastes designated as hazardous by the 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).

"High radiation area" means an area, accessible to individuals, in which radiation levels 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 from any surface that the radiation penetrates.

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

"HVL" (See "Half-value layer").

"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, which instantaneously converts an X-ray pattern into a corresponding light image of higher intensity.

"Image receptor" means any device, such as a fluorescent screen or radiographic film, which transforms incident X-ray photons either into a visible image or into another form which can be made into a visible image by further transformations.

"Image receptor support" means, for mammographic systems, that part of the system designed to support the image receptor during mammography.

"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.

"Independent certifying organization" means an independent organization that meets all of the criteria of Appendix K.

"Individual" means any human being.

"Individual monitoring" means the assessment of:

1. Dose equivalent (a) by the use of individual monitoring devices or (b) by the use of survey data; or

2. Committed effective dose equivalent (a) by bioassay or (b) 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, 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").

"Inherent filtration" means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.

"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: (1) Permanent markers placed at a disposal site, (2) public records and archives, (3) government ownership and regulations regarding land or resource use, and (4) 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 which requires continuing participation in measurement quality assurance with the National Institute of Standards and Technology or other equivalent national or international program.

"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 12 VAC 5-481-3160 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 12 VAC 5-481-3160.

"Isocenter" means the center of the sphere through which the useful beam axis passes while the gantry moves through its full range of motions.

"Kilovolt (kV) (kilo electron volt (keV))" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of 1000 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, and equipment which is intended to be used for the disposal of wastes into the subsurface of the land.

"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 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 which 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, i.e., 10 milliampere seconds, 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;

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.

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

"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.

"Licensing State" means any state with regulations equivalent to the Suggested State Regulations for Control of Radiation relating to, and an effective program for, the regulatory control of NARM and which has been granted final designation by the Conference of Radiation Control Program Directors, Inc.

"Light field" means that area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection.

"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. It is calculated using the following equation:

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

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" mean 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.

"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 12 VAC 5-481-3670.

"Logging supervisor" means the individual who uses sources of radiation or provides personal supervision of the utilization of sources of radiation at the well site.

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

"Lost or missing source of radiation" 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.

"Low specific activity (LSA) material" means radioactive material 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:

a. LSA-I

(i) Ores containing only naturally occurring radionuclides (for example, uranium or thorium decay series radionuclides) and uranium or thorium concentrates of such ores; or

(ii) Solid unirradiated natural uranium or depleted uranium or natural thorium or their solid or liquid compounds or mixtures; or

(iii) Radioactive material, other than fissile material, for which the A_2 value is unlimited; or

(iv) Mill tailings, contaminated earth, concrete, rubble, other bulk debris, and activated material in which the radioactive material is essentially uniformly distributed, and the average specific activity does not exceed 1.0 E-06 A_2/g.

b. LSA-II

(i) Water with tritium concentration up to 0.8 terabecquerel per liter (20.0 Ci/L); or

(ii) Material in which the radioactive material is distributed throughout, and the 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.

c. LSA-III

Solids in which:

(i) 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 (for example: concrete, bitumen, or ceramic); and

(ii) 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

(iii) The average specific activity of the solid 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 alpha emitters with a half-life of less than 10 days.

"Lung class" (See "Class").

"mAa" 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 12 VAC 5-481-10 of these regulations.

"Maximum line current" means the root-mean-square current in the supply line of an X-ray machine operating at its maximum rating.

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

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

"Megavolt (MV) (mega electron volt (MeV))" 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.

"Medical use" means the intentional internal or external administration of radioactive material, or the radiation therefrom, to humans in the practice of the healing arts.

"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 the administration of:

1. A radiopharmaceutical dosage greater than 1.11 megabecquerels (30 mCi) of either sodium iodide I-125 or I-131:

a. Involving the wrong patient or wrong radiopharmaceutical; or

b. When both the administered dosage differs from the prescribed dosage by more than 20% of the prescribed dosage and the difference between the administered dosage and prescribed dosage exceeds 1.11 megabecquerels (30 mCi);

2. A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131:

a. Involving the wrong patient, wrong radiopharmaceutical, or wrong route of administration; or

b. When the administered dosage differs from the prescribed dosage by more than 20% of the prescribed dosage;

3. A gamma stereotactic radiosurgery radiation dose:

a. Involving the wrong patient or wrong treatment site; or

b. When the calculated total administered dose differs from the total prescribed dose by more than 10% of the total prescribed dose;

4. A teletherapy radiation dose:

a. Involving the wrong patient, wrong mode of treatment, or wrong treatment site; or

b. When the treatment consists of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10% of the total prescribed dose; or

c. When the calculated weekly administered dose exceeds the weekly prescribed dose by 30% or more of the weekly prescribed dose; or

d. When the calculated total administered dose differs from the total prescribed dose by more than 20% of the total prescribed dose;

5. A brachytherapy radiation dose:

a. Involving the wrong patient, wrong radionuclide, or wrong treatment site (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site); or

b. Involving a sealed source that is leaking; or

c. When, for a temporary implant, one or more sealed sources are not removed upon completion of the procedure; or

d. When the calculated administered dose differs from the prescribed dose by more than 20% of the prescribed dose;

6. A diagnostic radiopharmaceutical dosage, other than quantities greater than 1.11 megabecquerels (30 mCi) of either sodium iodide I-125 or I-131, both:

a. Involving the wrong patient, wrong radiopharmaceutical, wrong route of administration, or when the administered dosage differs from the prescribed dosage; and

b. When the dose to the patient exceeds 50 millisieverts (5 rem) effective dose equivalent or 500 millisieverts (50 rem) dose equivalent to any individual organ.

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

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

"Monitor unit (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 (12 VAC 5-481-2660 et seq.) it

means: observing and making measurements to provide data to evaluate the performance and characteristics of the disposal site.

"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 which 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. For purposes of meeting the definition of a Licensing State by the Conference of Radiation Control Program Directors, Inc., NARM refers only to discrete sources of NARM. Diffuse sources of NARM are excluded from consideration by the Conference of Radiation Control Program Directors, Inc. for Licensing State designation purposes.

"Natural radioactivity" means radioactivity of naturally occurring nuclides.

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

"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.

"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:

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

where:

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

μ_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.

"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.

"Normal form radioactive material" means radioactive material which 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:

a. 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.

b. For X-ray irradiation, the virtual source or target to isocenter distance along the central axis of the useful beam. For non-isocentric equipment, this distance shall be that specified by the manufacturer.

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

"Nuclear waste" means a quantity of source, byproduct or special nuclear material (the definition of nuclear waste in this Part is used in the same way as in 49CFR 173.403) required to be in U. S. Nuclear Regulatory

Commission-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 dose received: from background radiation, or as a patient from medical practices, or 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.

"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.

"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.

"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 which 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, agency, political subdivision of this state, any other state or political subdivision or agency thereof, and any legal successor, representative, agent, or agency of the foregoing (, but shall not include 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.

"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 dispense 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.

"Primary beam" means radiation which 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 which will monitor the useful beam during irradiation and which will terminate irradiation when a pre-selected number of dose monitor units have been delivered.

"Primary protective barrier" (See "Protective barrier").

"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.

"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; or

2. For teletherapy, the total dose and dose per fraction as documented in the written directive; or

3. For brachytherapy, either the total source strength and exposure time, or the total dose, as documented in the written directive.

"Private inspector" means an individual who meets the requirements set forth in Appendix A 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, 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 barrier" means a barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:

1. "Primary protective barrier" means the material, excluding filters, placed in the useful beam;

2. "Secondary protective barrier" means the material which attenuates stray 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 sources of radiation from licensed or registered operations. Public dose does not include occupational dose, or dose received from

background radiation, or dose received as a patient from medical practices, or dose received from voluntary participation in medical research programs.

"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 which 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.

"Quality factor" (Q) means the modifying factor, listed in Tables I and II of 12 VAC 5-481-250, that is used to derive dose equivalent from absorbed dose.

"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).

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

"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 non-ionizing radiation, such as radiowaves or microwaves, or 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 detector" means a device which in the presence of radiation provides a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

"Radiation dose" (See "Dose").

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

"Radiation detector" means a device which, in the presence of radiation provides, by either direct or indirect means, a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

"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" means an individual who has the knowledge and responsibility to apply appropriate radiation protection regulations.

"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 12 VAC 5-481-1310.

"Radiation therapy physicist" means an individual qualified in accordance with 12 VAC 5-481-3720 D.

"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.

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

"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 12 VAC 5-481-1320.

"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 imaging system" means any system whereby a permanent or semi-permanent image is recorded on an image receptor by the action of ionizing radiation.

"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 (12 VAC 5-481-1170 et seq.).

"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.

"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.

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

"Radiography" (See "Industrial radiography").

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

"Reasonably maximally exposed individual" means, as used in Part XVI, 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.

"Recordable event" means the administration of:

1. A radiopharmaceutical or radiation without a written directive where a written directive is required;

2. A radiopharmaceutical or radiation where a written directive is required without daily recording of each administered radiopharmaceutical dosage or radiation dose in the appropriate record;

3. A radiopharmaceutical dosage greater than 1.11 megabecquerels (30 mCi) of sodium iodide I-125 or I-131 when both the administered dosage differs from the prescribed dosage by more than 10% of the prescribed dosage, and the difference between the administered dosage and the prescribed dosage exceeds 555 kilobecquerels (15 mCi);

4. A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131, when the administered dosage differs from the prescribed dosage by more than 10% of the prescribed dosage;

5. A teletherapy radiation dose when the calculated weekly administered dose exceeds the weekly prescribed dose by 15% or more of the weekly prescribed dose; or

6. A brachytherapy radiation dose when the calculated administered dose differs from the prescribed dose by more than 10% of the prescribed dose.

"Recording" means producing a permanent 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 pre-selected 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 which 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 and Parts 390-397.

"Regulations of the U. S. Nuclear Regulatory Commission" means the regulations in 10 CFR 71 for purposes of Part XIII (12 VAC 5-481-3280 et seq.).

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

"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.

"Respiratory protective equipment" 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 sources of radiation. 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.

"Roentgen" means the special unit of exposure. One roentgen (R) equals 2.58E-4 coulombs per kilogram of air (see "Exposure" and 12 VAC 5-481-250).

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

"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 pre-selected set of two or more scans performed consecutively under pre-selected 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 the radioactive material.

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

"Secondary protective barrier" (See "Protective barrier").

"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 U. S. Geological Survey.

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

"Shallow dose equivalent" (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^2) averaged over an area of one square centimeter.

"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 12 VAC 5-481-640 of these regulations.

"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" (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 (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 which obtains X-ray transmission data during a scan to produce a single tomogram.

"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% (0.05%) or more of uranium, thorium or any combination of uranium and thorium. Source material does not include special nuclear material.

"Source material milling" means any activity that results in the production of byproduct material as defined by definition (2) of "byproduct material".

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

"Source-skin distance (SSD)" (See "Target-skin distance").

"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 which 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:

a. It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;

b. The piece or capsule has at least one dimension not less than five millimeters (0.2 in.); and

c. It satisfies the test requirements specified by the Nuclear Regulatory Commission. A special form encapsulation designed in accordance with the Nuclear Regulatory Commission requirements in effect on June 30, 1983, and constructed prior to July 1, 1985, may continue to be used. A special form encapsulation designed in accordance with the Nuclear Regulatory Commission requirements

in effect on March 31, 1996, and constructed prior to April 1, 1998, may continue to be used. A special form encapsulation either designed or constructed after April 1, 1998, must meet requirements of this definition applicable at the time of its design or construction.

"Special nuclear material" means:

1. Plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material the Nuclear Regulatory Commission, pursuant to the provisions of section 51 of the Atomic Energy Act of 1954, as amended, 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:

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

"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 which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.

"Spot-film device" means a device intended to transport and/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.

"SSD" means the distance between the source and the skin entrance plane of the patient.

"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 these regulations, "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.

"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.

"Surface contaminated object" (SCO) means a solid object that is not itself classed as radioactive material, but which 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:

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

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

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

(iii) The non-fixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm^2 , or the area of the surface if less than 300 cm^2, does not exceed 4 E+04 becquerel per cm^2 (1 μCi/cm^2) for beta and gamma and low

toxicity alpha emitters, or 4 E+03 Becquerel per cm^2 (0.1 µCi/cm^2) for all other alpha emitters.

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

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

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

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

"Survey" means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of sources of radiation. When appropriate, such

evaluation includes, but is not limited to, tests, physical examinations, and measurements of levels of radiation or concentrations of radioactive material present.

"Survey" means a test or procedure done by a private or state inspector to determine if the equipment or procedures comply with the requirements of these regulations. Documentation, at a minimum, shall consist of completing forms approved by the agency in their entirety if such forms exist.

"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.

"Technologically Enhanced Naturally Occurring Radioactive Material (TENORM)" means, as used in Part XVI, 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 US NRC regulations.

"Technique factors" means the following conditions of operation:

1. For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;

2. For field emission equipment rated for pulsed operation, peak tube potential in kV, and number of X-ray pulses;

3. For CT X-ray systems designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in 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 mAs;

4. For CT X-ray systems not designed for pulsed operation, peak tube potential in kV, and either tube current in Ma and scan time in seconds, or the product of tube current and exposure time in mAs and the scan time when the scan time and exposure time are equivalent; and

5. For all other equipment, peak tube potential in kV, and either tube current in Ma and exposure time in seconds, or the product of tube current and exposure time in mAs.

"Teletherapy physicist" means an individual identified as the 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 is performed other than the location(s) listed in a specific license or certificate of registration. It also means a location where radioactive materials are present for the purpose of performing wireline service operations or subsurface tracer studies.

"Tenth-value layer (TVL)" means the thickness of a specified material which 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.

"Termination of irradiation" means the stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

"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.

"These regulations" mean all parts of these regulations.

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

"Tomographic plane" means that geometric plane which 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" (TEDE) means the sum of the deep dose equivalent for external exposures and the committed effective dose equivalent for internal exposures.

"Total organ dose equivalent" (TODE) means the sum of the deep dose equivalent and the committed dose equivalent to the organ receiving the highest dose as described in 12 VAC 5-481-1040 A 6 of these regulations.

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

"Transfer" means, as used in Part XVI, 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 which meets all applicable requirements of the U.S. Department of Transportation.

"Transport index" 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 expressing the maximum radiation level at one meter (3.3 feet) from the external surface of the package in millisievert (mSv) per hour multiplied by 100, which is thus equivalent to the maximum radiation level in millirem per hour at one meter.

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

"Tube housing assembly" means the tube housing with tube installed. It includes high-voltage and/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 Appendix L or may be determined by procedures described in Appendix L.

"Type B package" means a Type B packaging together with its radioactive contents. A Type B package design is designated as B(U) or B(M). B(U) refers to the need for unilateral approval of international shipments; B(M) refers to the need for multilateral approval. There is no distinction made in how packages with these designations may be used in domestic transportation. To determine their distinction for international transportation, refer to 49 CFR Part 173. A Type B package approved prior to September 6, 1983 was designated only as Type B. Limitations on its use are specified in 12 VAC 5-481-3340.

"Type B packaging" means a packaging designed to retain the integrity of containment and shielding when subjected to the normal conditions of transport and hypothetical accident test conditions set forth in 10 CFR Part 71.

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

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

"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.

"Unrefined and unprocessed ore" means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or refining.

"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 isotopes with the naturally occurring distribution of uranium, 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 emanating from the tube housing port or the radiation head and passing through the aperture of the beam limiting device when the exposure controls are in a mode to cause the system to produce radiation.

"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 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 from any surface that the radiation penetrates.

"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 that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level waste has the same meaning as in the Low-Level Radioactive Waste Policy Act, P.L. 96-573, as amended by P.L. 99-240, effective January 15, 1986; that is, radioactive waste (a) not classified as high-level radioactive waste, spent nuclear fuel, or byproduct material as defined in Section 11e.(2) of the Atomic Energy Act (uranium or thorium tailings and waste) and (b) classified as low-level radioactive waste consistent with existing law and in accordance with (a) by the Nuclear Regulatory Commission.

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

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

"Week" means seven consecutive days starting on Sunday.

"Weighting factor" (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[a/]
Whole Body	1.00[b/]

[a/] *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.*

[b/] *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 which 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 which is used to lower and raise

logging tools in the well-bore.

"Wireline service operation" means any evaluation or mechanical service which 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" (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" (WLM) means an exposure to one working level for 170 hours -- 2,000 working hours per year divided by 12 months per year is approximately equal to 170 hours per month.

"Written directive" means an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, except as specified in (6), containing the following information:

1. For any administration of quantities greater than 1.11 megabecquerels (30 mCi) of sodium iodide I-125 or I-131: the radionuclide, and dosage; or

2. For a therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131: the radiopharmaceutical, dosage, and route of administration; or

3. For gamma stereotactic radiosurgery: target coordinates, collimator size, plug pattern, and total dose; or

4. For teletherapy: the total dose, dose per fraction, treatment site, and overall treatment period; or

5. For high-dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, and total dose; or

6. For all other brachytherapy,

a. Prior to implantation: the radionuclide, number of sources, and source strengths; and

b. After implantation but prior to completion of the procedure: the radionuclide, treatment site, and total source strength and exposure time (or, equivalently, the total dose).

"X-ray exposure control" means a device, switch, button or other similar means by which an operator initiates and/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 and/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 which 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 exposure rate is one-fourth of the maximum in the intersection.

"X-ray high-voltage generator" means a device which 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 tube(s), 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 which 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 and/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, image intensifier, or spot-film device beneath the tabletop.

"X-ray tube" means any electron tube which 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 these regulations. 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 and that no day is omitted or duplicated in consecutive years.

12 VAC 5-481-20. Scope.

Except as otherwise specifically provided, these regulations apply to all persons who receive, possess, use, transfer, own, or acquire any source of radiation; provided, however, that nothing in these regulations shall apply to any person to the extent such person is subject to regulation by the Nuclear Regulatory Commission. Attention is directed to the fact that regulation by the state of source material, byproduct material, and special nuclear material in quantities not sufficient to form a critical mass is subject to the provisions of the agreement between the state and the Nuclear Regulatory Commission and to 10 CFR Part 150 of the Commission's regulations.

12 VAC 5-481-30. Authority for regulations.

The Radiation Control Act, which is codified as Title 32.1, Chapter 6, Article 8, Section 32.1-227 through 32.1-238 of the Code of Virginia, requires the Board of Health to establish a program to provide for the orderly regulation of radiation. Section 32.1-12 confers authority for Rules and Regulations on members of the Board of Health.

The Act also directs the board to promulgate regulations providing for (i) licenses to use, manufacture, produce, transfer, receive, acquire, own or possess quantities of, or devices or equipment utilizing, by-product, source, special nuclear, or other radioactive material occurring naturally or produced artificially, (ii) registration of the possession of a source of ionizing radiation and of information with respect thereto. And (iii) regulation of by-product, source and special nuclear material.

12 VAC 5-481-40. Administration of regulations.

These regulations are administered by the following:

A. The Board of Health is the governing body of the state Department of Health, of which the Radiological Health Program is a part. In this capacity, the board has the responsibility to promulgate, amend, and repeal, as appropriate, regulations necessary to implement the Radiation Control Act.

B. The state health commissioner is the chief executive officer of the state Department of Health. The commissioner has the authority to act, within the scope of regulations promulgated by the board, for the board when it is not in session.

C. The Radiation Advisory Board, established pursuant to Section 32.1-233, Code of Virginia, meets at least annually to review and evaluate the policies and programs of the Commonwealth relating to radiation, to make recommendations to the commissioner of Health and the Board of Health, and to furnish such technical advice as may be required on matters relating to development, utilization and regulation of sources of radiation.

12 VAC 5-481-50. Application of regulations.

These regulations have general application throughout the Commonwealth.

12 VAC 5-481-60. Application of the Administrative Process Act.

The provisions of the Virginia Administrative Process Act, which is codified as Chapter 1.1:1 of Title 9, Section 9-6.14:1 et seq., of the Code of Virginia, govern the adoption, amendment, modification, and revision of this chapter, and the conduct of all proceedings hereunder and appeals therefrom.

12 VAC 5-481-70. Severability.

If any provision of this chapter or the application thereof is held to be invalid, such invalidity shall not affect other provisions or application of any other part of this chapter which can be given effect without the invalid provisions or application, and to this end the provisions of this chapter and the various applications thereof are declared to be severable.

12 VAC 5-481-80. Scope.

Except as otherwise specifically provided, this chapter apply to all persons who use, manufacture, produce, transport, transfer, receive, acquire, own, or possess any source of ionizing radiation, provided, however, that nothing in this chapter shall apply to any person to the extent such person is subject to regulation by the U. S. Nuclear Regulatory Commission.

12 VAC 5-481-90. Exemptions from regulatory requirements.

A. General Provisions. The agency may, upon application or upon its own initiative, grant such exemptions or exceptions from the requirements of these regulations as it determines are authorized by law and will not result in undue hazard to public health and safety or property.

B. Department of Energy Contractors and Nuclear Regulatory Commission Contractors. Any Department of Energy contractor or subcontractor and any Nuclear Regulatory Commission contractor or subcontractor of the following categories operating within this state is exempt from these regulations to the extent that such contractor or subcontractor under his contract receives, possesses, uses, transfers, or acquires sources of radiation:

1. Prime contractors performing work for the Department of Energy at U.S. Government owned or controlled sites, including the transportation of sources of radiation to or from such sites and the performance of contract services during temporary interruptions of such transportation;

2. Prime contractors of the Department of Energy performing research in, or development, manufacture, storage, testing, or transportation of, atomic weapons or components thereof;

3. Prime contractors of the Department of Energy using or operating nuclear reactors or other nuclear devices in a United States Government-owned vehicle or vessel; and

4. Any other prime contractor or subcontractor of the Department of Energy or of the Nuclear Regulatory Commission when the state and the Nuclear Regulatory Commission jointly determine:

a. That the exemption of the prime contractor or subcontractor is authorized by law; and

b. That, under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety.

12 VAC 5-481-100. Records.

Each licensee and registrant shall maintain records showing the receipt, transfer, and disposal of all sources of radiation. Additional record requirements are specified elsewhere in these regulations.

12 VAC 5-481-110. Inspections and enforcement.

A. Each licensee and registrant shall afford the agency at all reasonable times opportunity to inspect sources of radiation and the premises and facilities wherein such sources of radiation are used or stored.

B. Each licensee and registrant shall make available to the agency for inspection, upon reasonable notice, records maintained pursuant to these regulations.

C. Enforcement: The following provisions of Chapter 1, Article 4 of Title 32.1 of the Code of Virginia, shall apply:

1. Right of entry to inspect, etc.: warrants. - Upon presentation of appropriate credentials and upon consent of the owner or custodian, the commissioner or his designee shall have the right to enter at any reasonable time onto any property to inspect, investigate, evaluate, conduct tests or take samples for testing as he reasonably deems necessary in order to determine whether the provisions of this chapter, any order of the board or commissioner or any conditions in a permit, license or certificate issued by the board or commissioner are being complied with. If the commissioner or his designee is denied entry, he may apply to an appropriate circuit court for an inspection warrant authorizing such investigation, evaluation, inspection, testing or taking of samples for testing as provided in Chapter 24 of Title 19.2.

2. Orders. - The board is authorized to issue orders to require any person to comply with the provisions of any law administered by the commissioner or the agency or any regulations promulgated by the board or to comply with any case decision as defined in 9-6.14:4 of the board or commissioner. Any such order shall be issued only after a hearing with at least 30 days notice to the affected person of the time, place and purpose thereof. Such order shall become effective not less than 15 days after mailing a copy thereof by certified mail to the last known address of such person. The provisions of this section shall not affect the authority of the board to issue separate orders and regulations to meet any emergency as provided in §32.1-13.

3. Penalties, injunctions, civil penalties and charges for violations.

a. Any person willfully violating or refusing, failing or neglecting to comply with any regulation or order of the board or commissioner or any provision of this title shall be guilty of a Class 1 misdemeanor unless a different penalty is specified.

b. Any person violating or failing, neglecting, or refusing to obey any lawful regulation or order of the board or commissioner or any provision of this title, may be compelled in a proceeding instituted in an appropriate court by the board or commissioner to obey such regulations, order or provision of this title and to comply therewith by injunction, mandamus, or other appropriate remedy.

c. Without limiting the remedies which may be obtained in Subsection 2, any person violating or failing, neglecting or refusing to obey any injunction, mandamus or other remedy obtained pursuant to Subsection 2 shall be subject, in the discretion of the Court, to a civil penalty not to exceed 10,000 dollars for each violation. Each day of violation shall constitute a separate offense.

d. With the consent of any person who has violated or failed, neglected or refused to obey any regulation or order of the board or commissioner or any provision of this title, the board may provide, in an order issued by the board against such person, for the payment of civil charges for past violations in specific sums, not to exceed the limit specified in Subsection 3. Such civil charges shall be instead of any appropriate civil penalty which could be imposed under Subsection 3 of this section.

12 VAC 5-481-120. Emergency regulations.

The board, pursuant to powers granted in §32.1-13 of the Code of Virginia, is authorized to promulgate emergency regulations. Any emergency regulations adopted under this section shall comply with the provisions of §9-6.14:4.1.C.5 of the Code of Virginia.

12 VAC 5-481-130. Impounding.

Sources of radiation shall be subject to impounding pursuant to Article 8 (§32.1-238 et seq.) of Chapter 6 of the Code of Virginia.

12 VAC 5-481-140. Prohibited uses.

A. A hand-held fluoroscopic screen shall not be used with X-ray equipment unless it has been listed in the Registry of Sealed Source and Devices or accepted for certification by the Food and Drug Administration, Center for Devices and Radiological Health.

B. Shoe-fitting fluoroscopic devices shall not be used.

C. No person shall intentionally apply or allow to be applied, either directly or indirectly, radiation to human beings except by, or under the supervision of, a practitioner of the healing arts licensed by this state, except in the case of healing arts screening programs approved in advance by the commissioner. Supervision, as used in this subsection, means the responsibility for and control of quality, radiation safety and technical aspects of the application of radiation to human beings

for diagnostic or therapeutic purposes. This prohibition does not apply to persons who are occupationally exposed to radiation or as otherwise provided in these regulations.

12 VAC 5-481-150. Communications.

All communications and reports concerning this chapter, and applications filed thereunder, should be addressed to the agency at the following address: Virginia Department of Health , Radiological Health Program, 1500 E. Main Street, Room 240, Richmond, Va. 23119-2448.

12 VAC 5-481-160. Effective date.

The application of these regulations to possess by-product materials, source and special nuclear materials shall not become operative until July 1, 1999 and until 30 days after publication in the Virginia Register of a notice of an agreement executed by the Commonwealth of Virginia and the Federal Government under the provisions of Section 274b of the Atomic Energy Act of 1954, as amended (73 Statute 689). All other applications of the provisions of this chapter shall become effective July 1,1999.

12 VAC 5-481-170. Removal of notices posted by agency prohibited.

Any sign, notice, warning or label affixed by the agency to equipment or facilities of any registrant or licensee shall not be removed, defaced or concealed by any person other than the agency without written permission.

12 VAC 5-481-180. Tests.

Each licensee and registrant shall perform upon instructions from the agency, or shall permit the agency to perform, such reasonable tests as the agency deems appropriate or necessary including, but not limited to, tests of:

A. Sources of radiation;

B. Facilities wherein sources of radiation are used or stored;

C. Radiation detection and monitoring instruments; and

D. Other equipment and devices used in connection with utilization or storage of licensed or registered sources of radiation.

12 VAC 5-481-190. Additional regulatory requirements.

The agency may, by rule, regulation, or order, impose upon any licensee or registrant such requirements in addition to those established in these regulations as it deems appropriate or necessary to minimize danger to public health and safety or property.

12 VAC 5-481-200. Violations.

An injunction or other court order may be obtained prohibiting any violation of any provision of the Act or any regulation or order issued thereunder. Any person who willfully violates any provision of the Act

or any regulation or order issued thereunder may be guilty of a felony, misdemeanor or crime and, upon conviction, may be punished by fine or imprisonment or both, as provided by law.

12 VAC 5-481-210. Impounding.

Sources of radiation shall be subject to impoundment pursuant to agency regulations.

12 VAC 5-481-220. Reserved.

12 VAC 5-481-230. Interpretations.

Except as specifically authorized by the agency in writing, no interpretation of these regulations by an officer or employee of the agency other than a written interpretation by the legal counsel will be recognized to be binding upon the agency.

12 VAC 5-481-240. Units of exposure and dose.

A. As used in these regulations, the unit of exposure is the coulomb per kilogram (C/kg) of air. One roentgen is equal to 2.58E-4 coulomb per kilogram of air.

B. As used in these regulations, the units of dose are:

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

2. Rad is 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 Gy).

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

4. Sievert (Sv) is 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).

C. As used in these regulations, the quality factors for converting absorbed dose to dose equivalent are shown in Table I.

TABLE I

QUALITY FACTORS AND ABSORBED DOSE EQUIVALENCIES

Type of Radiation	Quality Factor (Q)	Absorbed Dose Equal to a Unit Dose Equivalent[a]
X, gamma, or beta radiation and high-speed electrons	1	1
Alpha particles, multiple-charged particles, fission fragments and heavy particles of unknown charge	20	0.05
Neutrons of unknown energy	10	0.1
High-energy protons	10	0.1

[a] Absorbed dose in gray equal to one Sv or the absorbed dose in rad equal to one rem.

D. If it is more convenient to measure the neutron fluence rate than to determine the neutron dose equivalent rate in sievert per hour or rem per hour, as provided in 12 VAC 5-481-240 C, 0.01 Sv (1 rem) of neutron radiation of unknown energies may, for purposes of these regulations, be assumed to result from a total fluence of 25 million neutrons per square centimeter incident upon the body. If sufficient information exists to estimate the approximate energy distribution of the neutrons, the licensee or registrant may use the fluence rate per unit dose equivalent or the appropriate Q value from Table II to convert a measured tissue dose in gray or rad to dose equivalent in sievert or rem.

TABLE II

MEAN QUALITY FACTORS, Q, AND FLUENCE PER UNIT DOSE EQUIVALENT FOR MONOENERGETIC NEUTRONS

Neutron Energy (MeV)	Quality Factor[a] (Q)	Fluence per Unit Dose Equivalent[b] (Neutrons cm^{-2} rem^{-1})	Fluence per Unit Dose Equivalent[b] (Neutrons cm^{-2} Sv^{-1})
(thermal)			
2.5E-8	2	980E+6	980E+8
1E-7	2	980E+6	980E+8
1E-6	2	810E+6	810E+8
1E-5	2	810E+6	810E+8
1E-4	2	840E+6	840E+8
1E-3	2	980E+6	980E+8
1E-2	2.5	1010E+6	1010E+8
1E-1	7.5	170E+6	170E+8
5E-1	11	39E+6	39E+8

1	11	27E+6	27E+8
2.5	9	29E+6	29E+8
5	8	23E+6	23E+8
7	7	24E+6	24E+8
10	6.5	24E+6	24E+8
14	7.5	17E+6	17E+8
20	8	16E+6	16E+8
40	7	14E+6	14E+8
60	5.5	16E+6	16E+8
1E+2	4	20E+6	20E+8
2E+2	3.5	19E+6	19E+8
3E+2	3.5	16E+6	16E+8
4E+2	3.5	14E+6	14E+8

[a] *Value of quality factor (Q) at the point where the dose equivalent is maximum in a 30-centimeter diameter cylinder tissue-equivalent phantom.*

[b] *Monoenergetic neutrons incident normally on a 30-centimeter diameter cylinder tissue-equivalent phantom.*

12 VAC 5-481-250. Units of activity.

For purposes of these regulations, activity is expressed in the SI unit of becquerel (Bq) or in the special unit of curie (Ci), or their multiples, or disintegrations or transformations per unit of time.

A. One becquerel (Bq) = one disintegration or transformation per second (dps or tps).

B. One curie (Ci) = 3.7E+10 disintegrations or transformations per second (dps or tps) = 3.7E+10 becquerel (Bq) = 2.22E+12 disintegrations or transformations per minute (dpm or tpm).

PART II.

REGISTRATION OF RADIATION MACHINE FACILITIES AND SERVICES.

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12 VAC 5-481-260. Purpose and scope.

A. This Part provides for the registration of ionizing radiation machine facilities.

B. In addition to the requirements of this Part, all registrants are subject to the applicable provisions of these regulations.

12 VAC 5-481-270. Exemptions.

A. Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from the registration and notification requirements of this Part, provided that the dose equivalent rate averaged over an area of 10 square centimeters does not exceed 5 μSv (0.5 millirem) per hour at five centimeters from any accessible surface of such equipment. The production, testing, or factory servicing of such equipment shall not be exempt.

B. Radiation machines while in transit or storage incident thereto are exempt from the requirements of this Part.

C. Domestic television receivers are exempt from the requirements of this Part.

12 VAC 5-481-280. Shielding plan review.

A. Prior to construction, the floor plans, shielding specifications and equipment arrangement of all new installations, or modifications of existing installations, utilizing ionizing radiation machines shall be available to the agency for review. The required information is found in 12 VAC 5-481-280 E.

B. The agency may require the applicant to utilize the services of a private inspector to determine the shielding requirements prior to the plan review.

C. The review of such plans shall not preclude the requirement of additional modifications should a subsequent analysis of operating conditions indicate the possibility of an individual receiving a dose in excess of the limits prescribed in 12 VAC 5-481-640, 12 VAC 5-481-680, 12 VAC 5-481-690, 12 VAC 5-481-700, 12 VAC 5-481-710, 12 VAC 5-481-720 and 12 VAC 5-481-730 of these regulations.

D. After installation of a radiation machine, the registrant shall maintain for inspection by the agency:

1. The maximum rated technique factors of each machine;

2. A scale drawing of the room in which a stationary radiation machine system is located with such drawing indicating the use of areas adjacent to the room and an estimation of the extent of occupancy by an individual in such areas. In addition, the drawing shall include:

a. The results of a survey for radiation levels present at the operator's position and at pertinent points outside the room at specified test conditions; or

b. The type and thickness of materials, or lead equivalency, of each protective barrier.

E. Required information. In order for the private inspector to provide an evaluation, technical

advice, and approval on shielding requirements for a radiation installation, the following information shall be required.

1. The plans showing, as a minimum, the following:

a. The normal location of the system's radiation port; the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors or other openings; the location of the operator's booth; and the location of the control panel;

b. The structural composition and thickness or lead equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned;

c. The dimensions of the room(s) concerned;

d. The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present;

e. The make and model of the equipment, the maximum technique factors, and the energy waveform (single phase, three phase, etc.);

f. The type of examination(s) or treatment(s) which will be performed with the equipment.

2. Information on the anticipated workload of the system(s) in Ma-minutes per week.

3. A report showing all basic assumptions used in the development of the shielding specifications.

F. Design requirements for an operator's booth

1. Space requirements:

a. The operator shall be allotted not less than 0.70 square meter (7.5 square feet) of unobstructed floor space in the booth;

b. The operator's booth may be any geometric configuration with no dimension of less than 0.6 m (2 feet);

c. The space shall be allotted excluding any encumbrance by the X-ray control panel, such as overhang, cables, or other similar encroachments;

d. The booth shall be located or constructed such that unattenuated direct scatter radiation originating on the examination table or at the wall-mounted image receptor will not reach the operator's position in the booth.

2. Structural requirements:

a. The booth walls shall be permanently fixed barriers of at least two m (7 feet) high;

b. When a door or movable panel is used as an integral part of the booth structure, it must have an interlock which will prevent an exposure when the door or panel is not closed;

c. Shielding shall be provided to meet the requirements of Part IV (12 VAC 5-481-600 et seq.) of these regulations.

3. Radiation exposure control placement: The radiation exposure control for the system shall be fixed within the booth and:

a. Shall allow the operator to remain in the protected area and not be exposed to direct scatter, leakage or primary beam radiation;

b. Shall allow the operator to use the majority of the available viewing windows.

4. Viewing system requirements:

a. Each booth shall have at least one viewing device which will:

(1) Be so placed that the operator can view the patient during any exposure; and

(2) Be so placed that the operator can have full view of any occupant of the room and should be so placed that the operator can view any entry into the room. If any door which allows access to the room cannot be seen from the booth, then outside that door there shall be an "X-ray on" warning sign that will be lighted anytime the rotor of the X-ray tube is activated. Alternatively, an interlock shall be present such that exposures are prevented unless the door is closed.

b. When the viewing system is a window, the following requirements also apply:

(1) The window shall have a viewing area of at least 0.09 square meter (1 square foot); Regardless of size or shape, at least 0.09 square meter (1 square foot) of the window area must be centered no less than 0.6 meter (2 feet) from the open edge of the booth and no less than 1.5 meter (5.0 feet) from the floor;

(2) The window shall have at least the same lead equivalence as that required in the booth's wall in which it is mounted.

c. When the viewing system is by mirrors, the mirror(s) shall be so located as to accomplish the general requirements of 12 VAC 5-481-280 F 1.

d. When the viewing system is by electronic means:

(1) The camera shall be so located as to accomplish the general requirements of 12 VAC 5-481-280 F 1; and

(2) There shall be an alternate viewing system as a backup for the primary system.

12 VAC 5-481-290. Registration of radiation machine facilities.

Each person having a radiation machine facility shall:

A. Apply for registration of such facility with the agency within 30 days following installation of equipment. Application for registration shall be completed on forms furnished by the agency and shall contain all the information required by the form and accompanying instructions. Registrations filed with the agency prior to the effective date of these regulations shall remain in effect until a renewal notice is issued by the agency pursuant to 12 VAC 5-481-310 of these regulations.

B. Designate on the application form an individual to be responsible for radiation protection;

C. Submit to the agency as part of any application for registration or renewal of registration one copy of each radiation survey or calibration report for which records are required to be

maintained pursuant to 12 VAC 5-481-1590 A 12 c of these regulations. Records submitted once need not be submitted again for renewal of registration.

D. Have an initial inspection by a private or state inspector no later than 30 days after the registration of the equipment. Subsequent inspections shall be made periodically in accordance with other parts of these regulations or whenever the equipment is moved to a new location. The agency shall furnish a list of private inspectors.

12 VAC 5-481-300. Issuance of registration certificate.

A. Upon a determination that an applicant meets the requirements of this chapter and has paid the appropriate registration fee, the agency shall issue a registration certificate.

B. The agency may incorporate in the registration certificate at the time of issuance or thereafter by appropriate rule, regulation or order, such additional requirements and conditions with respect to the registrant's receipt, possession, use and transfer of radiation machines as he deems appropriate or necessary.

12 VAC 5-481-310. Renewal of registration.

A. Application for renewal of registration shall be filed in accordance with 12 VAC 5-481-290 of this part.

B. In any case in which a registrant not less than 30 days prior to the expiration of his existing registration certificate has filed an application in proper form for renewal, such existing registration certificate shall not expire until the application status has been finally determined by the agency.

12 VAC 5-481-320. Expiration of registration certificate.

Except as provided by 12 VAC 5-481-310 B, each registration certificate shall expire at the end of the specified day in the month and year stated therein or upon notice issued to the registrant by the agency.

12 VAC 5-481-330. Report of changes.

The registrant shall notify the agency in writing before making any change which would render the information contained in the application for registration and/or the notice of registration no longer accurate.

12 VAC 5-481-340. Approval not implied.

No person, in any advertisement, shall refer to the fact that he or his facility is registered with the agency pursuant to the provisions of 12 VAC 5-481-290, and no person shall state or imply that any activity under such registration has been approved by the agency.

12 VAC 5-481-350. Assembler and/or transfer obligation.

A. Any person who sells, leases, transfers, lends, disposes, assembles, or installs radiation machines or upon significant service or modification thereof of any radiation machine (such as tube inserts, generators or collimators) in this state shall notify the agency within 15 days of:

1. The name and address of persons who have received these machines;

2. The manufacturer, model, and serial number of each radiation machine transferred; and

3. The date of transfer of each radiation machine.

B. No person shall make, sell, lease, transfer, lend, assemble, or install radiation machines or the supplies used in connection with such machines unless such supplies and equipment when properly placed in operation and used shall meet the requirements of these regulations.

12 VAC 5-481-360. Reciprocal recognition of out-of-state radiation machines.

A. Whenever any radiation machine is to be brought into the state, for any temporary use, the person proposing to bring such machine into the state shall give written notice to the agency at least two working days before such machine is to be used in the state. The notice shall include:

1. The type of radiation machine;

2. The nature, duration, and scope of use;

3. The exact location(s) where the radiation machine is to be used; and

4. States in which this machine is registered.

B. If, for a specific case, the two working-day period would impose an undue hardship on the person, upon application to the agency, permission to proceed sooner may be granted.

C. The person referred to in 12 VAC 5-481-360 A shall:

1. Comply with all applicable regulations of the agency;

2. Supply the agency with such other information as the agency may reasonably request; and

3. Not operate within the state on a temporary basis in excess of 180 calendar days per year.

4. Supply the agency a copy of a medical physicist or private inspector report not less than one year old indicating the equipment is certified by another state.

12 VAC 5-481-370. Certification of X-ray systems.

A. Every owner or operator of an X-ray machine shall:

1. Have the machine certified by the agency within 60 days of the date of installation and thereafter according to the inspection survey schedule in Part VI (12 VAC 5-481-1580 et seq.), and

2. Have the machine inspected whenever the machine is moved to a new location or according to the schedule in Part VI (12 VAC 5-481-1580 et seq.), whichever occurs first, by a private or state inspector, and

3. Submit to the agency one copy of each radiation survey or calibration report for which records are required to be maintained pursuant to Part VI (12 VAC 5-481-1580 et seq.) and if the survey was performed by a state inspector and the survey not initiated by the agency pay the appropriate fee as established by the Board of Health.

4. Certification may be denied if any non-compliances are not corrected within 45 days from the date of inspection.

B. The agency shall issue a certificate when the data indicates the machine meets the boards standards. A copy of the certificate shall be displayed by the registrant in a conspicuous place in close proximity to the X-ray machine.

C. Certification may be denied if the machine does not meet the standards set forth in these regulations. If the certification is denied, the machine shall not be used for treatment, diagnosis, or evaluation of patients, whether human or animal, until the standards of the board have been met.

D. Final disposition of the machine, including electrical disconnection or storage, will be made within 90 days of agency review.

E. For facilities providing mammography services, the agency may conduct scheduled and random unannounced inspections, to ensure compliance with laws, regulations, or conditions specified by the Board.

PART III.

LICENSING OF RADIOACTIVE MATERIAL.

ARTICLE 1.

PURPOSE AND SCOPE.

12 VAC 5-481-380. Purpose and scope.

12 VAC 5-481-380. Purpose and scope.

A. This Part, and Parts VII (12 VAC 5-481-1660 et seq.), XI (12 VAC 5-481-2660 et seq.), and XIII (12 VAC 5-481-3280 et seq.)of these regulations, provide for the licensing of radioactive material. No person shall receive, possess, use, transfer, own, or acquire radioactive material except as authorized pursuant to this Part or Parts VII (12 VAC 5-481-1660 et seq.), XI (12 VAC 5-481-2660 et seq.), and XIII (12 VAC 5-481-3280 et seq.) of these regulations, or as otherwise provided in these Parts.

B. In addition to the requirements of this Part, all licensees are subject to the requirements of Parts I (12 VAC 5-481-10 et seq.), IV (12 VAC 5-481-600 et seq.), X (12 VAC 5-481-2580 et seq.), and XIII (12 VAC 5-481-3280 et seq.) of these regulations. Furthermore, licensees engaged in industrial radiographic operations are subject to the requirements of Part V (12 VAC 5-481-1170 et seq.) of these regulations, licensees using radionuclides in the healing arts are subject to the requirements of Part VI (12 VAC 5-481-1580 et seq.)I of these regulations, licensees engaged in land disposal of radioactive material are subject to the requirements of Part XI (12 VAC 5-481-2660 et seq.) of these regulations, and licensees engaged in wireline and subsurface tracer studies are subject to the requirements of Part XIV (12 VAC 5-481-3470 et seq.) of these regulations.

ARTICLE 2.

EXEMPTIONS FROM THE REGULATORY REQUIREMENTS.

12 VAC 5-481-390. Source material.

12 VAC 5-481-400. Radioactive material other than source material.

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12 VAC 5-481-390. Source material.

A. Any person is exempt from this Part to the extent that such person receives, possesses, uses, owns, or transfers source material in any chemical mixture, compound, solution, or alloy in which the source material is by weight less than 1/20 of 1% (0.05%) of the mixture, compound, solution, or alloy.

B. Any person is exempt from this Part to the extent that such person receives, possesses, uses, or transfers unrefined and unprocessed ore containing source material; provided that, except as authorized in a specific license, such person shall not refine or process such ore.

C. Any person is exempt from this Part to the extent that such person receives, possesses, uses, or transfers:

1. Any quantities of thorium contained in:

a. Incandescent gas mantles,

b. Vacuum tubes,

c. Welding rods,

d. Electric lamps for illuminating purposes provided that each lamp does not contain more than 50 milligrams of thorium,

e. Germicidal lamps, sunlamps, and lamps for outdoor or industrial lighting provided that each lamp does not contain more than two grams of thorium,

f. Rare earth metals and compounds, mixtures, and products containing not more than 0.25% by weight thorium, uranium, or any combination of these, or

g. Personnel neutron dosimeters, provided that each dosimeter does not contain more than 50 milligrams of thorium;

2. Source material contained in the following products:

a. Glazed ceramic tableware, provided that the glaze contains not more than 20% by weight source material,

b. Glassware containing not more than 10% by weight source material, but not including commercially manufactured glass brick, pane glass, ceramic tile, or other glass or ceramic used in construction,

c. Glass enamel or glass enamel frit containing not more than 10% by weight source material imported or ordered for importation into the United States, or initially

distributed by manufacturers in the United States, before July 25, 1983, or

d. Piezoelectric ceramic containing not more than 2% by weight source material;

3. Photographic film, negatives, and prints containing uranium or thorium;

4. Any finished product or part fabricated of, or containing, tungsten-thorium or magnesium-thorium alloys, provided that the thorium content of the alloy does not exceed 4% by weight and that this exemption shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such product or part;

5. Uranium contained in counterweights installed in aircraft, rockets, projectiles, and missiles, or stored or handled in connection with installation or removal of such counterweights, provided that:

a. The counterweights are manufactured in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission (NRC), authorizing distribution by the licensee pursuant to 10 CFR Part 40,

b. Each counterweight has been impressed with the following legend clearly legible through any plating or other covering: "DEPLETED URANIUM",

c. Each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: "UNAUTHORIZED

ALTERATIONS PROHIBITED", and

d. This exemption shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such counterweights other than repair or restoration of any plating or other covering;

e. The requirements specified in 12 VAC 5-481-390 C 5 b and c need not be met by counterweights manufactured prior to December 31, 1969; provided, that such counterweights are impressed with the legend, "CAUTION - RADIOACTIVE MATERIAL - URANIUM", as previously required by the regulations.

6. Natural or depleted uranium metal used as shielding constituting part of any shipping container, provided that:

a. The shipping container is conspicuously and legibly impressed with the legend "CAUTION - RADIOACTIVE SHIELDING - URANIUM", and

b. The uranium metal is encased in mild steel or equally fire resistant metal of minimum wall thickness of 3.2 mm;

7. Thorium contained in finished optical lenses, provided that each lens does not contain more than 30% by weight of thorium, and that this exemption shall not be deemed to authorize either:

a. The shaping, grinding, or polishing of such lens or manufacturing processes other than the assembly of such lens into optical systems and devices without any alteration of the lens, or

b. The receipt, possession, use, or transfer of thorium contained in contact lenses, or in spectacles, or in eyepieces in binoculars or other optical instruments;

8. Uranium contained in detector heads for use in fire detection units, provided that each detector head contains not more than 0.005 microcurie of uranium; or

9. Thorium contained in any finished aircraft engine part containing nickel-thoria alloy, provided that:

a. The thorium is dispersed in the nickel-thoria alloy in the form of finely divided thoria (thorium dioxide), and

b. The thorium content in the nickel-thoria alloy does not exceed 4% by weight.

D. The exemptions in 12 VAC 5-481-390 C do not authorize the manufacture of any of the products described.

12 VAC 5-481-400. Radioactive material other than source material.

A. Exempt concentrations

1. Except as provided in 12 VAC 5-481-400 A 2, any person is exempt from this Part to the extent that such person receives, possesses, uses, transfers, owns or acquires products containing radioactive material introduced in concentrations not in excess of those listed in Appendix B.

2. No person may introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under Subdivision 12 VAC 5-481-400 A 1 or equivalent regulations of the Nuclear Regulatory Commission, any Agreement State or Licensing State, except in accordance with a specific license issued pursuant to Paragraph 12 VAC 5-481-480 A or the general license provided in 12 VAC 5-481-590.

B. Exempt quantities

1. Except as provided in 12 VAC 5-481-400 B 3 and 4, any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material in individual quantities each of which does not exceed the applicable quantity set forth in Appendix C.

2. Any person who possesses radioactive material received or acquired under the general license formerly provided in 2060 B is exempt from the requirements for a license set forth in this Part to the extent that such person possesses, uses, transfers or owns such

radioactive material. Such exemption does not apply for radium-226.

3. This paragraph 12 VAC 5-481-400 B does not authorize the production, packaging or repackaging of radioactive material for purposes of commercial distribution, or the incorporation of radioactive material into products intended for commercial distribution.

4. No person may, for purposes of commercial distribution, transfer radioactive material in the individual quantities set forth in Appendix C, knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt under 12 VAC 5-481-400 B. or equivalent regulations of the Nuclear Regulatory Commission, any Agreement State or Licensing State, except in accordance with a specific license issued by the Nuclear Regulatory Commission pursuant to Section 32.18 of 10 CFR Part 32 or by the agency pursuant to Paragraph 12 VAC 5-481-480 B which license states that the radioactive material may be transferred by the licensee to persons exempt under 12 VAC 5-481-400 B or the equivalent regulations of the Nuclear Regulatory Commission, an Agreement State, or Licensing State.

C. Exempt items

1. Certain Items Containing Radioactive Material. Except for persons who apply radioactive material to, or persons who incorporate radioactive material into the following products, any person is exempt from these regulations to the extent that he receives, possesses, uses, transfers, owns, or acquires the following products (Authority to transfer possession or control by the manufacturer, processor, or producer of any

equipment, device, commodity, or other product containing byproduct 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, D.C. 20555):

a. Timepieces or hands or dials containing not more than the following specified quantities of radioactive material and not exceeding the following specified radiation dose rate:

(1) 25 millicuries (925 MBq) of tritium per timepiece.

(2) 5 millicuries (185 MBq) of tritium per hand.

(3) 15 millicuries (555 MBq) of tritium per dial (bezels when used shall be considered as part of the dial).

(4) 100 microcuries (3.7 MBq) of promethium-147 per watch or 200 microcuries (7.4 MBq) of promethium-147 per any other timepiece.

(5) 20 microcuries (0.74 MBq) of promethium-147 per watch hand or 40 microcuries (1.48 MBq) of promethium-147 per other timepiece hand.

(6) 60 microcuries (2.22 MBq) of promethium-147 per watch dial or 120 microcuries (4.44 MBq) of promethium-147 per other timepiece dial

(bezels when used shall be considered as part of the dial).

(7) The radiation dose rate from hands and dials containing promethium-147 will not exceed, when measured through 50 milligrams per square centimeter of absorber:

(a) For wrist watches, 0.1 millirad (1 μGy) per hour at 10 centimeters from any surface.

(b) For pocket watches, 0.1 millirad (1 μGy) per hour at one centimeter from any surface.

(c) For any other timepiece, 0.2 millirad (2 μGy) per hour at 10 centimeters from any surface.

(8) One microcurie (37 kBq) of radium-226 per timepiece in timepieces acquired prior to the effective date of this regulation.

b. Lock illuminators containing not more than 15 millicuries (555 MBq) of tritium or not more than two millicuries (74 MBq) of promethium-147 installed in automobile locks. The radiation dose rate from each lock illuminator containing promethium-147 will not exceed one millirad (10 μGy) per hour at one centimeter from any surface when measured through 50 milligrams per square centimeter of absorber.

c. Precision balances containing not more than one millicurie (37 MBq) of tritium per balance or not more than 0.5 millicurie (18.5 MBq) of tritium per balance part.

d. Automobile shift quadrants containing not more than 25 millicuries (925 MBq) of tritium.

e. Marine compasses containing not more than 750 millicuries (27.8 GBq) of tritium gas and other marine navigational instruments containing not more than 250 millicuries (9.25 GBq) of tritium gas.

f. Thermostat dials and pointers containing not more than 25 millicuries (925 MBq) of tritium per thermostat.

g. Electron tubes; provided, that each tube does not contain more than one of the following specified quantities of radioactive material:

(1) 150 millicuries (5.55 GBq) of tritium per microwave receiver protector tube or 10 millicuries (370 MBq) of tritium per any other electron tube.

(2) 1 microcurie (37 kBq) of cobalt-60.

(3) 5 microcuries (185 kBq) of nickel-63.

(4) 30 microcuries (1.11 MBq) of krypton-85.

(5) 5 microcuries (185 kBq) of cesium-137.

(6) 30 microcuries (1.11 MBq) of promethium-147.

And provided further, that the radiation dose rate from each electron tube containing radioactive material will not exceed one millirad (10 µGy) per hour at one centimeter from any surface when measured through seven milligrams per square centimeter of absorber. For purposes of 12 VAC 5-481-230 C 1 g, "electron tubes" include spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pick-up tubes, radiation detection tubes, and any other completely sealed tube that is designed to conduct or control electrical currents.

h. Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, one or more sources of radioactive material, provided that:

(1) Each source contains no more than one exempt quantity set forth in Appendix C, and

(2) Each instrument contains no more than 10 exempt quantities. For

purposes of this requirement, an instrument's source(s) may contain either one or different types of radionuclides and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in Appendix C, provided that the sum of such fractions shall not exceed unity.

(3) For americium-241, 0.05 microcurie (1.85 kBq) is considered an exempt quantity under 12 VAC 5-481-400 C 1 h.

i. Spark gap irradiators containing not more than one microcurie (37 kBq) of cobalt-60 per spark gap irradiator for use in electrically ignited fuel oil burners having a firing rate of at least three gallons (11.4 l) per hour.

2. Self-luminous products containing radioactive material

a. Tritium, Krypton-85, or Promethium-147. Except for persons who manufacture, process, or produce self-luminous products containing tritium, krypton-85, or promethium-147, any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, owns, or acquires tritium, krypton-85 or promethium-147 in self-luminous products manufactured, processed, produced, imported, or transferred in accordance with a specific license issued by the Nuclear Regulatory Commission pursuant to Section 32.22 of 10 CFR Part 32, which license authorizes the transfer of the product to persons who are exempt from regulatory requirements. The exemption in 12 VAC 5-481-

400 C 2 does not apply to tritium, krypton-85, or promethium-147 used in products primarily for frivolous purposes or in toys or adornments.

b. Radium-226. Any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, or owns articles containing less than 0.1 microcurie (3.7 kBq) of radium-226 which were acquired prior to the effective date of this regulation.

3. Gas and aerosol detectors containing radioactive material

a. Except for persons who manufacture, process, or produce gas and aerosol detectors containing radioactive material, any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards provided that detectors containing radioactive material shall have been manufactured, imported, or transferred in accordance with a specific license issued by the Nuclear Regulatory Commission pursuant to Section 32.26 of 10 CFR Part 32; or a Licensing State pursuant to 12 VAC 5-481-480 C, which authorizes the transfer of the detectors to persons who are exempt from regulatory requirements. (Authority to transfer possession or control by the manufacturer, processor or producer of any equipment, device, commodity, or other product containing byproduct 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, D.C. 20555.)

b. Gas and aerosol detectors previously manufactured and distributed to general licensees in accordance with a specific license issued by an Agreement State shall be considered exempt under 12 VAC 5-481-400 C 3 a, provided that the device is labeled in accordance with the specific license authorizing distribution of the generally licensed device, and provided further that they meet the requirements of 12 VAC 5-481-480 C.

c. Gas and aerosol detectors containing NARM previously manufactured and distributed in accordance with a specific license issued by a Licensing State shall be considered exempt under 12 VAC 5-481-400 C 3 a, provided that the device is labeled in accordance with the specific license authorizing distribution, and provided further that they meet the requirements of 12 VAC 5-481-480 C.

4. Resins containing Scandium-46 and designed for sand consolidation in oil wells. Any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, owns or acquires synthetic plastic resins containing scandium-46 which are designed for sand consolidation in oil wells. Such resins shall have been manufactured or imported in accordance with a specific license issued by the Nuclear Regulatory Commission, or shall have been manufactured in accordance with the specifications contained in a specific license issued by the agency or any Agreement State to the manufacturer of such resins pursuant to licensing requirements equivalent to those in Sections 32.16 and 32.17 of 10 CFR Part 32 of the regulations of the Nuclear

Regulatory Commission. This exemption does not authorize the manufacture of any resins containing scandium-46.

ARTICLE 3.

LICENSES.

12 VAC 5-481-410. Types of licenses.

12 VAC 5-481-420. General licenses - source material.

12 VAC 5-481-430. General licenses - radioactive material other than source material.

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12 VAC 5-481-410. Types of licenses.

Licenses for radioactive materials are of two types: general and specific.

A. General licenses provided in this Part are effective without the filing of applications with the agency or the issuance of licensing documents to the particular persons, although the filing of a certificate with the agency may be required by the particular general license. The general licensee is subject to all other applicable portions of these regulations and any limitations of the general license.

B. Specific licenses require the submission of an application to the agency and the issuance of a licensing document by the agency. The licensee is subject to all applicable portions of these

regulations as well as any limitations specified in the licensing document.

12 VAC 5-481-420. General licenses - source material.

A. A general license is hereby issued authorizing commercial and industrial firms, research, educational and medical institutions, and state and local government agencies to use and transfer not more than 15 pounds (6.82 kg) of source material at any one time for research, development, educational, commercial, or operational purposes. A person authorized to use or transfer source material, pursuant to this general license, may not receive more than a total of 150 pounds (68.2 kg) of source material in any one calendar year.

B. Persons who receive, possess, use, or transfer source material pursuant to the general license issued in 12 VAC 5-481-420 A are exempt from the provisions of Parts IV (12 VAC 5-481-600 et seq.) and X (12 VAC 5-481-2580 et seq.) of these regulations to the extent that such receipt, possession, use, or transfer is within the terms of such general license; provided, however, that this exemption shall not be deemed to apply to any such person who is also in possession of source material under a specific license issued pursuant to this Part.

C. Persons who receive, possess, use, or transfer source material pursuant to the general license in 12 VAC 5-481-420 A are prohibited from administering source material, or the radiation therefrom, either externally or internally, to human beings except as may be authorized by the agency in a specific license.

D. A general license is hereby issued authorizing the receipt of title to source material without

regard to quantity. This general license does not authorize any person to receive, possess, use, or transfer source material.

E. Depleted uranium in industrial products and devices

1. A general license is hereby issued to receive, acquire, possess, use, or transfer, in accordance with the provisions of 12 VAC 5-481-420 E 2 through 5, depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.

2. The general license in 12 VAC 5-481-420 E 1 applies only to industrial products or devices which have been manufactured either in accordance with a specific license issued to the manufacturer of the products or devices pursuant to 12 VAC 5-481-480 M or in accordance with a specific license issued to the manufacturer by the Nuclear Regulatory Commission or an Agreement State which authorizes manufacture of the products or devices for distribution to persons generally licensed by the Nuclear Regulatory Commission or an Agreement State.

3. a. Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license established by 12 VAC 5-481-420 E 1 shall file agency form RH-F-13 "Certificate - Use of Depleted Uranium Under General License", with the agency. The form shall be submitted within 30 days after the first receipt or acquisition of such depleted uranium. The general licensee shall furnish on agency form RH-F-13 the following information and such other information as

may be required by that form:

(1) Name and address of the general licensee;

(2) A statement that the general licensee has developed and will maintain procedures designed to establish physical control over the depleted uranium described in 12 VAC 5-481-420 E 1 and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and

(3) Name and title, address, and telephone number of the individual duly authorized to act for and on behalf of the general licensee in supervising the procedures identified in 12 VAC 5-481-420 E 3 a (2).

b. The general licensee possessing or using depleted uranium under the general license established by 12 VAC 5-481-420 E 1 shall report in writing to the agency any changes in information furnished by him in agency form RH-F-13 "Certificate - Use of Depleted Uranium Under General License". The report shall be submitted within 30 days after the effective date of such change.

4. A person who receives, acquires, possesses, or uses depleted uranium pursuant to the general license established by 12 VAC 5-481-420 E 1:

a. Shall not introduce such depleted uranium, in any form, into a chemical, physical,

or metallurgical treatment or process, except a treatment or process for repair or restoration of any plating or other covering of the depleted uranium;

b. Shall not abandon such depleted uranium;

c. Shall transfer or dispose of such depleted uranium only by transfer in accordance with the provisions of 12 VAC 5-481-570. In the case where the transferee receives the depleted uranium pursuant to the general license established by 12 VAC 5-481-420 E 1, the transferor shall furnish the transferee a copy of this regulation and a copy of agency form RH-F-13. In the case where the transferee receives the depleted uranium pursuant to a general license contained in the Nuclear Regulatory Commission's or Agreement State's regulation equivalent to 12 VAC 5-481-420 E 1, the transferor shall furnish the transferee a copy of this regulation and a copy of agency form RH-F-13 accompanied by a note explaining that use of the product or device is regulated by the Nuclear Regulatory Commission or Agreement State under requirements substantially the same as those in this regulation;

d. Within 30 days of any transfer, shall report in writing to the agency the name and address of the person receiving the depleted uranium pursuant to such transfer; and

e. Shall not export such depleted uranium except in accordance with a license issued by the Nuclear Regulatory Commission pursuant to 10 CFR Part 110.

5. Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general license established by 12 VAC 5-481-420 E 1 is exempt from the requirements of Parts IV (12 VAC 5-481-600 et seq.) and X (12 VAC 5-481-2580 et seq.) of these regulations with respect to the depleted uranium covered by that general license.

12 VAC 5-481-430. General licenses - radioactive material other than source material.

(Note: Different general licenses are issued in this section, each of which has its own specific conditions and requirements.)

A. Certain devices and equipment. A general license is hereby issued to transfer, receive, acquire, own, possess, and use radioactive material incorporated in the following devices or equipment which have been manufactured, tested and labeled by the manufacturer in accordance with a specific license issued to the manufacturer by the Nuclear Regulatory Commission for use pursuant to Section 31.3 of 10 CFR Part 31. This general license is subject to the provisions of 12 VAC 5-481-90 through 12 VAC 5-481-210; 12 VAC 5-481-400 A 2; 12 VAC 5-481-500; 12 VAC 5-481-570; 12 VAC 5-481-580 and Parts IV (12 VAC 5-481-600 et seq.), X (12 VAC 5-481-2580 et seq.), and XIII (12 VAC 5-481-3280 et seq.) of these regulations. (Attention is directed particularly to the provisions of Part IV (12 VAC 5-481-600 et seq.) of these regulations which relate to the labeling of containers.)

1. Static elimination device. Devices designed for use as static eliminators which contain,

as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries (18.5 MBq) of polonium-210 per device.

2. Ion generating tube. Devices designed for ionization of air which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries (18.5 MBq) of polonium-210 per device or a total of not more than 50 millicuries (1.85 GBq) of hydrogen-3 (tritium) per device.

B. Reserved

C. Reserved

D. Certain measuring, gauging or controlling devices

1. A general license is hereby issued to commercial and industrial firms and to research, educational and medical institutions, individuals in the conduct of their business, and state or local government agencies to own, receive, acquire, possess, use or transfer in accordance with the provisions of 12 VAC 5-481-430 D 2 through 12 VAC 5-481-430 D 4, radioactive material, excluding special nuclear material, contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

2. The general license in 12 VAC 5-481-430 D 1 applies only to radioactive material

contained in devices which have been manufactured and labeled in accordance with the specifications contained in a specific license issued by the agency pursuant to 12 VAC 5-481-480 D or in accordance with the specifications contained in a specific license issued by the Nuclear Regulatory Commission, an Agreement State or a Licensing State, which authorizes distribution of devices to persons generally licensed by the Nuclear Regulatory Commission, an Agreement State or a Licensing State. (Regulations under the Federal Food, Drug, and Cosmetic Act authorizing the use of radioactive control devices in food production require certain additional labeling thereon which is found in 21 CFR 179.21.)

3. Any person who owns, receives, acquires, possesses, uses, or transfers radioactive material in a device pursuant to the general license in 12 VAC 5-481-430 D 1:

a. Shall assure that all labels affixed to the device at the time of receipt, and bearing a statement that removal of the label is prohibited, are maintained thereon and shall comply with all instructions and precautions provided by such labels;

b. Shall assure that the device is tested for leakage of radioactive material and proper operation of the "on-off" mechanism and indicator, if any, at no longer than 6-month intervals or at such other intervals as are specified in the label, however,

(1) Devices containing only krypton need not be tested for leakage of radioactive material, and

(2) Devices containing only tritium or not more than 100 microcuries (3.7 MBq) of other beta- and/or gamma-emitting material or 10 microcuries (0.37 MBq) of alpha-emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose;

c. Shall assure that other testing, installation, servicing, and removal from installation involving the radioactive material, its shielding or containment, are performed:

(1) In accordance with the instructions provided by the labels, or

(2) By a person holding an applicable specific license from the agency, the Nuclear Regulatory Commission, an Agreement State or a Licensing State to perform such activities;

d. Shall maintain records showing compliance with the requirements of 12 VAC 5-481-430 D 3 a and b. The records shall show the results of tests. The records also shall show the dates of performance of, and the names of persons performing testing, installation, servicing, and removal from installation concerning the radioactive material, its shielding or containment. Records of tests for leakage of radioactive material required by 12 VAC 5-481-430 D 3 a shall be maintained for one year after the next required leak test is performed or until the sealed source is

transferred or disposed of. Records of tests of the "on-off" mechanism and indicator required by 12 VAC 5-481-430 D 3 b shall be maintained for one year after the next required test of the "on-off" mechanism and indicator is performed or until the sealed source is transferred or disposed of. Records which are required by 12 VAC 5-481-430 3 C shall be maintained for a period of two years from the date of the recorded event or until the device is transferred or disposed of;

e. Upon the occurrence of a failure of or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the "on-off" mechanism or indicator, or upon the detection of 0.005 microcurie (185 Bq) or more removable radioactive material, shall immediately suspend operation of the device until it has been repaired by the manufacturer or other person holding an applicable specific license from the agency, the Nuclear Regulatory Commission, an Agreement State or a Licensing State to repair such devices, or disposed of by transfer to a person authorized by an applicable specific license to receive the radioactive material contained in the device and, within 30 days, furnish to the agency a report containing a brief description of the event and the remedial action taken;

f. Shall not abandon the device containing radioactive material;

g. Except as provided in 12 VAC 5-481-430 D 3 h, shall transfer or dispose of the device containing radioactive material only by transfer to a specific licensee of

the agency, the Nuclear Regulatory Commission, an Agreement State or a Licensing State whose specific license authorizes him to receive the device and within 30 days after transfer of a device to a specific licensee shall furnish to the agency a report containing identification of the device by manufacturer's name and model number and the name and address of the person receiving the device. No report is required if the device is transferred to the specific licensee in order to obtain a replacement device;

h. Shall transfer the device to another general licensee only:

(1) Where the device remains in use at a particular location. In such case the transferor shall give the transferee a copy of this regulation and any safety documents identified in the label on the device and within 30 days of the transfer, report to the agency the manufacturer's name and model number of device transferred, the name and address of the transferee, and the name and/or position of an individual who may constitute a point of contact between the agency and the transferee; or

(2) Where the device is held in storage in the original shipping container at its intended location of use prior to initial use by a general licensee; and

i. Shall comply with the provisions of 12 VAC 5-481-1090 and 12 VAC 5-481-1100 of these regulations for reporting radiation incidents, theft, or loss of licensed material, but shall be exempt from the other requirements of Parts IV (12

VAC 5-481-600 et seq.) and X (12 VAC 5-481-2580 et seq.) of these regulations.

4. The general license in 12 VAC 5-481-420 D 1 does not authorize the manufacture of devices containing radioactive material.

5. The general license provided in 12 VAC 5-481-420 D 1 is subject to the provisions of 12 VAC 5-481-100 through 12 VAC 5-481-210; 12 VAC 5-481-500; 12 VAC 5-481-570; 12 VAC 5-481-580 and Part XIII (12 VAC 5-481-3280 et seq.) of these regulations.

E. Luminous safety devices for aircraft

1. A general license is hereby issued to own, receive, acquire, possess, and use tritium or promethium-147 contained in luminous safety devices for use in aircraft, provided:

a. Each device contains not more than 10 curies (370 GBq) of tritium or 300 millicuries (11.1 GBq) of promethium-147; and

b. Each device has been manufactured, assembled or imported in accordance with a specific license issued by the Nuclear Regulatory Commission, or each device has been manufactured or assembled in accordance with the specifications contained in a specific license issued by the agency or any Agreement State to the manufacturer or assembler of such device pursuant to licensing requirements equivalent to those in Section 32.53 of 10 CFR Part 32.

2. Persons who own, receive, acquire, possess, or use luminous safety devices pursuant to the general license in 12 VAC 5-481-430 E 1 are exempt from the requirements of Parts IV (12 VAC 5-481-600 et seq.) and X (12 VAC 5-481-2580 et seq.) of these regulations except that they shall comply with the provisions of 12 VAC 5-481-1090 and 12 VAC 5-481-1100.

3. This general license does not authorize the manufacture, assembly, or repair of luminous safety devices containing tritium or promethium-147.

4. This general license does not authorize the ownership, receipt, acquisition, possession or use of promethium-147 contained in instrument dials.

5. This general license is subject to the provisions of 12 VAC 5-481-100 through 12 VAC 5-481-210; 12 VAC 5-481-500; 12 VAC 5-481-570; 12 VAC 5-481-580; and Part XIII (12 VAC 5-481-3280 et seq.) of these regulations.

F. Ownership of radioactive material. A general license is hereby issued to own radioactive material without regard to quantity. Notwithstanding any other provisions of this Part, this general license does not authorize the manufacture, production, transfer, receipt, possession or use of radioactive material.

G. Calibration and reference sources.

1. A general license is hereby issued to those persons listed below to own, receive, acquire,

possess, use, and transfer, in accordance with the provisions of 12 VAC 5-481-430 G 4 and 5, americium-241 in the form of calibration or reference sources:

a. Any person who holds a specific license issued by the agency which authorizes him to receive, possess, use, and transfer radioactive material; and

b. Any person who holds a specific license issued by the Nuclear Regulatory Commission which authorizes him to receive, possess, use, and transfer special nuclear material.

2. A general license is hereby issued to own, receive, possess, use, and transfer plutonium in the form of calibration or reference sources in accordance with the provisions of 12 VAC 5-481-430 G 4 and 5 to any person who holds a specific license issued by the agency which authorizes him to receive, possess, use, and transfer radioactive material.

3. A general license is hereby issued to own, receive, possess, use, and transfer radium-226 in the form of calibration or reference sources in accordance with the provisions of 12 VAC 5-481-430 G 4 and 5to any person who holds a specific license issued by the agency which authorizes him to receive, possess, use, and transfer radioactive material.

4. The general licenses in 12 VAC 5-481-430 G 1 through 12 VAC 5-481-430 G 3 apply only to calibration or reference sources which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer or importer of the sources by the Nuclear Regulatory Commission pursuant to Section 32.57

of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70, or which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer by the agency, any Agreement State or Licensing State pursuant to licensing requirements equivalent to those contained in Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70.

5. The general licenses provided in 12 VAC 5-481-430 G 1 through 12 VAC 5-481-430 G 3 are subject to the provisions of 12 VAC 5-481-100 through 12 VAC 5-481-210; 12 VAC 5-481-500; 12 VAC 5-481-570; 12 VAC 5-481-580 and Parts IV (12 VAC 5-481-600 et seq.); X (12 VAC 5-481-2580 et seq.); and XIII (12 VAC 5-481-3280 et seq.) of these regulations. In addition, persons who own, receive, acquire, possess, use, or transfer one or more calibration or reference sources pursuant to these general licenses:

a. Shall not possess at any one time, at any one location of storage or use, more than five microcuries (185 kBq) of americium-241, five microcuries (185 kBq) of plutonium, or five microcuries (185 kBq) of radium-226 in such sources;

b. Shall not receive, possess, use, or transfer such source unless the source, or the storage container, bears a label which includes one of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, as appropriate:

(1) The receipt, possession, use and transfer of this source, Model , Serial No. , are subject to a general license and the

regulations 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. Do not remove this label.

CAUTION - RADIOACTIVE MATERIAL

THIS SOURCE CONTAINS (AMERICIUM-241).

(PLUTONIUM) (Showing only the name of the appropriate material.)

DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

Name of manufacturer or importer

(2) The receipt, possession, use and transfer of this source, Model , Serial No. , are subject to a general license and the regulations of a Licensing State. Do not remove this label.

CAUTION - RADIOACTIVE MATERIAL

THIS SOURCE CONTAINS RADIUM-226.

DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

Name of manufacturer or importer

c. Shall not transfer, abandon, or dispose of such source except by transfer to a person authorized by a license from the agency, the Nuclear Regulatory Commission, an Agreement State or a Licensing State to receive the source;

d. Shall store such source, except when the source is being used, in a closed container adequately designed and constructed to contain americium-241, plutonium, or radium-226 which might otherwise escape during storage; and

e. Shall not use such source for any purpose other than the calibration of radiation detectors or the standardization of other sources.

11. These general licenses do not authorize the manufacture of calibration or reference sources containing americium-241, plutonium, or radium-226.

H. Reserved

I. General license for use of radioactive material for certain in vitro clinical or laboratory testing. (The New Drug provisions of the Federal Food, Drug, and Cosmetic Act also govern the availability and use of any specific diagnostic drugs in interstate commerce.)

1. A general license is hereby issued to any physician, veterinarian, clinical laboratory or hospital to receive, acquire, possess, transfer or use, for any of the following stated tests, in accordance with the provisions of 12 VAC 5-481-430 I 2 through 12 VAC 5-481-430 I 6, the following radioactive materials in prepackaged units for use in in-vitro clinical or

laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals:

a. Carbon-14, in units not exceeding 10 microcuries (370 kBq) each.

b. Cobalt-57, in units not exceeding 10 microcuries (370 kBq) each.

c. Hydrogen-3 (tritium), in units not exceeding 50 microcuries (1.85 MBq) each.

d. Iodine-125, in units not exceeding 10 microcuries (370 kBq) each.

e. Mock Iodine-125 reference or calibration sources, in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (1.85 Bq) of americium-241 each.

f. Iodine-131, in units not exceeding 10 microcuries (370 kBq) each.

g. Iron-59, in units not exceeding 20 microcuries (740 kBq) each.

h. Selenium-75, in units not exceeding 10 microcuries (370 kBq) each.

2. No person shall receive, acquire, possess, use or transfer radioactive material pursuant to the general license established by 12 VAC 5-481-430 I 1 until he has filed agency form RH-F-14, "Certificate - In Vitro Testing with Radioactive Material Under General

License", with the agency and received from the agency a validated copy of agency form RH-F-14 with certification number assigned. The physician, veterinarian, clinical laboratory or hospital shall furnish on agency form RH-F-14 the following information and such other information as may be required by that form:

a. Name and address of the physician, veterinarian, clinical laboratory or hospital;

b. The location of use; and

c. A statement that the physician, veterinarian, clinical laboratory or hospital has appropriate radiation measuring instruments to carry out in vitro clinical or laboratory tests with radioactive material as authorized under the general license in 12 VAC 5-481-430 I 1 and that such tests will be performed only by personnel competent in the use of such instruments and in the handling of the radioactive material.

3. A person who receives, acquires, possesses or uses radioactive material pursuant to the general license established by 12 VAC 5-481-430 I 1 shall comply with the following:

a. The general licensee shall not possess at any one time, pursuant to the general license in 12 VAC 5-481-430 I 1, at any one location of storage or use, a total amount of iodine-125, iodine-131, selenium-75, iron-59, and/or cobalt-57 in excess of 200 microcuries (7.4 MBq).

b. The general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection.

c. The general licensee shall use the radioactive material only for the uses authorized by 12 VAC 5-481-430 I 1.

d. The general licensee shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the agency, the Nuclear Regulatory Commission, any Agreement State or Licensing State, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.

e. The general licensee shall dispose of the Mock Iodine-125 reference or calibration sources described in 12 VAC 5-481-430 I 1 h as required by 12 VAC 5-481-720 of these regulations.

4. The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to 12 VAC 5-481-430 I 1:

a. Except as prepackaged units which are labeled in accordance with the provisions of an applicable specific license issued pursuant to 12 VAC 5-481-480 H or in accordance with the provisions of a specific license issued by the Nuclear Regulatory Commission, any Agreement State or Licensing State which authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14,

hydrogen-3 (tritium), iron-59, selenium-75, cobalt-57, or Mock Iodine-125 to persons generally licensed under 12 VAC 5-481-430 I or its equivalent, and

b. Unless one of the following statements, as appropriate, or a substantially similar statement which 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 which accompanies the package:

(1) This radioactive material shall 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 Commission has entered into an agreement for the exercise of regulatory authority.

_____

Name of manufacturer

(2) This radioactive material shall 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 physician, veterinarian, clinical laboratory or hospital possessing or using radioactive material under the general license of 12 VAC 5-481-430 I 1 shall report in writing to the agency, any changes in the information furnished by him in the "Certificate - In Vitro Testing with Radioactive Material Under General License", agency form RH-F-14. The report shall be furnished within 30 days after the effective date of such change.

6. Any person using radioactive material pursuant to the general license of 12 VAC 5-481-430 I 1 is exempt from the requirements of Parts IV (12 VAC 5-481-600 et seq.) and X (12 VAC 5-481-2580 et seq.) of these regulations with respect to radioactive material covered by that general license, except that such persons using the Mock Iodine-125 described in 12 VAC 5-481-430 I 1 h shall comply with the provisions of 12 VAC 5-481-720, 12 VAC 5-481-1090 and 12 VAC 5-481-1100 of these regulations.

J. Ice detection devices

1. A general license is hereby issued to own, receive, acquire, possess, use, and transfer

strontium-90 contained in ice detection devices, provided each device contains not more than 50 microcuries (1.85 MBq) of strontium-90 and each device has been manufactured or imported in accordance with a specific license issued by the Nuclear Regulatory Commission, or each device has been manufactured in accordance with the specifications contained in a specific license issued by the agency or an Agreement State to the manufacturer of such device pursuant to licensing requirements equivalent to those in Section 32.61 of 10 CFR Part 32.

2. Persons who own, receive, acquire, possess, use, or transfer strontium-90 contained in ice detection devices pursuant to the general license in 12 VAC 5-481-430 J 1:

a. Shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating to the device, discontinue use of the device until it has been inspected, tested for leakage and repaired by a person holding a specific license from the Nuclear Regulatory Commission or an Agreement State to manufacture or service such devices; or shall dispose of the device pursuant to the provisions of 12 VAC 5-481-720 of these regulations;

b. Shall assure that all labels affixed to the device at the time of receipt, and which bear a statement which prohibits removal of the labels, are maintained thereon; and

c. Are exempt from the requirements of Parts IV (12 VAC 5-481-600 et seq.) and X (12 VAC 5-481-2580 et seq.) of these regulations except that such persons shall

comply with the provisions of 12 VAC 5-481-720; 12 VAC 5-481-1090; 12 VAC 5-481-1100.

3. This general license does not authorize the manufacture, assembly, disassembly or repair of strontium-90 in ice detection devices.

4. This general license is subject to the provisions of 12 VAC 5-481-100 through 12 VAC 5-481-210; 12 VAC 5-481-500; 12 VAC 5-481-570; 12 VAC 5-481-580 and Part XIII (12 VAC 5-481-3280 et seq.) of these regulations.

ARTICLE 4.

SPECIFIC LICENSES.

12 VAC 5-481-440 Filing application for specific licenses.

12 VAC 5-481-450. General requirements for the issuance of specific licenses.

12 VAC 5-481-460. Special requirements for issuance of certain specific licenses for radioactive material.

12 VAC 5-481-470. Special requirements for specific licenses of broad scope.

12 VAC 5-481-480. Special requirements for a specific license to manufacture, assemble, repair, or distribute commodities, products, or devices which contain radioactive material.

12 VAC 5-481-490. Issuance of specific licenses.

12 VAC 5-481-500. Specific terms and conditions of licenses.

12 VAC 5-481-510. Expiration and termination of licenses.

12 VAC 5-481-520. Renewal of licenses.

12 VAC 5-481-530. Amendment of licenses at request of licensee.

12 VAC 5-481-540. Agency action on applications to renew or amend.

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12 VAC 5-481-440. 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. In his application, the applicant may incorporate by reference information contained in previous applications, statements, or reports filed with the agency provided such references are clear and specific.

F. Applications and documents submitted to the agency may be made available for public inspection except that the agency may withhold any document or part thereof from public inspection if disclosure of its content is not required in the public interest and would adversely affect the interest of a person concerned.

12 VAC 5-481-450. General requirements for the issuance of specific licenses.

A license application will be approved if the agency determines that:

A. The applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with these regulations in such a manner as to minimize danger to public health and safety or property;

B. The applicant's proposed equipment, facilities, and procedures are adequate to minimize danger to public health and safety or property;

C. The issuance of the license will not be inimical to the health and safety of the public; and

D. The applicant satisfies any applicable special requirements in 12 VAC 5-481-460; 12 VAC 5-481-470; 12 VAC 5-481-480; Part V (12 VAC 5-481-1170 et seq.); Part VII (12 VAC 5-481-1660 et seq.); Part XI (12 VAC 5-481-2660 et seq.); or Part XIV (12 VAC 5-481-3470 et seq.) of these regulations.

E. Environmental report, commencement of construction. In the case of an application for a license

to receive and possess radioactive material for commercial waste disposal by land burial, or for the conduct of any other activity which the agency determines will significantly affect the quality of the environment, the agency, before commencement of construction of the plant or facility in which the activity will be conducted, has concluded, after weighing the environmental, economic, technical and other benefits against environmental costs and considering available alternatives, that the action called for is the issuance of the proposed license, with any appropriate conditions to protect environmental values. Commencement of construction prior to such conclusion shall be grounds for denial of a license to receive and possess radioactive material in such plant or facility. As used in this paragraph the term "commencement of construction" means any clearing of land, excavation, or other substantial action that would adversely affect the environment of a site. The term does not mean site exploration, necessary roads for site exploration, borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the suitability of the site or the protection of environmental values.

F. Financial surety arrangements for site reclamation

1. Pursuant to Section 32.1-231 of the Code of Virginia, and as otherwise provided, financial surety arrangements for site reclamation which may consist of surety bonds, cash deposits, certificates of deposit, deposits of government securities, letters or lines of credit, or any combination of the above for the categories of licensees listed in 12 VAC 5-481-450 F 4 shall be established to ensure the protection of the public health and safety in the event of abandonment, default, or other inability of the licensee to meet the requirements of the Act and these regulations.

a. The amount of funds to be ensured by such surety arrangements shall be based on agency-approved cost estimates.

b. Self insurance, or any arrangement which essentially constitutes self insurance, will not satisfy the surety requirement since this provides no additional assurance other than that which already exists through license requirements.

2. The arrangements required in 12 VAC 5-481-450 F 1 shall be established prior to issuance of the license to assure that sufficient funds will be available to carry out the decontamination and decommissioning of the facility.

3. Amendments to licenses in effect on the effective date of this regulation may be issued providing that the required surety arrangements are established within 90 days after the effective date of 12 VAC 5-481-450 F.

4. The following specific licensees are required to make financial surety arrangements:

a. Major processors;

b. Waste handling licensees;

c. Former U.S. Atomic Energy Commission or Nuclear Regulatory Commission licensed facilities; and

d. All others except persons exempt pursuant to 12 VAC 5-481-450 F 5.

5. The following persons are exempt from the requirements of 12 VAC 5-481-450 F 1:

a. All state, local, or other government agencies, unless they are subject to 12 VAC 5-481-450 F 4 b;

b. Persons authorized to possess no more than 1,000 times the quantity specified in Appendix C or combination of radioactive material listed therein as given in Appendix C, Note 1;

c. Persons authorized to possess hydrogen-3 contained as hydrogen gas in a sealed source; or

d. Persons authorized to possess radioactive noble gases in sealed sources with no radioactive daughter product with half-life greater than 30 days.

G. Reserved

12 VAC 5-481-460. Special requirements for issuance of certain specific licenses for radioactive material.

A. Reserved

B. Reserved

C. Reserved

D. Reserved

E. Use of sealed sources in industrial radiography. In addition to the requirements set forth in 12 VAC 5-481-450, a specific license for use of sealed sources in industrial radiography will be issued if:

1. The applicant will have an adequate program for training radiographic personnel and submits to the agency a schedule or description of such program which specifies the:

a. Initial training,

b. Periodic training,

c. On-the-job training, and

d. Means to be used by the licensee to determine the radiographic personnel's knowledge and understanding of and ability to comply with agency regulations and licensing requirements, and the operating and emergency procedures of the applicant.

2. The applicant has established and submits to the agency satisfactory written operating and emergency procedures described in 12 VAC 5-481-1330 of these regulations;

3. The applicant will have an internal inspection system adequate to assure that these regulations, license provisions, and the applicant's operating and emergency procedures are followed by radiographic personnel; the inspection system shall include the performance of internal inspections at intervals not to exceed three months and the retention of records of such inspections for two years;

4. The applicant submits to the agency a description of the overall organizational structure pertaining to the industrial radiography program, including specified delegations of authority and responsibility for operation of the program;

5. The applicant who desires to conduct his own leak tests has established adequate procedures to be followed in testing sealed sources for possible leakage and contamination and submits to the agency a description of such procedures including:

a. Instrumentation to be used,

b. Method of performing tests, and

c. Pertinent experience of the individual who will perform the test; and

6. The licensee shall conduct a program for inspection and maintenance of radiographic exposure devices and storage containers to assure proper functioning of components important to safety.

12 VAC 5-481-470. Special requirements for specific licenses of broad scope.

This section prescribes requirements for the issuance of specific licenses of broad scope for radioactive material and certain regulations governing holders of such licenses. (Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing byproduct 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, D.C. 20555.)

A. The different types of broad scope licenses are set forth below:

1. A "Type A specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of the radioactive material specified in the license, but not exceeding quantities specified in the license, for any authorized purpose. The quantities specified are usually in the multi-curie range.

2. A "Type B specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in Appendix D, for any authorized purpose. The

possession limit for a Type B license of broad scope, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Appendix D, Column I. If two or more radionuclides are possessed thereunder, the possession limit for each is determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in Appendix D, Column I, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

3. A "Type C specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use, and transfer of any chemical or physical form of radioactive material specified in Appendix D, for any authorized purpose. The possession limit for a Type C license of broad scope, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Appendix D, Column II. If two or more radionuclides are possessed thereunder, the possession limit is determined for each as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in Appendix D, Column II, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

B. An application for a Type A specific license of broad scope will be approved if:

1. The applicant satisfies the general requirements specified in 12 VAC 5-481-450;

2. The applicant has engaged in a reasonable number of activities involving the use of

radioactive material; and

3. The applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that are necessary to assure safe operations, including:

a. The establishment of a radiation safety committee composed of such persons as a radiation safety officer, a representative of management, and persons trained and experienced in the safe use of radioactive material;

b. The appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters; and

c. The establishment of appropriate administrative procedures to assure:

(1) Control of procurement and use of radioactive material;

(2) Completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and

(3) Review, approval, and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with 12 VAC 5-481-470 B 3 c (2) prior to use of the radioactive material.

C. An application for a Type B specific license of broad scope will be approved if:

1. The applicant satisfies the general requirements specified in 12 VAC 5-481-450; and

2. The applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that are necessary to assure safe operations, including:

a. The appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters, and

b. The establishment of appropriate administrative procedures to assure,

(1) Control of procurement and use of radioactive material,

(2) Completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or

handling procedures, and

(3) Review, approval, and recording by the radiation safety officer of safety evaluations of proposed uses prepared in accordance with 12 VAC 5-481-470 C 2 b (2) prior to use of the radioactive material.

D. An application for a Type C specific license of broad scope will be approved if:

1. The applicant satisfies the general requirements specified in 12 VAC 5-481-450;

2. The applicant submits a statement that radioactive material will be used only by, or under the direct supervision of, individuals who have received:

a. A college degree at the bachelor level, or equivalent training and experience, in the physical or biological sciences or in engineering, and

b. At least 40 hours of training and experience in the safe handling of radioactive material, and in the characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation, and biological hazards of exposure to radiation appropriate to the type and forms of radioactive material to be used; and

3. The applicant has established administrative controls and provisions relating to procurement of radioactive material, procedures, record keeping, material control and

accounting, and management review necessary to assure safe operations.

E. Specific licenses of broad scope are subject to the following conditions:

1. Unless specifically authorized, persons licensed pursuant to 12 VAC 5-481-470 shall not:

a. Conduct tracer studies in the environment involving direct release of radioactive material;

b. Receive, acquire, own, possess, use, or transfer devices containing 100,000 curies (3.7 PBq) or more of radioactive material in sealed sources used for irradiation of materials;

c. Conduct activities for which a specific license issued by the agency under 12 VAC 5-481-460, 12 VAC 5-481-480 or Parts VII (12 VAC 5-481-1660 et seq.) and XI (12 VAC 5-481-2660 et seq.) of these regulations is required; or

d. Add or cause the addition of radioactive material to any food, beverage, cosmetic, drug, or other product designed for ingestion or inhalation by, or application to, a human being.

2. Each Type A specific license of broad scope issued under this Part shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety

committee.

3. Each Type B specific license of broad scope issued under this Part shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety officer.

4. Each Type C specific license of broad scope issued under this Part shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals who satisfy the requirements of 12 VAC 5-481-470 D.

12 VAC 5-481-480. Special requirements for a specific license to manufacture, assemble, repair, or distribute commodities, products, or devices which contain radioactive material.

A. Licensing the introduction of radioactive material into products in exempt concentrations

1. In addition to the requirements set forth in 12 VAC 5-481-450, a specific license authorizing the introduction of radioactive material into a product or material owned by or in the possession of the licensee or another to be transferred to persons exempt under 12 VAC 5-481-400 A 1 will be issued if:

a. The applicant submits a description of the product or material into which the radioactive material will be introduced, intended use of the radioactive material

and the product or material into which it is introduced, method of introduction, initial concentration of the radioactive material in the product or material, control methods to assure that no more than the specified concentration is introduced into the product or material, estimated time interval between introduction and transfer of the product or material, and estimated concentration of the radioactive material in the product or material at the time of transfer; and

b. The applicant provides reasonable assurance that the concentrations of radioactive material at the time of transfer will not exceed the concentrations in Appendix B, that reconcentration of the radioactive material in concentrations exceeding those in Appendix B is not likely, that use of lower concentrations is not feasible, and that the product or material is not likely to be incorporated in any food, beverage, cosmetic, drug or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

2. Each person licensed under 12 VAC 5-481-480 A shall file an annual report with the agency which shall identify the type and quantity of each product or material into which radioactive material has been introduced during the reporting period; name and address of the person who owned or possessed the product or material, into which radioactive material has been introduced, at the time of introduction; the type and quantity of radionuclide introduced into each such product or material; and the initial concentrations of the radionuclide in the product or material at time of transfer of the radioactive material by the licensee. If no transfers of radioactive material have been made pursuant to 12 VAC 5-481-480 A during the reporting period, the report shall so indicate. The

report shall cover the year ending June 30, and shall be filed within 30 days thereafter.

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 byproduct 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, D.C. 20555.)

1. An application for a specific license to distribute NARM to persons exempted from these regulations pursuant to 12 VAC 5-481-400 B will be approved if:

a. The radioactive material is not contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being;

b. The radioactive material is in the form of processed chemical elements, compounds, or mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources, or similar substances, identified as radioactive and to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution; and

c. The applicant submits copies of prototype labels and brochures and the agency

approves such labels and brochures.

2. The license issued under 12 VAC 5-481-480 B 1 is subject to the following conditions:

a. No more than 10 exempt quantities shall be sold or transferred in any single transaction. However, an exempt quantity may be composed of fractional parts of one or more of the exempt quantity provided the sum of the fractions shall not exceed unity.

b. Each exempt quantity shall be separately and individually packaged. No more than 10 such packaged exempt quantities shall be contained in any outer package for transfer to persons exempt pursuant to 12 VAC 5-481-400 B. The outer package shall be such that the dose rate at the external surface of the package does not exceed 0.5 millirem (5 μSv) per hour.

c. The immediate container of each quantity or separately packaged fractional quantity of radioactive material shall bear a durable, legible label which:

(1) Identifies the radionuclide and the quantity of radioactivity, and

(2) Bears the words "Radioactive Material".

d. In addition to the labeling information required by 12 VAC 5-481-480 B 2 c, the label affixed to the immediate container, or an accompanying brochure, shall:

(1) State that the contents are exempt from Licensing State requirements,

(2) Bear the words "Radioactive Material - Not for Human Use - Introduction into Foods, Beverages, Cosmetics, Drugs, or Medicinals, or into Products Manufactured for Commercial Distribution is Prohibited--Exempt Quantities Should Not Be Combined", and

(3) Set forth appropriate additional radiation safety precautions and instructions relating to the handling, use, storage, and disposal of the radioactive material.

3. Each person licensed under 12 VAC 5-481-480 B shall maintain records identifying, by name and address, each person to whom radioactive material is transferred for use under 12 VAC 5-481-400 B or the equivalent regulations of a Licensing State, and stating the kinds and quantities of radioactive material transferred. An annual summary report stating the total quantity of each radionuclide transferred under the specific license shall be filed with the agency. Each report shall cover the year ending June 30, and shall be filed within 30 days thereafter. If no transfers of radioactive material have been made pursuant to 12 VAC 5-481-400 B during the reporting period, the report shall so indicate.

C. Licensing the incorporation of naturally occurring and accelerator-produced radioactive material into gas and aerosol detectors. An application for a specific license authorizing the incorporation of NARM into gas and aerosol detectors to be distributed to persons exempt under 12 VAC 5-

481-400 C 3 will be approved if the application satisfies requirements equivalent to those contained in Section 32.26 of 10 CFR Part 32. The maximum quantity of radium-226 in each device shall not exceed 0.1 microcurie (3.7 kBq).

D. Licensing the manufacture and distribution of devices to persons generally licensed under 12 VAC 5-481-430 D.

1. An application for a specific license to manufacture or distribute devices containing radioactive material, excluding special nuclear material, to persons generally licensed under 12 VAC 5-481-430 D or equivalent regulations of the Nuclear Regulatory Commission, an Agreement State, or a Licensing State will be approved if:

a. The applicant satisfies the general requirements of 12 VAC 5-481-450;

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 the table in 12 VAC 5-481-630 A of these regulations, 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 following organ doses:

Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye	15 rem (150 mSv)
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter	200 rem (2 Sv)
Other organs	50 rem (500 mSv); and

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 distributor

(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 distributor

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 which 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 which 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 12 VAC 5-481-430 D, or under equivalent regulations of the Nuclear Regulatory Commission, an Agreement State, or a Licensing 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 the table in 12 VAC 5-481-630 A of these regulations.

4. Each person licensed under 12 VAC 5-481-430 D to distribute devices to generally licensed persons shall:

a. Furnish a copy of the general license contained in 12 VAC 5-481-430 D 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 12 VAC 5-481-430 D;

b. Furnish a copy of the general license contained in the Nuclear Regulatory Commission's, Agreement State's, or Licensing State's regulation equivalent to 12

VAC 5-481-430 D, or alternatively, furnish a copy of the general license contained in 12 VAC 5-481-430 D 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 Nuclear Regulatory Commission, the Agreement State, or the Licensing State. If a copy of the general license in 12 VAC 5-481-430 D is furnished to such a person, it shall be accompanied by a note explaining that the use of the device is regulated by the Nuclear Regulatory Commission, Agreement State, or Licensing State under requirements substantially the same as those in 12 VAC 5-481-430 D;

c. Report to the agency all transfers of such devices to persons for use under the general license in 12 VAC 5-481-430 D. 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 12 VAC 5-481-430 D 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 Nuclear Regulatory Commission all transfers of such devices to persons for use under the Nuclear Regulatory Commission general license in Section 31.5 of 10 CFR Part 31.

(2) Report to the responsible state agency all transfers of devices manufactured and distributed pursuant to 12 VAC 5-481-480 D for use under a general license in that State's regulations equivalent to 12 VAC 5-481-430 D.

(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 Nuclear Regulatory Commission

licensees during the reporting period, this information shall be reported to the Nuclear Regulatory Commission.

(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 12 VAC 5-481-430 D, or equivalent regulations of the Nuclear Regulatory Commission, an Agreement State, or a Licensing 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 12 VAC 5-481-480 D 4.

E. Special requirements for the manufacture, 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 12 VAC 5-481-430 E will be approved if:

1. The applicant satisfies the general requirements specified in 12 VAC 5-481-450; and

2. The applicant satisfies the requirements of Sections 32.53, 32.54, 32.55, 32.56, and

32.101 of 10 CFR Part 32, or their equivalent.

F. Special requirements for license to manufacture calibration sources containing americium-241, plutonium or radium-226 for distribution to persons generally licensed under 12 VAC 5-481-430 G. An application for a specific license to manufacture calibration and reference sources containing americium-241, plutonium or radium-226 to persons generally licensed under 12 VAC 5-481-430 G will be approved if:

1. The applicant satisfies the general requirement of 12 VAC 5-481-450; and

2. The applicant satisfies the requirements of Sections 32.57, 32.58, 32.59, and 32.102 of 10 CFR Part 32 and Section 70.39 of 10 CFR Part 70 or their equivalent.

G. Reserved

H. 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 12 VAC 5-481-430 I will be approved if:

1. The applicant satisfies the general requirements specified in 12 VAC 5-481-450.

2. The radioactive material is to be prepared for distribution in prepackaged units of:

a. Carbon-14 in units not exceeding 10 microcuries (370 kBq) each.

b. Cobalt-57 in units not exceeding 10 microcuries (370 kBq) each.

c. Hydrogen-3 (tritium) in units not exceeding 50 microcuries (1.85 MBq) each.

d. Iodine-125 in units not exceeding 10 microcuries (370 kBq) each.

e. Mock iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each.

f. Iodine-131 in units not exceeding 10 microcuries (370 kBq) each.

g. Iron-59 in units not exceeding 20 microcuries (740 kBq) each.

h. Selenium-75 in units not exceeding 10 microcuries (370 kBq) 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 10 microcuries (370 kBq) of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; 50 microcuries (1.85 MBq) of hydrogen-3 (tritium); 20 microcuries (740 kBq) of iron-59; or mock iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of

iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each; and

b. Displaying the radiation caution symbol described in 12 VAC 5-481-660 A 1 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 which 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 which 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 must also contain directions to the licensee regarding the waste disposal requirements set out in 12 VAC 5-481-720 of these regulations.

I. 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 12 VAC 5-481-430 J will be approved if:

1. The applicant satisfies the general requirements of 12 VAC 5-481-450; and

2. The criteria of Sections 32.61, 32.62, and 32.103 of 10 CFR Part 32 are met.

J. Manufacture and distribution of radiopharmaceuticals containing radioactive material for medical use under group licenses. An application for a specific license to manufacture and distribute radiopharmaceuticals containing radioactive material for use by persons licensed pursuant to this Part for the uses listed in 12 VAC 5-481-1940, 12 VAC 5-481-1960 and 12 VAC 5-481-2000 of these regulations will be approved if:

1. The applicant satisfies the general requirements specified in 12 VAC 5-481-450 of this Part;

2. The applicant submits evidence that:

a. The radiopharmaceutical containing radioactive material will be manufactured, labeled, and packaged in accordance with the Federal Food, Drug and Cosmetic Act or the Public Health Service Act, such as a new drug application (NDA) approved by the Food and Drug Administration (FDA), or a "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by the FDA, or

b. The manufacture and distribution of the radiopharmaceutical containing radioactive material is not subject to the Federal Food, Drug and Cosmetic Act and the Public Health Service Act;

3. The applicant submits information on the radionuclide, chemical and physical form,

packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material which is appropriate for safe handling and storage of radiopharmaceuticals by group licensees; and

4. a. The label affixed to each package of the radiopharmaceutical contains information on the radionuclide, quantity, and date of assay and the label affixed to each package, or the leaflet or brochure which accompanies each package, contains a statement that the radiopharmaceutical is licensed by the agency for distribution to persons licensed pursuant to this Part for the uses listed in 12 VAC 5-481-1940, 12 VAC 5-481-1960 and 12 VAC 5-481-2000 of these regulations or under equivalent licenses of the Nuclear Regulatory Commission, an Agreement State, or a Licensing State.

b. The labels, leaflets, or brochures required by 12 VAC 5-481-480 J 4 a are in addition to the labeling required by the Food and Drug Administration (FDA) and they may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA.

K. Manufacture and distribution of generators or reagent kits for preparation of radiopharmaceuticals containing radioactive material. An application for a specific license to manufacture and distribute generators or reagent kits containing radioactive material for preparation of radiopharmaceuticals by persons licensed. (Although the agency does not regulate the manufacture and distribution of reagent kits that do not contain radioactive material, it does regulate the use of such reagent kits for the preparation of radiopharmaceuticals

containing radioactive material as part of its licensing and regulation of the users of radioactive material. Any manufacturer of reagent kits that do not contain radioactive material who desires to have his reagent kits approved by the agency for use by persons licensed pursuant to 12 VAC 5-481-1960 of these regulations may submit the pertinent information specified in 12 VAC 5-481-480 K.) pursuant to this Part for the uses listed in 12 VAC 5-481-1960 of these regulations will be approved if:

1. The applicant satisfies the general requirements specified in12 VAC 5-481-450;

2. The applicant submits evidence that:

a. The generator or reagent kit is to be manufactured, labeled and packaged in accordance with the Federal Food, Drug and Cosmetic Act or the Public Health Service Act, such as a new drug application (NDA) approved by the Food and Drug Administration (FDA), or a "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by the FDA, or

b. The manufacture and distribution of the generator or reagent kit are not subject to the Federal Food, Drug and Cosmetic Act and the Public Health Service Act;

3. The applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material contained in the generator or reagent kit;

4. The label affixed to the generator or reagent kit contains information on the radionuclide, quantity, and date of assay; and

5. The label affixed to the generator or reagent kit, or the leaflet or brochure which accompanies the generator or reagent kit, contains:

a. Adequate information, from a radiation safety standpoint, on the procedures to be followed and the equipment and shielding to be used in eluting the generator or processing radioactive material with the reagent kit, and

b. A statement that this generator or reagent kit, as appropriate, is approved for use by persons licensed by the agency pursuant to 12 VAC 5-481-1960 of these regulations or under equivalent licenses of the Nuclear Regulatory Commission, an Agreement State, or a Licensing State. The labels, leaflets, or brochures required by 12 VAC 5-481-480 K are in addition to the labeling required by the Food and Drug Administration (FDA) and they may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA.

L. 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 (12 VAC 5-481-1660 et seq.) for use as a calibration or reference source or for the uses listed in 12 VAC 5-481-2040 and 12 VAC 5-481-2060 of these regulations will be approved if:

1. The applicant satisfies the general requirements in 12 VAC 5-481-450 of this Part;

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 which are too lengthy for such label may be summarized on the label and printed in detail on a brochure which 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 (12 VAC 5-481-1660 et seq.) and 12 VAC 5-481-2040 and 12 VAC 5-481-2060 of these regulations or under equivalent licenses of the Nuclear Regulatory Commission, an Agreement State, or a Licensing State, provided that such labeling for sources which do not require long term storage may be on a leaflet or brochure which 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, he shall include in his application 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; and

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.

M. 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 12 VAC 5-481-420 D or equivalent regulations of the Nuclear Regulatory Commission or an Agreement State will be approved if:

a. The applicant satisfies the general requirements specified in 12 VAC 5-481-450;

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 12 VAC 5-481-630 A of these regulations; 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 12 VAC 5-481-480 M

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 12 VAC 5-481-480 M if the end use(s) of the industrial product or device cannot be reasonably foreseen.

4. Each person licensed pursuant to 12 VAC 5-481-480 M 1 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 of the product or device and the number of the license under which the product or device was manufactured, 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 Nuclear Regulatory Commission or an 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 12 VAC 5-481-420 D and a copy of agency form RH-F-13 to each person to whom he transfers depleted uranium in a product or device for use pursuant to the general license contained in 12 VAC 5-481-420 D, or

(2) Furnish a copy of the general license contained in the Nuclear Regulatory Commission's or Agreement State's regulation equivalent to 12 VAC 5-481-420 D and a copy of the Nuclear Regulatory Commission's or Agreement State's certificate, or alternatively, furnish a copy of the general license contained in 12 VAC 5-481-420 D and a copy of agency form RH-F-13 to each person to whom he transfers depleted uranium in a product or device for use pursuant to the general license of the Nuclear Regulatory Commission or an Agreement State, with a note explaining that use of the product or device is regulated by the Nuclear Regulatory Commission or an Agreement State under requirements substantially the same as those in 12 VAC 5-481-420 D;

e. Report to the agency all transfers of industrial products or devices to persons for use under the general license in 12 VAC 5-481-420 D. 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 12 VAC 5-481-420 D during the reporting period, the report shall so indicate;

f. Do the following:

(1) Report to the Nuclear Regulatory Commission all transfers of industrial products or devices to persons for use under the Nuclear Regulatory Commission general license in Section 40.25 of 10 CFR Part 40,

(2) Report to the agency all transfers of devices manufactured and distributed pursuant to 12 VAC 5-481-480 M for use under a general license in that State's regulations equivalent to 12 VAC 5-481-420 D,

(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 Nuclear Regulatory Commission licensees during the reporting period, this information shall be reported to the Nuclear Regulatory Commission, and

(5) If no transfers have been made to general licensees within a particular Agreement State during the reporting period, this information shall be reported to the 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 12 VAC 5-481-420 D or equivalent regulations of the Nuclear Regulatory Commission or an 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.

12 VAC 5-481-490. Issuance of specific licenses.

A. Upon a determination that an application meets the requirements of the Act and the regulations

of the agency, the agency will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.

B. The agency may incorporate in any license at the time of issuance, or thereafter by appropriate rule, regulation, or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use, and transfer of radioactive material subject to this Part as it deems appropriate or necessary in order to:

1. Minimize danger to public health and safety or property;

2. Require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be appropriate or necessary; and

3. Prevent loss or theft of material subject to this Part.

12 VAC 5-481-500. Specific terms and conditions of licenses.

A. Each license issued pursuant to this Part shall be subject to all the provisions of the Act, now or hereafter in effect, and to all rules, regulations, and orders of the agency.

B. No license issued or granted under this Part and no right to possess or utilize radioactive material granted by any license issued pursuant to this Part shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the agency shall, after securing full information find

that the transfer is in accordance with the provisions of the Act, now or hereafter in effect, and to all valid rules, regulations, and orders of the agency, and shall give its consent in writing.

C. Each person licensed by the agency pursuant to this Part shall confine use and possession of the material licensed to the locations and purposes authorized in the license.

D. Each licensee shall notify the agency in writing when the licensee decides to permanently discontinue all activities involving materials authorized under the license.

E. Each licensee shall notify the agency in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against:

1. The licensee;

2. An entity (as that term is defined in 11 U.S.C. 101(14)) controlling the licensee or listing the license or licensee as property of the estate; or

3. An affiliate (as that term is defined in 11 U.S.C. 101(2)) of the licensee.

F. The notification specified in 12 VAC 5-481-500 E shall indicate the bankruptcy court in which the petition for bankruptcy was filed and the date of the filing of the petition.

12 VAC 5-481-510. Expiration and termination of licenses.

A. Except as provided in 12 VAC 5-481-520 B, each specific license shall expire at the end of the specified day in the month and year stated therein.

B. Each licensee shall notify the agency immediately, in writing, and request termination of the license when the licensee decides to terminate all activities involving radioactive material authorized under the license. This notification and request for termination of the license must include the reports and information specified in 12 VAC 5-481-510 D 1 d and e.

C. No less than 30 days before the expiration date specified in the license, the licensee shall either:

1. Submit an application for license renewal under 12 VAC 5-481-520; or

2. Notify the agency, in writing, if the licensee decides not to renew the license.

D. Do the following:

1. If a licensee does not submit an application for license renewal under 12 VAC 5-481-520, the licensee shall, on or before the expiration date specified in the license:

a. Terminate use of radioactive material;

b. Remove radioactive contamination to the extent practicable;

c. Properly dispose of radioactive material;

d. Submit a completed appropriate agency form; and

e. Submit a radiation survey report to confirm the absence of radioactive material or to establish the levels of residual radioactive contamination, unless the licensee demonstrates the absence of residual radioactive contamination in some other manner. The licensee shall, as appropriate:

(1) Report levels of radiation in units of microrads per hour of beta and gamma radiation at one centimeter and gamma radiation at one meter from surfaces and report levels of radioactivity, including alpha, in units of transformations per minute (or microcuries) per 100 square centimeters removable and fixed on surfaces, microcuries per milliliter in water, and picocuries per gram in contaminated solids such as soils or concrete; and

(2) Specify the instrumentation used and certify that each instrument was properly calibrated and tested.

2. If no residual radioactive contamination attributable to activities conducted under the license is detected, the licensee shall submit a certification that no detectable radioactive contamination was found. The agency will notify the licensee, in writing, of the termination of the license.

3. Do the following:

a. If detectable levels of residual radioactive contamination attributable to activities conducted under the license are found, the license continues in effect beyond the expiration date, if necessary, with respect to possession of residual radioactive material present as contamination until the agency notifies the licensee in writing that the license is terminated. During this time the licensee is subject to the provisions of 12 VAC 5-481-510 E.

b. In addition to the information submitted under 12 VAC 5-481-510 D 1 d and e, the licensee shall submit a plan for decontamination, if required, as regards residual radioactive contamination remaining at the time the license expires.

E. Each licensee who possesses residual radioactive material under 12 VAC 5-481-510 D 3, following the expiration date specified in the license shall:

1. Limit actions involving radioactive material to those related to decontamination and other activities related to preparation for release for unrestricted use; and

2. Continue to control entry to restricted areas until they are suitable for release for unrestricted use and the agency notifies the licensee in writing that the license is terminated.

12 VAC 5-481-520. Renewal of licenses.

A. Applications for renewal of specific licenses shall be filed in accordance with 12 VAC 5-481-440.

B. In any case in which a licensee, not less than 30 days prior to expiration of his existing license, has filed an application in proper form for renewal or for a new license authorizing the same activities, such existing license shall not expire until final action by the agency.

12 VAC 5-481-530. Amendment of licenses at request of licensee.

Applications for amendment of a license shall be filed in accordance with 12 VAC 5-481-440 and shall specify the respects in which the licensee desires the license to be amended and the grounds for such amendment.

12 VAC 5-481-540. Agency action on applications to renew or amend.

In considering an application by a licensee to renew or amend the license, the agency will apply the criteria set forth in 12 VAC 5-481-450 through 12 VAC 5-481-480 and in Parts V (12 VAC 5-481-1170 et seq.), VII (12 VAC 5-481-1660 et seq.), XI (12 VAC 5-481-2660 et seq.), or XIV (12 VAC 5-481-3470 et seq.) of these regulations, as applicable.

ARTICLE 5.

LICENSES HELD AT THE TIME OF THE EFFECTIVE DATE OF THESE REGULATIONS

12 VAC 5-481-550. Persons possessing a license for source, byproduct, or special nuclear material in quantities not sufficient to form a critical mass on effective date of these regulations.

12 VAC 5-481-560. Persons possessing naturally occurring and accelerator-produced radioactive material (NARM) on effective date of these regulations.

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12 VAC 5-481-550. Persons possessing a license for source, byproduct, or special nuclear material in quantities not sufficient to form a critical mass on effective date of these regulations.

Any person who, on the effective date of these regulations, possesses a general or specific license for source, byproduct, or special nuclear material in quantities not sufficient to form a critical mass, issued by the Nuclear Regulatory Commission, shall be deemed to possess a like license issued under this Part and the Act, such license to expire either 90 days after receipt from the agency of a notice of expiration of such license, or on the date or expiration specified in the Nuclear Regulatory Commission license, whichever is earlier.

12 VAC 5-481-560. Persons possessing naturally occurring and accelerator-produced radioactive material (NARM) on effective date of these regulations.

Any person who, on the effective date of these regulations, possesses NARM for which a specific license is required by the Act or this Part shall be deemed to possess such a license issued under the Act and this Part. Such license shall expire 90 days after the effective date of these regulations; provided, however, that if within the 90 days the person possessing such material files an application in proper form for a license, such existing license shall not expire until the application has been finally determined by the agency.

ARTICLE 6.

TRANSFER OF MATERIAL.

12 VAC 5-481-570. Transfer of material.

12 VAC 5-481-570. Transfer of material.

A. No licensee shall transfer radioactive material except as authorized pursuant to 12 VAC 5-481-570.

B. Except as otherwise provided in his license and subject to the provisions of 12 VAC 5-481-570 C and D, any licensee may transfer radioactive material:

1. To the agency only after receiving prior approval from the agency.

2. To the U.S. Department of Energy;

3. To any person exempt from these regulations to the extent permitted under such exemption;

4. To any person authorized to receive such material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the agency, the Nuclear Regulatory Commission, any Agreement State or any Licensing State, or to any person otherwise authorized to receive such material by the Federal Government or any agency thereof, the agency, an Agreement State, or a Licensing State; or

5. As otherwise authorized by the agency in writing.

C. Before transferring radioactive material to a specific licensee of the agency, the Nuclear Regulatory Commission, an Agreement State or a Licensing State, or to a general licensee who is required to register with the agency, the Nuclear Regulatory Commission, an Agreement State or a Licensing State prior to receipt of the radioactive material, the licensee transferring the material shall verify that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred.

D. Any of the following methods for the verification required by 12 VAC 5-481-570 C is acceptable:

1. The transferor may possess and read a current copy of the transferee's specific license or

registration certificate.

2. The transferor may possess a written certification by the transferee that the transferee is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date.

3. For emergency shipments, the transferor may accept oral certification by the transferee that the transferee is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date; provided, that the oral certification is confirmed in writing within 10 days.

4. The transferor may obtain other information compiled by a reporting service from official records of the agency, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State regarding the identity of licensees and the scope and expiration dates of licenses and registration.

5. When none of the methods of verification described in 12 VAC 5-481-570 D 1 through 12 VAC 5-481-570 D 4 are readily available or when a transferor desires to verify that information received by one of such methods is correct or up-to-date, the transferor may obtain and record confirmation from the agency, the Nuclear Regulatory Commission, or an Agreement State, or a Licensing State that the transferee is licensed to receive the radioactive material.

E. Shipment and transport of radioactive material shall be in accordance with the provisions of Part XIII (12 VAC 5-481-3280 et seq.) of these regulations.

ARTICLE 7.

MODIFICATION AND REVOCATION OF LICENSES.

12 VAC 5-481-580. Modification and revocation of licenses.

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12 VAC 5-481-580. Modification and revocation of licenses.

A. The terms and conditions of all licenses shall be subject to amendment, revision, or modification or the license may be suspended or revoked by reason of amendments to the Act, or by reason of rules, regulations, and orders issued by the agency.

B. Any license may be revoked, suspended, or modified, in whole or in part, for any material false statement in the application or any statement of fact required under provisions of the Act, or because of conditions revealed by such application or statement of fact or any report, record, or inspection or other means which would warrant the agency to refuse to grant a license on an original application, or for violation of, or failure to observe any of the terms and conditions of the Act, or of the license, or of any rule, regulation, or order of the agency.

C. Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, no license shall be modified, suspended, or revoked unless, prior to the institution of proceedings therefor, facts or conduct which may warrant such action shall have been called to the attention of the licensee in writing and the licensee shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

ARTICLE 8.

RECIPROCITY.

12 VAC 5-481-590. Reciprocal recognition of licenses.

12 VAC 5-481-590. Reciprocal recognition of licenses.

A. Licenses of byproduct, 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 Nuclear Regulatory Commission or an 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 this state for a period not in excess of 180 days in any calendar year 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 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 12 VAC 5-481-590 A 1;

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 which may be inconsistent with applicable regulations of the agency;

d. The out-of-state licensee supplies such other information as the agency may request; and

e. The out-of-state licensee shall not transfer or dispose of radioactive material

possessed or used under the general license provided in 12 VAC 5-481-590 A 1 except by transfer to a person:

(1) Specifically licensed by the agency or by the Nuclear Regulatory Commission to receive such material, or

(2) Exempt from the requirements for a license for such material under 12 VAC 5-481-400 A.

2. Notwithstanding the provisions of 12 VAC 5-481-590 A 1, any person who holds a specific license issued by the Nuclear Regulatory Commission or an Agreement State authorizing the holder to manufacture, transfer, install, or service a device described in 12 VAC 5-481-430 D 1 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

Nuclear Regulatory Commission or an 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 12 VAC 5-481-430 D 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 Nuclear Regulatory Commission or an 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.

B. Licenses of naturally occurring and accelerator-produced radioactive material

1. Subject to these regulations, any person who holds a specific license from a Licensing 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 this state for a period not in excess of 180 days in any calendar year 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 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 12 VAC 5-481-590 B 1;

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 which may be inconsistent with applicable regulations of the agency;

d. The out-of-state licensee supplies such other information as the agency may request; and

e. The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in 12 VAC 5-481-590 B 1 except by transfer to a person:

(1) Specifically licensed by the agency or by another Licensing State to receive such material, or

(2) Exempt from the requirements for a license for such material under 12 VAC 5-481-400.

2. Notwithstanding the provisions of 12 VAC 5-481-590 B 1, any person who holds a specific license issued by a Licensing State authorizing the holder to manufacture, transfer, install, or service a device described in 12 VAC 5-481-430 D 1 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 a Licensing 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 12 VAC 5-481-430 D 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 a Licensing 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.

Part IV.

STANDARDS FOR PROTECTION AGAINST RADIATION.

ARTICLE 1.

GENERAL PROVISIONS.

12 VAC 5-481-600. Purpose.

A. Part IV (12 VAC 5-481-600 et seq.) establishes standards for protection against ionizing radiation resulting from activities conducted pursuant to licenses or registrations issued by the agency. These regulations are issued pursuant to the Act, as amended.

B. The requirements of Part IV (12 VAC 5-481-600 et seq.) are designed to control the receipt, possession, use, transfer, and disposal of sources of radiation by any licensee or registrant so the total dose to an individual, including doses resulting from all sources of radiation other than background radiation, does not exceed the standards for protection against radiation prescribed in Part IV (12 VAC 5-481-600 et seq.). However, nothing in Part IV (12 VAC 5-481-600 et

seq.) shall be construed as limiting actions that may be necessary to protect health and safety in an emergency.

12 VAC 5-481-610. Scope.

Except as specifically provided in other Parts of these regulations, Part IV (12 VAC 5-481-600 et seq.) applies to persons licensed or registered by the agency to receive, possess, use, transfer, or dispose of sources of radiation. The limits in Part IV (12 VAC 5-481-600 et seq.) do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, or to voluntary participation in medical research programs.

12 VAC 5-481-620. Implementation.

A. Any existing license or registration condition that is more restrictive than Part IV (12 VAC 5-481-600 et seq.) remains in force until there is an amendment or renewal of the license or registration.

B. If a license or registration condition exempts a licensee or registrant from a provision of Part IV (12 VAC 5-481-600 et seq.) in effect on or before the effective date of these regulations, it also exempts the licensee or registrant from the corresponding provision of Part IV (12 VAC 5-481-600 et seq.).

C. If a license or registration condition cites provisions of Part IV (12 VAC 5-481-600 et seq.) in effect prior to effective date of these regulations, which do not correspond to any provisions of

Part IV (12 VAC 5-481-600 et seq.), the license or registration condition remains in force until there is an amendment or renewal of the license or registration that modifies or removes this condition.

ARTICLE 2.

RADIATION PROTECTION PROGRAMS.

12 VAC 5-481-630. Radiation protection programs.

12 VAC 5-481-630. Radiation protection programs.

A. Each licensee or registrant shall develop, document, and implement a radiation protection program sufficient to ensure compliance with the provisions of Part IV (12 VAC 5-481-600 et seq.). See 12 VAC 5-481-990 for recordkeeping requirements relating to these programs.

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

C. The licensee or registrant shall, at intervals not to exceed 12 months, review the radiation protection program content and implementation.

ARTICLE 3.

OCCUPATIONAL DOSE LIMITS.

12 VAC 5-481-640. Occupational dose limits for adults.

A. The licensee or registrant shall control the occupational dose to individual adults, except for planned special exposures pursuant to 12 VAC 5-481-690, to the following dose limits:

1. An annual limit, which is the more limiting of:

a. The total effective dose equivalent being equal to 0.05 Sv (5 rem); or

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

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

a. An eye dose equivalent of 0.15 Sv (15 rem); and

b. A shallow dose equivalent of 0.5 Sv (50 rem) to the skin or to any extremity.

B. Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, shall be subtracted from the limits for planned special exposures that the individual may receive during the current year and during the individual's lifetime. See 12 VAC 5-481-690 E 1 and 2.

C. The assigned deep dose equivalent and shallow dose equivalent shall be for the portion of the body receiving the highest exposure:

1. The deep dose equivalent, eye dose equivalent and shallow dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable; or

2. When a protective apron is worn while working with medical fluoroscopic equipment and monitoring is conducted as specified in 12 VAC 5-481-760 A 4, the effective dose equivalent for external radiation shall be determined as follows:

a. When only one individual monitoring device is used and it is located at the neck outside the protective apron, the reported deep dose equivalent shall be the effective dose equivalent for external radiation; or

b. When only one individual monitoring device is used and it is located at the neck outside the protective apron, and the reported dose exceeds 25% of the limit specified in 12 VAC 5-481-640, the reported deep dose equivalent value multiplied by 0.3 shall be the effective dose equivalent for external radiation; or

c. When individual monitoring devices are worn, both under the protective apron at the waist and outside the protective apron at the neck, the effective dose equivalent for external radiation shall be assigned the value of the sum of the deep dose equivalent reported for the individual monitoring device located at the waist under the protective apron multiplied by 1.5 and the deep dose equivalent reported for the individual monitoring device located at the neck outside the protective apron multiplied by 0.04.

D. Derived air concentration (DAC) and annual limit on intake (ALI) values are specified in Table I of Appendix F and may be used to determine the individual's dose and to demonstrate compliance with the occupational dose limits. See 12 VAC 5-481-1040.

E. Notwithstanding the annual dose limits, the licensee or registrant shall limit the soluble uranium intake by an individual to 10 milligrams in a week in consideration of chemical toxicity. See footnote C of Appendix F.

F. The licensee or registrant shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person during the current year. See 12 VAC 5-481-680.

12 VAC 5-481-650. Compliance with requirements for summation of external and internal doses.

A. If the licensee or registrant is required to monitor pursuant to both 12 VAC 5-481-760 A and B, the licensee or registrant shall demonstrate compliance with the dose limits by summing external and internal doses. If the licensee or registrant is required to monitor only pursuant to 12 VAC 5-481-760 A or only pursuant to 12 VAC 5-481-760 B, then summation is not required to demonstrate compliance with the dose limits. The licensee or registrant may demonstrate compliance with the requirements for summation of external and internal doses pursuant to 12 VAC 5-481-650 B, C and D. The dose equivalents for the lens of the eye, the skin, and the extremities are not included in the summation, but are subject to separate limits.

B. Intake by Inhalation. If the only intake of radionuclides is by inhalation, the total effective dose equivalent limit is not exceeded if the sum of the deep dose equivalent divided by the total effective dose equivalent limit, and one of the following, does not exceed unity:

1. The sum of the fractions of the inhalation ALI for each radionuclide; or

2. The total number of derived air concentration-hours (DAC-hours) for all radionuclides divided by 2,000; or

3. The sum of the calculated committed effective dose equivalents to all significantly irradiated organs or tissues (T) calculated from bioassay data using appropriate biological models and expressed as a fraction of the annual limit. For purposes of this requirement, an organ or tissue is deemed to be significantly irradiated if, for that organ or tissue, the product of the weighting factors, w_T, and the committed dose equivalent, $H_{T,50}$, per unit intake is greater than 10% of the maximum weighted value of $H_{T,50}$, that is, $w_T H_{T,50}$, per unit intake for any organ or tissue.

C. Intake by oral ingestion. If the occupationally exposed individual receives an intake of radionuclides by oral ingestion greater than 10% of the applicable oral ALI, the licensee or registrant shall account for this intake and include it in demonstrating compliance with the limits.

D. Intake through wounds or absorption through skin. The licensee or registrant shall evaluate and, to the extent practical, account for intakes through wounds or skin absorption. The intake

through intact skin has been included in the calculation of DAC for hydrogen-3 and does not need to be evaluated or accounted for pursuant to 12 VAC 5-481-650 D.

12 VAC 5-481-660. Determination of external dose from airborne radioactive material.

A. Licensees or registrants shall, when determining the dose from airborne radioactive material, include the contribution to the deep dose equivalent, eye dose equivalent, and shallow dose equivalent from external exposure to the radioactive cloud. See Appendix F, footnotes [a/] and [b/].

B. Airborne radioactivity measurements and DAC values shall not be used as the primary means to assess the deep dose equivalent when the airborne radioactive material includes radionuclides other than noble gases or if the cloud of airborne radioactive material is not relatively uniform. The determination of the deep dose equivalent to an individual shall be based upon measurements using instruments or individual monitoring devices.

12 VAC 5-481-670. Determination of internal exposure.

A. For purposes of assessing dose used to determine compliance with occupational dose equivalent limits, the licensee or registrant shall, when required pursuant to 12 VAC 5-481-760, take suitable and timely measurements of:

1. Concentrations of radioactive materials in air in work areas; or

2. Quantities of radionuclides in the body; or

3. Quantities of radionuclides excreted from the body; or

4. Combinations of these measurements.

B. Unless respiratory protective equipment is used, as provided in 12 VAC 5-481-830, or the assessment of intake is based on bioassays, the licensee or registrant shall assume that an individual inhales radioactive material at the airborne concentration in which the individual is present.

C. When specific information on the physical and biochemical properties of the radionuclides taken into the body or the behavior of the material in an individual is known, the licensee or registrant may:

1. Use that information to calculate the committed effective dose equivalent, and, if used, the licensee or registrant shall document that information in the individual's record; and

2. Upon prior approval of the agency, adjust the DAC or ALI values to reflect the actual physical and chemical characteristics of airborne radioactive material, for example, aerosol size distribution or density; and

3. Separately assess the contribution of fractional intakes of Class D, W, or Y compounds of a given radionuclide to the committed effective dose equivalent. See Appendix F.

D. If the licensee or registrant chooses to assess intakes of Class Y material using the measurements given in 12 VAC 5-481-670 A 2 or 3, the licensee or registrant may delay the recording and reporting of the assessments for periods up to seven months, unless otherwise required by 12 VAC 5-481-1100 or 12 VAC 5-481-1110. This delay permits the licensee or registrant to make additional measurements basic to the assessments.

E. If the identity and concentration of each radionuclide in a mixture are known, the fraction of the DAC applicable to the mixture for use in calculating DAC-hours shall be either:

1. The sum of the ratios of the concentration to the appropriate DAC value, that is, D, W, or Y, from Appendix F for each radionuclide in the mixture; or

2. The ratio of the total concentration for all radionuclides in the mixture to the most restrictive DAC value for any radionuclide in the mixture.

F. If the identity of each radionuclide in a mixture is known, but the concentration of one or more of the radionuclides in the mixture is not known, the DAC for the mixture shall be the most restrictive DAC of any radionuclide in the mixture.

G. When a mixture of radionuclides in air exists, a licensee or registrant may disregard certain radionuclides in the mixture if:

1. The licensee or registrant uses the total activity of the mixture in demonstrating compliance with the dose limits in 12 VAC 5-481-640 and in complying with the monitoring requirements in 12 VAC 5-481-760 B; and

2. The concentration of any radionuclide disregarded is less than 10% of its DAC; and

3. The sum of these percentages for all of the radionuclides disregarded in the mixture does not exceed 30%.

H. When determining the committed effective dose equivalent, the following information may be considered:

1. In order to calculate the committed effective dose equivalent, the licensee or registrant may assume that the inhalation of one ALI, or an exposure of 2,000 DAC-hours, results in a committed effective dose equivalent of 0.05 Sv (5 rem) for radionuclides that have their ALIs or DACs based on the committed effective dose equivalent;

2. For an ALI and the associated DAC determined by the nonstochastic organ dose limit of 0.5 Sv (50 rem), the intake of radionuclides that would result in a committed effective dose equivalent of 0.05 Sv (5 rem), that is, the stochastic ALI, is listed in parentheses in Table I of Appendix F. The licensee or registrant may, as a simplifying assumption, use the stochastic ALI to determine committed effective dose equivalent. However, if the licensee or registrant uses the stochastic ALI, the licensee or registrant shall also demonstrate that the limit in 12 VAC 5-481-640 A 1 b is met.

12 VAC 5-481-680. Determination of prior occupational dose.

A. For each individual who may enter the licensee's or registrant's restricted area and is likely to receive, in a year, an occupational dose requiring monitoring pursuant to 12 VAC 5-481-660, the licensee or registrant shall:

1. Determine the occupational radiation dose received during the current year; and

2. Attempt to obtain the records of lifetime cumulative occupational radiation dose.

B. Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant shall determine:

1. The internal and external doses from all previous planned special exposures; and

2. All doses in excess of the limits, including doses received during accidents and emergencies, received during the lifetime of the individual.

C. In complying with the requirements of 12 VAC 5-481-680 A, a licensee or registrant may:

1. Accept, as a record of the occupational dose that the individual received during the current year, a written signed statement from the individual, or from the individual's most

recent employer for work involving radiation exposure, that discloses the nature and the amount of any occupational dose that the individual received during the current year; and

2. Accept, as the record of lifetime cumulative radiation dose, an up-to-date agency form Y or equivalent, signed by the individual and countersigned by an appropriate official of the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee or registrant; and

3. Obtain reports of the individual's dose equivalent from the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee or registrant, by telephone, telegram, facsimile, or letter. The licensee or registrant shall request a written verification of the dose data if the authenticity of the transmitted report cannot be established.

D. Do the following:

1. The licensee or registrant shall record the exposure history, as required by 12 VAC 5-481-680, on agency form Y, or other clear and legible record, of all the information required on that form. The form or record shall show each period in which the individual received occupational exposure to radiation or radioactive material and shall be signed by the individual who received the exposure. For each period for which the licensee or registrant obtains reports, the licensee or registrant shall use the dose shown in the report in preparing agency form Y or equivalent. For any period in which the licensee or registrant does not obtain a report, the licensee or registrant shall place a notation on

agency form Y or equivalent indicating the periods of time for which data are not available.

2. Licensees or registrants are not required to partition historical dose between external dose equivalent(s) and internal committed dose equivalent(s). Further, occupational exposure histories obtained and recorded on agency form Y or equivalent before the effective date of these regulations, might not have included effective dose equivalent, but may be used in the absence of specific information on the intake of radionuclides by the individual.

E. If the licensee or registrant is unable to obtain a complete record of an individual's current and previously accumulated occupational dose, the licensee or registrant shall assume:

1. In establishing administrative controls pursuant to 12 VAC 5-481-640 F for the current year, that the allowable dose limit for the individual is reduced by 12.5 mSv (1.25 rem) for each quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure; and

2. That the individual is not available for planned special exposures.

F. The licensee or registrant shall retain the records on agency form Y or equivalent until the agency terminates each pertinent license or registration requiring this record. The licensee or registrant shall retain records used in preparing agency form Y or equivalent for three years after the record is made.

12 VAC 5-481-690. Planned special exposures.

A licensee or registrant may authorize an adult worker to receive doses in addition to and accounted for separately from the doses received under the limits specified in 12 VAC 5-481-640 provided that each of the following conditions is satisfied:

A. The licensee or registrant authorizes a planned special exposure only in an exceptional situation when alternatives that might avoid the higher exposure are unavailable or impractical;

B. The licensee or registrant, and employer if the employer is not the licensee or registrant, specifically authorizes the planned special exposure, in writing, before the exposure occurs;

C. Before a planned special exposure, the licensee or registrant ensures that each individual involved is:

1. Informed of the purpose of the planned operation; and

2. Informed of the estimated doses and associated potential risks and specific radiation levels or other conditions that might be involved in performing the task; and

3. Instructed in the measures to be taken to keep the dose ALARA considering other risks that may be present;

D. Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant ascertains prior doses as required by 12 VAC 5-481-680 B during the lifetime of the individual for each individual involved;

E. Subject to 12 VAC 5-481-640 B., the licensee or registrant shall not authorize a planned special exposure that would cause an individual to receive a dose from all planned special exposures and all doses in excess of the limits to exceed:

1. The numerical values of any of the dose limits in 12 VAC 5-481-640 A in any year; and

2. Five times the annual dose limits in 12 VAC 5-481-640 A during the individual's lifetime;

F. The licensee or registrant maintains records of the conduct of a planned special exposure in accordance with 12 VAC 5-481-1030 and submits a written report in accordance with 12 VAC 5-481-1120;

G. The licensee or registrant records the best estimate of the dose resulting from the planned special exposure in the individual's record and informs the individual, in writing, of the dose within 30 days from the date of the planned special exposure. The dose from planned special exposures shall not be considered in controlling future occupational dose of the individual pursuant to 12 VAC 5-481-640 A but shall be included in evaluations required by 12 VAC 5-481-690 D and E.

12 VAC 5-481-700. Occupational dose limits for minors.

The annual occupational dose limits for minors are 10% of the annual occupational dose limits specified for adult workers in 12 VAC 5-481-640.

12 VAC 5-481-710. Dose to an embryo/fetus.

A. The licensee or registrant shall ensure that the dose to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed five mSv (0.5 rem). See 12 VAC 5-481-1040 for recordkeeping requirements.

B. The licensee or registrant shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in 12 VAC 5-481-710 A.

C. The dose to an embryo/fetus shall be taken as the sum of:

1. The dose to the embryo/fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman; and

2. The dose that is most representative of the dose to the embryo/fetus from external radiation, that is, in the mother's lower torso region.

a. If multiple measurements have not been made, assignment of the highest deep dose equivalent for the declared pregnant woman shall be the dose to the embryo/fetus, in accordance with 12 VAC 5-481-680 C; or

b. If multiple measurements have been made, assignment of the deep dose equivalent for the declared pregnant woman from the individual monitoring device which is most representative of the dose to the embryo/fetus shall be the dose to the embryo/fetus. Assignment of the highest deep dose equivalent for the declared pregnant woman to the embryo/fetus is not required unless that dose is also the most representative deep dose equivalent for the region of the embryo/fetus.

D. If by the time the woman declares pregnancy to the licensee or registrant, the dose to the embryo/fetus has exceeded 4.5 mSv (0.45 rem), the licensee or registrant shall be deemed to be in compliance with 12 VAC 5-481-710 A if the additional dose to the embryo/fetus does not exceed 0.5 mSv (0.05 rem) during the remainder of the pregnancy.

ARTICLE 4.

RADIATION DOSE LIMITS FOR INDIVIDUAL MEMBERS OF THE PUBLIC.

12 VAC 5-481-720. Dose limits for individual members of the public.

12 VAC 5-481-730. Compliance with dose limits for individual members of the public.

12 VAC 5-481-720. Dose limits for individual members of the public.

A. Each licensee or registrant shall conduct operations so that:

1. Except as provided in 12 VAC 5-481-720 A 3, the total effective dose equivalent to individual members of the public from the licensed or registered operation does not exceed one mSv (0.1 rem) in a year, exclusive of the dose contribution from the licensee's or registrant's disposal of radioactive material into sanitary sewerage in accordance with 12 VAC 5-481-930; (Retrofit shall not be required for locations within facilities where only radiation machines existed prior to the effective date of these regulations and met the previous requirements of five mSv (0.5 rem) in a year.); and

2. The dose in any unrestricted area from external sources does not exceed 0.02 mSv (0.002 rem) in any one hour; and

3. The total effective dose equivalent to individual members of the public from infrequent exposure to radiation from radiation machines does not exceed five mSv (0.5 rem).

B. If the licensee or registrant permits members of the public to have access to restricted areas, the limits for members of the public continue to apply to those individuals.

C. A licensee, registrant, or an applicant for a license or registration may apply for prior agency authorization to operate up to an annual dose limit for an individual member of the public of five mSv (0.5 rem). This application shall include the following information:

1. Demonstration of the need for and the expected duration of operations in excess of the limit in 12 VAC 5-481-720 A; and

2. The licensee's or registrant's program to assess and control dose within the five mSv (0.5 rem) annual limit; and

3. The procedures to be followed to maintain the dose ALARA.

D. In addition to the requirements of Part IV (12 VAC 5-481-600 et seq.), a licensee or registrant subject to the provisions of the Environmental Protection Agency's generally applicable environmental radiation standards in 40 CFR 190 shall comply with those standards.

E. The agency may impose additional restrictions on radiation levels in unrestricted areas and on the total quantity of radionuclides that a licensee or registrant may release in effluents in order to restrict the collective dose.

12 VAC 5-481-730. Compliance with dose limits for individual members of the public.

A. The licensee or registrant shall make or cause to be made surveys of radiation levels in unrestricted areas and radioactive materials in effluents released to unrestricted areas to demon-

strate compliance with the dose limits for individual members of the public in 12 VAC 5-481-720.

B. A licensee or registrant shall show compliance with the annual dose limit in 12 VAC 5-481-720 by:

1. Demonstrating by measurement or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed or registered operation does not exceed the annual dose limit; or

2. Demonstrating that:

a. The annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in Table II of Appendix F; and

b. If an individual were continuously present in an unrestricted area, the dose from external sources would not exceed 0.02 mSv (0.002 rem) in an hour and 0.5 mSv (0.05 rem) in a year.

C. Upon approval from the agency, the licensee or registrant may adjust the effluent concentration values in Appendix F, Table II, for members of the public, to take into account the actual physical and chemical characteristics of the effluents, such as aerosol size distribution, solubility, density, radioactive decay equilibrium, and chemical form.

ARTICLE 5.

TESTING FOR LEAKAGE OR CONTAMINATION OF SEALED SOURCES.

12 VAC 5-481-740. Testing for leakage or contamination of sealed sources.

12 VAC 5-481-740. Testing for leakage or contamination of sealed sources.

A. The licensee or registrant in possession of any sealed source shall assure that:

1. Each sealed source, except as specified in 12 VAC 5-481-740 B, is tested for leakage or contamination and the test results are received before the sealed source is put into use unless the licensee or registrant has a certificate from the transferor indicating that the sealed source was tested within six months before transfer to the licensee or registrant;

2. Each sealed source that is not designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed six months or at alternative intervals approved by the agency, after evaluation of information specified by 12 VAC 5-481-480 L 4 and 5 of these regulations, an Agreement State, a Licensing State, or the Nuclear Regulatory Commission;

3. Each sealed source that is designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed three months or at alternative intervals approved by the agency, after evaluation of information specified by 12 VAC 5-481-480 L 4 and 5 of these regulations, an Agreement State, a Licensing State, or the Nuclear Regulatory Commission;

4. For each sealed source that is required to be tested for leakage or contamination, at any other time there is reason to suspect that the sealed source might have been damaged or might be leaking, the licensee or registrant shall assure that the sealed source is tested for leakage or contamination before further use;

5. Tests for leakage for all sealed sources, except brachytherapy sources manufactured to contain radium, shall be capable of detecting the presence of 185 Bq of radioactive material on a test sample. Test samples shall be taken from the sealed source or from the surfaces of the container in which the sealed source is stored or mounted on which one might expect contamination to accumulate. For a sealed source contained in a device, test samples are obtained when the source is in the "off" position;

6. The test for leakage for brachytherapy sources manufactured to contain radium shall be capable of detecting an absolute leakage rate of 37 Bq of radon-222 in a 24-hour period when the collection efficiency for radon-222 and its daughters has been determined with respect to collection method, volume and time;

7. Tests for contamination from radium daughters shall be taken on the interior surface of brachytherapy source storage containers and shall be capable of detecting the presence of 185 Bq of a radium daughter which has a half-life greater than four days.

B. A licensee or registrant need not perform test for leakage or contamination on the following sealed sources:

1. Sealed sources containing only radioactive material with a half-life of less than 30 days;

2. Sealed sources containing only radioactive material as a gas;

3. Sealed sources containing 3.7 MBq or less of beta or photon-emitting material or 370 kBq or less of alpha-emitting material;

4. Sealed sources containing only hydrogen-3;

5. Seeds of iridium-192 encased in nylon ribbon; and

6. Sealed sources, except teletherapy and brachytherapy sources, which are stored, not being used and identified as in storage. The licensee or registrant shall, however, test each such sealed source for leakage or contamination and receive the test results before any use or transfer unless it has been tested for leakage or contamination within six months before the date of use or transfer.

C. Tests for leakage or contamination from sealed sources shall be performed by persons specifically authorized by the agency, an Agreement State, a Licensing State, or the Nuclear Regulatory Commission to perform such services.

D. Test results shall be kept in units of becquerel or microcurie and maintained for inspection by the agency. Records of test results for sealed sources shall be made pursuant to 12 VAC 5-481-1010.

E. The following shall be considered evidence that a sealed source is leaking:

1. The presence of 185 Bq or more of removable contamination on any test sample;

2. Leakage of 37 Bq of radon-222 per 24 hours for brachytherapy sources manufactured to contain radium;

3. The presence of removable contamination resulting from the decay of 185 Bq or more of radium.

F. The licensee or registrant shall immediately withdraw a leaking sealed source from use and shall take action to prevent the spread of contamination. The leaking sealed source shall be repaired or disposed of in accordance with this Part.

G. Reports of test results for leaking or contaminated sealed sources shall be made pursuant to 12 VAC 5-481-1150.

ARTICLE 6.

SURVEYS AND MONITORING.

12 VAC 5-481-750. General.

12 VAC 5-481-760. Conditions requiring individual monitoring of external and internal occupational dose.

12 VAC 5-481-770. Location of individual monitoring devices.

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12 VAC 5-481-750. General.

A. Each licensee or registrant shall make, or cause to be made, surveys that:

1. Are necessary for the licensee or registrant to comply with Part IV (12 VAC 5-481-600 et seq.); and

2. Are necessary under the circumstances to evaluate:

a. Radiation levels; and

b. Concentrations or quantities of radioactive material; and

c. The potential radiological hazards that could be present.

B. The licensee or registrant shall ensure that instruments and equipment used for quantitative radiation measurements, for example, dose rate and effluent monitoring, are calibrated at intervals not to exceed 12 months for the radiation measured, except when a more frequent interval is specified in another applicable Part of these regulations or a license condition.

C. All personnel dosimeters, except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to any extremity, that require processing to determine the radiation dose and that are used by licensees and registrants to comply with 12 VAC 5-481-640, with other applicable provisions of these regulations, or with conditions specified in a license or registration shall be processed and evaluated by a dosimetry processor:

1. Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program of the National Institute of Standards and Technology; and

2. Approved in this accreditation process for the type of radiation or radiations included in the National Voluntary Laboratory Accreditation Program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

D. The licensee or registrant shall ensure that adequate precautions are taken to prevent a deceptive exposure of an individual monitoring device.

12 VAC 5-481-760. Conditions requiring individual monitoring of external and internal occupational dose.

Each licensee or registrant shall monitor exposures from sources of radiation at levels sufficient to demonstrate compliance with the occupational dose limits of Part IV (12 VAC 5-481-600 et seq.). As a minimum:

A. Each licensee or registrant shall monitor occupational exposure to radiation and shall supply and require the use of individual monitoring devices by:

1. Adults likely to receive, in one year from sources external to the body, a dose in excess of 10% of the limits in 12 VAC 5-481-640 A.; and

2. Minors and declared pregnant women likely to receive, in one year from sources external to the body, a dose in excess of 10% of any of the applicable limits in 12 VAC 5-481-700 or 12 VAC 5-481-710; and

3. Individuals entering a high or very high radiation area;

4. Individuals working with medical fluoroscopic equipment.

a. An individual monitoring device used for the dose to an embryo/fetus of a declared pregnant woman, pursuant to 12 VAC 5-481-710 A, shall be located under the protective apron at the waist.

b. An individual monitoring device used for eye dose equivalent shall be located at the neck, or an unshielded location closer to the eye, outside the protective apron.

c. When only one individual monitoring device is used to determine the effective dose equivalent for external radiation pursuant to 12 VAC 5-481-640 C 2, it shall be located at the neck outside the protective apron. When a second individual monitoring device is used, for the same purpose, it shall be located under the protective apron at the waist. The second individual monitoring device is required for a declared pregnant woman.

B. Each licensee or registrant shall monitor, to determine compliance with 12 VAC 5-481-670, the occupational intake of radioactive material and assess the committed effective dose equivalent to:

1. Adults likely to receive, in one year, an intake in excess of 10% of the applicable ALI in Table I, Columns 1 and 2, of Appendix F; and

2. Minors and declared pregnant women likely to receive, in one year, a committed effective dose equivalent in excess of 0.5 mSv (0.05 rem).

12 VAC 5-481-770. Location of individual monitoring devices.

Each licensee or registrant shall ensure that individuals who are required to monitor occupational doses in accordance with 12 VAC 5-481-760 wear individual monitoring devices as follows:

A. An individual monitoring device used for monitoring the dose to the whole body shall be worn at the unshielded location of the whole body likely to receive the highest exposure. When a protective apron is worn, the location of the individual monitoring device is typically at the neck (collar);

B. An individual monitoring device used for monitoring the dose to an embryo/fetus of a declared pregnant woman, pursuant to 12 VAC 5-481-710 A, shall be located at the waist under any protective apron being worn by the woman;

C. An individual monitoring device used for monitoring the eye dose equivalent, to demonstrate compliance with 12 VAC 5-481-640 A 2 a, shall be located at the neck (collar), outside any protective apron being worn by the monitored individual, or at an unshielded location closer to the eye;

D. An individual monitoring device used for monitoring the dose to the extremities, to demonstrate compliance with 12 VAC 5-481-640 A 2 b, shall be worn on the extremity likely to receive the highest exposure. Each individual monitoring device shall be oriented to measure the highest dose to the extremity being monitored.

ARTICLE 7.

CONTROL OF EXPOSURE FROM EXTERNAL SOURCES IN RESTRICTED AREAS.

12 VAC 5-481-780. Control of access to high radiation areas.

12 VAC 5-481-790. Control of access to very high radiation areas.

12 VAC 5-481-800. Control of access to very high radiation areas - irradiators.

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12 VAC 5-481-780. Control of access to high radiation areas.

A. The licensee or registrant shall ensure that each entrance or access point to a high radiation area has one or more of the following features:

1. A control device that, upon entry into the area, causes the level of radiation to be reduced below that level at which an individual might receive a deep dose equivalent of one mSv (0.1 rem) in one hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates; or

2. A control device that energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry; or

3. Entryways that are locked, except during periods when access to the areas is required, with positive control over each individual entry.

B. In place of the controls required by 12 VAC 5-481-780 A for a high radiation area, the licensee or registrant may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry.

C. The licensee or registrant may apply to the agency for approval of alternative methods for controlling access to high radiation areas.

D. The licensee or registrant shall establish the controls required by 12 VAC 5-481-780 A and C in a way that does not prevent individuals from leaving a high radiation area.

E. The licensee or registrant is not required to control each entrance or access point to a room or other area that is a high radiation area solely because of the presence of radioactive materials prepared for transport and packaged and labeled in accordance with the regulations of the Department of Transportation provided that:

1. The packages do not remain in the area longer than three days; and

2. The dose rate at one meter from the external surface of any package does not exceed 0.1 mSv (0.01 rem) per hour.

F. The licensee or registrant is not required to control entrance or access to rooms or other areas in hospitals solely because of the presence of patients containing radioactive material, provided that there are personnel in attendance who are taking the necessary precautions to prevent the

exposure of individuals to radiation or radioactive material in excess of the established limits in Part IV (12 VAC 5-481-600 et seq.) and to operate within the ALARA provisions of the licensee's or registrant's radiation protection program.

G. The registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a high radiation area as described in 12 VAC 5-481-780 if the registrant has met all the specific requirements for access and control specified in other applicable Parts of these regulations, such as, Part V (12 VAC 5-481-1170 et seq.) for industrial radiography, Part VI (12 VAC 5-481-1580 et seq.) for X-rays in the healing arts, and Part IX (12 VAC 5-481-2470 et seq.) for particle accelerators.

12 VAC 5-481-790. Control of access to very high radiation areas.

A. In addition to the requirements in 12 VAC 5-481-780, the licensee or registrant shall institute measures to ensure that an individual is not able to gain unauthorized or inadvertent access to areas in which radiation levels could be encountered at five Gy (500 rad) or more in one hour at one meter from a source of radiation or any surface through which the radiation penetrates. This requirement does not apply to rooms or areas in which diagnostic X-ray systems are the only source of radiation, or to non-self-shielded irradiators.

B. The registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a very high radiation area as described in 12 VAC 5-481-790 A if the registrant has met all the specific requirements for access and control specified in other applicable Parts of these regulations, such as, Part V (12 VAC 5-481-1170 et seq.) for

industrial radiography, Part VI (12 VAC 5-481-1580 et seq.) for x- rays in the healing arts, and Part IX (12 VAC 5-481-2470 et seq.) for particle accelerators.

12 VAC 5-481-800. Control of access to very high radiation areas - irradiators.

A. 12 VAC 5-481-800 applies to licensees or registrants with sources of radiation in non-self-shielded irradiators. 12 VAC 5-481-800 does not apply to sources of radiation that are used in teletherapy, in industrial radiography, or in completely self-shielded irradiators in which the source of radiation is both stored and operated within the same shielding radiation barrier and, in the designed configuration of the irradiator, is always physically inaccessible to any individual and cannot create high levels of radiation in an area that is accessible to any individual.

B. Each area in which there may exist radiation levels in excess of five Gy (500 rad) in one hour at one meter from a source of radiation that is used to irradiate materials shall meet the following requirements:

1. Each entrance or access point shall be equipped with entry control devices which:

a. Function automatically to prevent any individual from inadvertently entering a very high radiation area; and

b. Permit deliberate entry into the area only after a control device is actuated that causes the radiation level within the area, from the source of radiation, to be

reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of one mSv (0.1 rem) in one hour; and

c. Prevent operation of the source of radiation if it would produce radiation levels in the area that could result in a deep dose equivalent to an individual in excess of one mSv (0.1 rem) in one hour.

2. Additional control devices shall be provided so that, upon failure of the entry control devices to function as required by 12 VAC 5-481-800 B 1:

a. The radiation level within the area, from the source of radiation, is reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of one mSv (0.1 rem) in one hour; and

b. Conspicuous visible and audible alarm signals are generated to make an individual attempting to enter the area aware of the hazard and at least one other authorized individual, who is physically present, familiar with the activity, and prepared to render or summon assistance, aware of the failure of the entry control devices.

3. The licensee or registrant shall provide control devices so that, upon failure or removal of physical radiation barriers other than the sealed source's shielded storage container:

a. The radiation level from the source of radiation is reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of one mSv (0.1 rem) in one hour; and

b. Conspicuous visible and audible alarm signals are generated to make potentially affected individuals aware of the hazard and the licensee or registrant or at least one other individual, who is familiar with the activity and prepared to render or summon assistance, aware of the failure or removal of the physical barrier.

4. When the shield for stored sealed sources is a liquid, the licensee or registrant shall provide means to monitor the integrity of the shield and to signal, automatically, loss of adequate shielding.

5. Physical radiation barriers that comprise permanent structural components, such as walls, that have no credible probability of failure or removal in ordinary circumstances need not meet the requirements of 12 VAC 5-481-800 B 3 and 4.

6. Each area shall be equipped with devices that will automatically generate conspicuous visible and audible alarm signals to alert personnel in the area before the source of radiation can be put into operation and in time for any individual in the area to operate a clearly identified control device, which must be installed in the area and which can prevent the source of radiation from being put into operation.

7. Each area shall be controlled by use of such administrative procedures and such devices as are necessary to ensure that the area is cleared of personnel prior to each use of the source of radiation.

8. Each area shall be checked by a radiation measurement to ensure that, prior to the first individual's entry into the area after any use of the source of radiation, the radiation level from the source of radiation in the area is below that at which it would be possible for an individual to receive a deep dose equivalent in excess of one mSv (0.1 rem) in one hour.

9. The entry control devices required in 12 VAC 5-481-800 B 1 shall be tested for proper functioning. See 12 VAC 5-481-1070 for recordkeeping requirements.

a. Testing shall be conducted prior to initial operation with the source of radiation on any day, unless operations were continued uninterrupted from the previous day; and

b. Testing shall be conducted prior to resumption of operation of the source of radiation after any unintentional interruption; and

c. The licensee or registrant shall submit and adhere to a schedule for periodic tests of the entry control and warning systems.

10. The licensee or registrant shall not conduct operations, other than those necessary to place the source of radiation in safe condition or to effect repairs on controls, unless control devices are functioning properly.

11. Entry and exit portals that are used in transporting materials to and from the irradiation area, and that are not intended for use by individuals, shall be controlled by such devices and administrative procedures as are necessary to physically protect and warn against inadvertent entry by any individual through these portals. Exit portals for irradiated materials shall be equipped to detect and signal the presence of any loose radioactive material that is carried toward such an exit and automatically to prevent loose radioactive material from being carried out of the area.

C. Licensees, registrants, or applicants for licenses or registrations for sources of radiation within the purview of 12 VAC 5-481-800 B which will be used in a variety of positions or in locations, such as open fields or forests, that make it impracticable to comply with certain requirements of 12 VAC 5-481-800 B, such as those for the automatic control of radiation levels, may apply to the agency for approval of alternative safety measures. Alternative safety measures shall provide personnel protection at least equivalent to those specified in 12 VAC 5-481-800 B. At least one of the alternative measures shall include an entry-preventing interlock control based on a measurement of the radiation that ensures the absence of high radiation levels before an individual can gain access to the area where such sources of radiation are used.

D. The entry control devices required by 12 VAC 5-481-800 B and C shall be established in such a way that no individual will be prevented from leaving the area.

ARTICLE 8.

RESPIRATORY PROTECTION AND CONTROLS TO RESTRICT INTERNAL EXPOSURE IN RESTRICTED AREAS.

12 VAC 5-481-810. Use of process or other engineering controls.

The licensee or registrant shall use, to the extent practicable, process or other engineering controls, such as containment or ventilation, to control the concentrations of radioactive material in air.

12 VAC 5-481-820. Use of other controls.

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

A. Control of access; or

B. Limitation of exposure times; or

C. Use of respiratory protection equipment; or

D. Other controls.

12 VAC 5-481-830. Use of individual respiratory protection equipment.

A. If the licensee or registrant uses respiratory protection equipment to limit intakes pursuant to 12 VAC 5-481-820:

1. Except as provided in 12 VAC 5-481-830 A 2, the licensee or registrant shall use only respiratory protection equipment that is tested and certified or had certification extended by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration;

2. The licensee or registrant may use equipment that has not been tested or certified by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration, has not had certification extended by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration, or for which there is no schedule for testing or certification, provided the licensee or registrant has submitted to the agency and the agency has approved an application for authorized use of that equipment, including a demonstration by testing, or a demonstration on the

basis of test information, that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use;

3. The licensee or registrant shall implement and maintain a respiratory protection program that includes:

a. Air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate exposures; and

b. Surveys and bioassays, as appropriate, to evaluate actual intakes; and

c. Testing of respirators for operability immediately prior to each use; and

d. Written procedures regarding selection, fitting, issuance, maintenance, and testing of respirators, including testing for operability immediately prior to each use; supervision and training of personnel; monitoring, including air sampling and bioassays; and recordkeeping; and

e. Determination by a physician prior to initial fitting of respirators, and at least every 12 months thereafter, that the individual user is physically able to use the respiratory protection equipment;

4. The licensee or registrant shall issue a written policy statement on respirator usage covering:

a. The use of process or other engineering controls, instead of respirators; and

b. The routine, nonroutine, and emergency use of respirators; and

c. The length of periods of respirator use and relief from respirator use;

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

6. The licensee or registrant shall use respiratory protection equipment within the equipment manufacturer's expressed limitations for type and mode of use and shall provide proper visual, communication, and other special capabilities, such as adequate skin protection, when needed.

B. When estimating exposure of individuals to airborne radioactive materials, the licensee or registrant may make allowance for respiratory protection equipment used to limit intakes pursuant to 12 VAC 5-481-820, provided that the following conditions, in addition to those in 12 VAC 5-481-830 A, are satisfied:

1. The licensee or registrant selects respiratory protection equipment that provides a protection factor, specified in Appendix E, greater than the multiple by which peak concentrations of airborne radioactive materials in the working area are expected to exceed the values specified in Appendix F, Table I, Column 3. However, if the selection of respiratory protection equipment with a protection factor greater than the peak concentration is inconsistent with the goal specified in 12 VAC 5-481-820 of keeping the total effective dose equivalent ALARA, the licensee or registrant may select respiratory protection equipment with a lower protection factor provided that such a selection would result in a total effective dose equivalent that is ALARA. The concentration of radioactive material in the air that is inhaled when respirators are worn may be initially estimated by dividing the average concentration in air, during each period of uninterrupted use, by the protection factor. If the exposure is later found to be greater than initially estimated, the corrected value shall be used; if the exposure is later found to be less than initially estimated, the corrected value may be used;

2. The licensee or registrant shall obtain authorization from the agency before assigning respiratory protection factors in excess of those specified in Appendix E. The agency may authorize a licensee or registrant to use higher protection factors on receipt of an application that:

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

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

C. In an emergency, the licensee or registrant shall use as emergency equipment only respiratory protection equipment that has been specifically certified or had certification extended for emergency use by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration.

D. The licensee or registrant shall notify the agency in writing at least 30 days before the date that respiratory protection equipment is first used pursuant to either 12 VAC 5-481-830 A or B.

ARTICLE 9.

SECURITY AND CONTROL OF LICENSED OR REGISTERED SOURCES OF RADIATION.

12 VAC 5-481-840. Security and control of licensed or registered sources of radiation.

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12 VAC 5-481-840. Security and control of licensed or registered sources of radiation.

A. The licensee or registrant shall secure licensed or registered radioactive material from unauthorized removal or access.

B. The licensee or registrant shall maintain constant surveillance, and use devices or administrative procedures to prevent unauthorized use of licensed or registered radioactive material that is in an unrestricted area and that is not in storage.

C. The registrant shall secure registered radiation machines from unauthorized removal.

D. The registrant shall use devices or administrative procedures to prevent unauthorized use of registered radiation machines.

ARTICLE 10.

PRECAUTIONARY PROCEDURES.

12 VAC 5-481-850. Caution signs.

12 VAC 5-481-860. Posting requirements.

12 VAC 5-481-870. Exceptions to posting requirements.

12 VAC 5-481-880. Labeling containers and radiation machines.

12 VAC 5-481-890. Exemptions to labeling requirements.

12 VAC 5-481-900. Procedures for receiving and opening packages.

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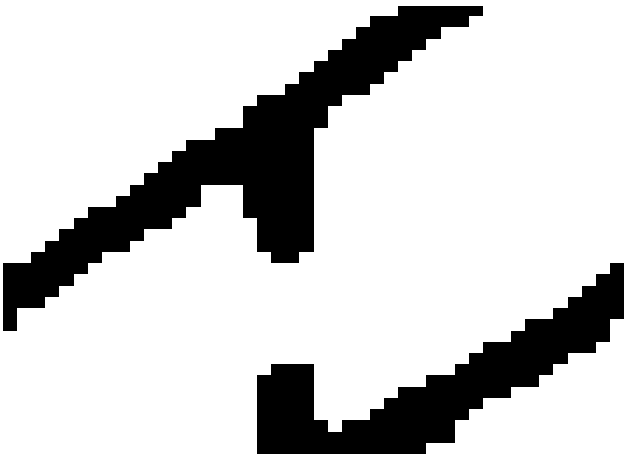
12 VAC 5-481-850. Caution signs.

A. Standard radiation symbol. Unless otherwise authorized by the agency, the symbol prescribed by 12 VAC 5-481-850 shall use the colors magenta, or purple, or black on yellow background. The symbol prescribed is the three-bladed design as follows:



1. Cross-hatched area is to be magenta, or purple, or black, and

2. The background is to be yellow.

Figure 1. Radiation Symbol.

B. Exception to color requirements for standard radiation symbol. Notwithstanding the requirements of 12 VAC 5-481-850 A, licensees or registrants are authorized to label sources, source holders, or device components containing sources of radiation that are subjected to high temperatures, with conspicuously etched or stamped radiation caution symbols and without a color requirement.

C. Additional information on signs and labels. In addition to the contents of signs and labels prescribed in Part IV (12 VAC 5-481-600 et seq.), the licensee or registrant may provide, on or near the required signs and labels, additional information, as appropriate, to make individuals aware of potential radiation exposures and to minimize the exposures.

12 VAC 5-481-860. Posting requirements.

A. Posting of radiation areas. The licensee or registrant shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIATION AREA."

B. Posting of high radiation areas. The licensee or registrant shall post each high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, HIGH RADIATION AREA" or "DANGER, HIGH RADIATION AREA."

C. Posting of very high radiation areas. The licensee or registrant shall post each very high radiation area with a conspicuous sign or signs bearing the radiation symbol and words "GRAVE DANGER, VERY HIGH RADIATION AREA."

D. Posting of airborne radioactivity areas. The licensee or registrant shall post each airborne radioactivity area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, AIRBORNE RADIOACTIVITY AREA" or "DANGER, AIRBORNE RADIOACTIVITY AREA."

E. Posting of areas or rooms in which licensed or registered material is used or stored. The licensee or registrant shall post each area or room in which there is used or stored an amount of licensed or registered material exceeding 10 times the quantity of such material specified in Appendix G with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)."

12 VAC 5-481-870. Exceptions to posting requirements.

A. A licensee or registrant is not required to post caution signs in areas or rooms containing sources of radiation for periods of less than eight hours, if each of the following conditions is met:

1. The sources of radiation are constantly attended during these periods by an individual who takes the precautions necessary to prevent the exposure of individuals to sources of radiation in excess of the limits established in Part IV (12 VAC 5-481-600 et seq.); and

2. The area or room is subject to the licensee's or registrant's control.

B. Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs pursuant to 12 VAC 5-481-860 provided that the requirements of 12 VAC 5-481-2020 A 2 or 12 VAC 5-481-2080 A 2 of these regulations are met.

C. Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs, provided that:

1. A patient being treated with a permanent implant could be released from confinement pursuant to 12 VAC 5-481-1900 of these regulations; or

2. A patient being treated with a therapeutic radiopharmaceutical could be released from confinement pursuant to 12 VAC 5-481-2020 C of these regulations.

D. A room or area is not required to be posted with a caution sign because of the presence of a sealed source provided the radiation level at 30 centimeters from the surface of the sealed source container or housing does not exceed 0.05 mSv (0.005 rem) per hour.

E. A room or area is not required to be posted with a caution sign because of the presence of radiation machines used solely for diagnosis in the healing arts.

12 VAC 5-481-880. Labeling containers and radiation machines.

A. The licensee or registrant shall ensure that each container of licensed or registered material bears a durable, clearly visible label bearing the radiation symbol and the words "CAUTION,

RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL." The label shall also provide information, such as the radionuclides present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, kinds of materials, and mass enrichment, to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures.

B. Each licensee or registrant shall, prior to removal or disposal of empty uncontaminated containers to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials.

C. Each registrant shall ensure that each radiation machine is labeled in a conspicuous manner which cautions individuals that radiation is produced when it is energized.

12 VAC 5-481-890. Exemptions to labeling requirements.

A licensee or registrant is not required to label:

A. Containers holding licensed or registered material in quantities less than the quantities listed in Appendix G; or

B. Containers holding licensed or registered material in concentrations less than those specified in Table III of Appendix F; or

C. Containers attended by an individual who takes the precautions necessary to prevent the exposure of individuals in excess of the limits established by Part IV (12 VAC 5-481-600 et seq.); or

D. Containers when they are in transport and packaged and labeled in accordance with the regulations of the Department of Transportation; (Labeling of packages containing radioactive materials is required by the Department of Transportation if the amount and type of radioactive material exceeds the limits for an excepted quantity or article as defined and limited by Department of Transportation regulations 49 CFR 173.403(m) and (w) and 173.421-424.); or

E. Containers that are accessible only to individuals authorized to handle or use them, or to work in the vicinity of the containers, if the contents are identified to these individuals by a readily available written record. Examples of containers of this type are containers in locations such as water-filled canals, storage vaults, or hot cells. The record shall be retained as long as the containers are in use for the purpose indicated on the record; or

F. Installed manufacturing or process equipment, such as piping and tanks.

12 VAC 5-481-900. Procedures for receiving and opening packages.

A. Each licensee or registrant who expects to receive a package containing quantities of radioactive material in excess of a Type A quantity, as defined in 12 VAC 5-481-10 and Appendix L of these regulations, shall make arrangements to receive:

1. The package when the carrier offers it for delivery; or

2. The notification of the arrival of the package at the carrier's terminal and to take possession of the package expeditiously.

B. Each licensee or registrant shall:

1. Monitor the external surfaces of a labeled (labeled means labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in Department of Transportation regulations 49 CFR 172.403 and 172.436-440.) package for radioactive contamination unless the package contains only radioactive material in the form of gas or in special form as defined in 12 VAC 5-481-10 of these regulations; and

2. Monitor the external surfaces of a labeled package for radiation levels unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, as defined in 12 VAC 5-481-10 and Appendix L of these regulations; and

3. Monitor all packages known to contain radioactive material for radioactive contamination and radiation levels if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.

C. The licensee or registrant shall perform the monitoring required by 12 VAC 5-481-900 B as soon as practicable after receipt of the package, but not later than three hours after the package is

received at the licensee's or registrant's facility if it is received during the licensee's or registrant's normal working hours or if there is evidence of degradation of package integrity, such as a package that is crushed, wet, or damaged. If a package is received after working hours, and has no evidence of degradation of package integrity, the package shall be monitored no later than three hours from the beginning of the next working day.

D. The licensee or registrant shall immediately notify the final delivery carrier and, by telephone and either telegram, mailgram, or facsimile, the agency when:

1. Removable radioactive surface contamination exceeds the limits of 12 VAC 5-481-3410 H of these regulations; or

2. External radiation levels exceed the limits of 12 VAC 5-481-3410 I and J of these regulations.

E. Each licensee or registrant shall:

1. Establish, maintain, and retain written procedures for safely opening packages in which radioactive material is received; and

2. Ensure that the procedures are followed and that due consideration is given to special instructions for the type of package being opened.

F. Licensees or registrants transferring special form sources in vehicles owned or operated by the licensee or registrant to and from a work site are exempt from the contamination monitoring requirements of 12 VAC 5-481-900 B, but are not exempt from the monitoring requirement in 12 VAC 5-481-900 B for measuring radiation levels that ensures that the source is still properly lodged in its shield.

ARTICLE 11.

WASTE DISPOSAL.

12 VAC 5-481-910. General requirements.

A. A licensee or registrant shall dispose of licensed or registered material only:

1. By transfer to an authorized recipient as provided in 12 VAC 5-481-960 or in Parts III (12 VAC 5-481-380 et seq.) or XI (12 VAC 5-481-2660 et seq.) of these regulations, or to the Department of Energy; or

2. By decay in storage; or

3. By release in effluents within the limits in 12 VAC 5-481-720; or

4. As authorized pursuant to 12 VAC 5-481-920; 12 VAC 5-481-930; 12 VAC 5-481-940 or 12 VAC 5-481-950.

B. A person shall be specifically licensed or registered to receive waste containing licensed or registered material from other persons for:

1. Treatment prior to disposal; or

2. Treatment or disposal by incineration; or

3. Decay in storage; or

4. Disposal at a land disposal facility licensed pursuant to Part XI (12 VAC 5-481-2660 et seq.) of these regulations; or

5. Storage until transferred to a storage or disposal facility authorized to receive the waste.

12 VAC 5-481-920. Method for obtaining approval of proposed disposal procedures.

A licensee or registrant or applicant for a license or registration may apply to the agency for approval of proposed procedures, not otherwise authorized in these regulations, to dispose of licensed or registered material generated in the licensee's or registrant's operations. Each application shall include:

A. A description of the waste containing licensed or registered material to be disposed of, including the physical and chemical properties that have an impact on risk evaluation, and the proposed manner and conditions of waste disposal; and

B. An analysis and evaluation of pertinent information on the nature of the environment; and

C. The nature and location of other potentially affected facilities; and

D. Analyses and procedures to ensure that doses are maintained ALARA and within the dose limits in Part IV (12 VAC 5-481-600 et seq.).

12 VAC 5-481-930. Disposal by release into sanitary sewerage.

A. A licensee or registrant may discharge licensed or registered material into sanitary sewerage if each of the following conditions is satisfied:

1. The material is readily soluble, or is readily dispersible biological material, in water; and

2. The quantity of licensed or registered radioactive material that the licensee or registrant releases into the sewer in one month divided by the average monthly volume of water released into the sewer by the licensee or registrant does not exceed the concentration listed in Table III of Appendix F; and

3. If more than one radionuclide is released, the following conditions must also be satisfied:

a. The licensee or registrant shall determine the fraction of the limit in Table III of Appendix F represented by discharges into sanitary sewerage by dividing the actual monthly average concentration of each radionuclide released by the licensee or registrant into the sewer by the concentration of that radionuclide listed in Table III of Appendix F; and

b. The sum of the fractions for each radionuclide required by 12 VAC 5-481-930 A 3 a does not exceed unity; and

4. The total quantity of licensed or registered radioactive material that the licensee or registrant releases into the sanitary sewerage in a year does not exceed 185 GBq (5 Ci) of hydrogen-3, 37 GBq (1 Ci) of carbon-14, and 37 GBq (1 Ci) of all other radioactive materials combined.

B. Excreta from individuals undergoing medical diagnosis or therapy with radioactive material are not subject to the limitations contained in 12 VAC 5-481-930 A.

12 VAC 5-481-940. Treatment or disposal by incineration.

A licensee or registrant may treat or dispose of licensed or registered material by incineration only in the form and concentration specified in 12 VAC 5-481-950 or as specifically approved by the agency pursuant to 12 VAC 5-481-920.

12 VAC 5-481-950. Disposal of specific wastes.

A. A licensee or registrant may dispose of the following licensed or registered material as if it were not radioactive:

1. 1.85 kBq, or less, of hydrogen-3 or carbon-14 per gram of medium used for liquid scintillation counting; and

2. 1.85 kBq, or less, of hydrogen-3 or carbon-14 per gram of animal tissue, averaged over the weight of the entire animal.

B. A licensee or registrant shall not dispose of tissue pursuant to 12 VAC 5-481-950 A 2 in a manner that would permit its use either as food for humans or as animal feed.

C. The licensee or registrant shall maintain records in accordance with 12 VAC 5-481-1060.

12 VAC 5-481-960. Transfer for disposal and manifests.

A. The requirements of 12 VAC 5-481-960 and Appendix H are designed to control transfers of low-level radioactive waste intended for disposal at a licensed low-level radioactive waste disposal facility, establish a manifest tracking system, and supplement existing requirements concerning transfers and recordkeeping for those wastes.

B. Each shipment of radioactive waste designated for disposal at a licensed low-level radioactive waste disposal facility shall be accompanied by a shipment manifest as specified in Appendix H-I.

C. Each shipment manifest shall include a certification by the waste generator as specified in Appendix H-II.

D. Each person involved in the transfer of waste for disposal or in the disposal of waste, including the waste generator, waste collector, waste processor, and disposal facility operator, shall comply with the requirements specified in Appendix H-III.

12 VAC 5-481-970. Compliance with environmental and health protection regulations.

Nothing in 12 VAC 5-481-910; 12 VAC 5-481-920; 12 VAC 5-481-930; 12 VAC 5-481-940; 12 VAC 5-481-950 or 12 VAC 5-481-960 relieves the licensee or registrant from complying with other applicable Federal, state and local regulations governing any other toxic or hazardous properties of materials that may be disposed of to 12 VAC 5-481-910; 12 VAC 5-481-920; 12 VAC 5-481-930; 12 VAC 5-481-940; 12 VAC 5-481-950 or 12 VAC 5-481-960.

ARTICLE 12.

RECORDS.

12 VAC 5-481-980. General provisions.

A. Each licensee or registrant shall use the SI units becquerel, gray, sievert and coulomb per kilogram, or the special units curie, rad, rem and roentgen, including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by Part IV (12 VAC 5-481-600 et seq.).

B. The licensee or registrant shall make a clear distinction among the quantities entered on the records required by Part IV (12 VAC 5-481-600 et seq.), such as, total effective dose equivalent, total organ dose equivalent, shallow dose equivalent, eye dose equivalent, deep dose equivalent, or committed effective dose equivalent.

12 VAC 5-481-990. Records of radiation protection programs.

A. Each licensee or registrant shall maintain records of the radiation protection program, including:

1. The provisions of the program; and

2. Audits and other reviews of program content and implementation.

B. The licensee or registrant shall retain the records required by 12 VAC 5-481-990 A 1 until the agency terminates each pertinent license or registration requiring the record. The licensee or registrant shall retain the records required by 12 VAC 5-481-990 A 2 for three years after the record is made.

12 VAC 5-481-1000. Records of surveys.

A. Each licensee or registrant shall maintain records showing the results of surveys and calibrations required by 12 VAC 5-481-750 and 12 VAC 5-481-900 B. The licensee or registrant shall retain these records for three years after the record is made.

B. The licensee or registrant shall retain each of the following records until the agency terminates each pertinent license or registration requiring the record:

1. Records of the results of surveys to determine the dose from external sources of radiation used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents; and

2. Records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose; and

3. Records showing the results of air sampling, surveys, and bioassays required pursuant to 12 VAC 5-481-830 A 3 a and b; and

4. Records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment.

C. Upon termination of the license or registration, the licensee or registrant shall permanently store records on agency form Y or equivalent, or shall make provision with the agency for transfer to the agency.

12 VAC 5-481-1010. Records of tests for leakage or contamination of sealed sources.

Records of tests for leakage or contamination of sealed sources (required by 12 VAC 5-481-740) shall be kept in units of becquerel or microcurie and maintained for inspection by the agency for five years after the records are made.

12 VAC 5-481-1020. Records of prior occupational dose.

A. The licensee or registrant shall retain the records of prior occupational dose and exposure history as specified in 12 VAC 5-481-680 on agency form Y or equivalent until the agency terminates each pertinent license or registration requiring this record. The licensee or registrant shall retain records used in preparing agency form Y or equivalent for three years after the record is made.

B. Upon termination of the license or registration, the licensee or registrant shall permanently store records on agency form Y or equivalent, or shall make provision with the agency for transfer to the agency.

12 VAC 5-481-1030. Records of planned special exposures.

A. For each use of the provisions of 12 VAC 5-481-690 for planned special exposures, the licensee or registrant shall maintain records that describe:

1. The exceptional circumstances requiring the use of a planned special exposure; and

2. The name of the management official who authorized the planned special exposure and a copy of the signed authorization; and

3. What actions were necessary; and

4. Why the actions were necessary; and

5. What precautions were taken to assure that doses were maintained ALARA; and

6. What individual and collective doses were expected to result; and

7. The doses actually received in the planned special exposure.

B. The licensee or registrant shall retain the records until the agency terminates each pertinent license or registration requiring these records.

C. Upon termination of the license or registration, the licensee or registrant shall permanently store records on agency form Y or equivalent, or shall make provision with the agency for transfer to the agency.

12 VAC 5-481-1040. Records of individual monitoring results.

A. Recordkeeping requirement. Each licensee or registrant shall maintain records of doses received by all individuals for whom monitoring was required pursuant to 12 VAC 5-481-760, and records of doses received during planned special exposures, accidents, and emergency conditions. Assessments of dose equivalent and records made using units in effect before the

effective date of Part IV (12 VAC 5-481-600 et seq.) need not be changed. These records shall include, when applicable:

1. The deep dose equivalent to the whole body, eye dose equivalent, shallow dose equivalent to the skin, and shallow dose equivalent to the extremities; and

2. The estimated intake of radionuclides, see 12 VAC 5-481-650; and

3. The committed effective dose equivalent assigned to the intake of radionuclides; and

4. The specific information used to calculate the committed effective dose equivalent pursuant to 12 VAC 5-481-670 C; and

5. The total effective dose equivalent when required by 12 VAC 5-481-650; and

6. The total of the deep dose equivalent and the committed dose to the organ receiving the highest total dose.

B. Recordkeeping frequency. The licensee or registrant shall make entries of the records specified in 12 VAC 5-481-1040 A at intervals not to exceed one year.

C. Recordkeeping format. The licensee or registrant shall maintain the records specified in 12 VAC 5-481-1040 A on agency form Z, in accordance with the instructions for agency form Z, or in clear and legible records containing all the information required by agency form Z.

D. The licensee or registrant shall maintain the records of dose to an embryo/fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy, including the estimated date of conception, shall also be kept on file, but may be maintained separately from the dose records.

E. The licensee or registrant shall retain each required form or record until the agency terminates each pertinent license or registration requiring the record.

F. Upon termination of the license or registration, the licensee or registrant shall permanently store records on agency form Y or equivalent, or shall make provision with the agency for transfer to the agency.

12 VAC 5-481-1050. Records of dose to individual members of the public.

A. Each licensee or registrant shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public. See 12 VAC 5-481-720.

B. The licensee or registrant shall retain the records required by 12 VAC 5-481-1050 A until the agency terminates each pertinent license or registration requiring the record.

12 VAC 5-481-1060. Records of waste disposal.

A. Each licensee or registrant shall maintain records of the disposal of licensed or registered materials made pursuant to 12 VAC 5-481-1020 through 12 VAC 5-481-950, Part XI (12 VAC 5-481-2660 et seq.) of these regulations, and disposal by burial in soil, including burials authorized before the effective date of rule that removed the authorization.

B. The licensee or registrant shall retain the records required by 12 VAC 5-481-1060 A until the agency terminates each pertinent license or registration requiring the record.

12 VAC 5-481-1070. Records of testing entry control devices for very high radiation areas.

A. Each licensee or registrant shall maintain records of tests made pursuant to 12 VAC 5-481-800 B 9 on entry control devices for very high radiation areas. These records must include the date, time, and results of each such test of function.

B. The licensee or registrant shall retain the records required by 12 VAC 5-481-1070 A for three years after the record is made.

12 VAC 5-481-1080. Form of records.

Each record required by Part IV (12 VAC 5-481-600 et seq.) shall be legible throughout the specified retention period. The record shall 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 or 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.

ARTICLE 13.

REPORTS.

12 VAC 5-481-1090. Reports of stolen, lost, or missing licensed or registered sources of radiation.

12 VAC 5-481-1100. Notification of incidents.

12 VAC 5-481-1110. Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the limits.

12 VAC 5-481-1120. Reports of planned special exposures.

12 VAC 5-481-1130. Reports of individual monitoring.

12 VAC 5-481-1140. Notifications and reports to individuals.

12 VAC 5-481-1150. Reports of leaking or contaminated sealed sources.

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12 VAC 5-481-1090. Reports of stolen, lost, or missing licensed or registered sources of radiation.

A. Telephone reports. Each licensee or registrant shall report to the agency by telephone as follows:

1. Immediately after its occurrence becomes known to the licensee or registrant, stolen, lost, or missing licensed or registered radioactive material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in Appendix G under such circumstances that it appears to the licensee or registrant that an exposure could result to individuals in unrestricted areas; or

2. Within 30 days after its occurrence becomes known to the licensee or registrant, lost, stolen, or missing licensed or registered radioactive material in an aggregate quantity greater than 10 times the quantity specified in Appendix G that is still missing;

3. Immediately after its occurrence becomes known to the registrant, a stolen, lost, or missing radiation machine.

B. Written reports. Each licensee or registrant required to make a report pursuant to 12 VAC 5-481-1090 A shall, within 30 days after making the telephone report, make a written report to the agency setting forth the following information:

1. A description of the licensed or registered source of radiation involved, including, for radioactive material, the kind, quantity, and chemical and physical form; and, for radiation machines, the manufacturer, model and serial number, type and maximum energy of radiation emitted;

2. A description of the circumstances under which the loss or theft occurred; and

3. A statement of disposition, or probable disposition, of the licensed or registered source of radiation involved; and

4. Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas; and

5. Actions that have been taken, or will be taken, to recover the source of radiation; and

6. Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed or registered sources of radiation.

C. Subsequent to filing the written report, the licensee or registrant shall also report additional substantive information on the loss or theft within 30 days after the licensee or registrant learns of such information.

D. The licensee or registrant shall prepare any report filed with the agency pursuant to 12 VAC 5-481-1090 so that names of individuals who may have received exposure to radiation are stated in a separate and detachable portion of the report.

12 VAC 5-481-1100. Notification of incidents.

A. Immediate notification. Notwithstanding other requirements for notification, each licensee or registrant shall immediately report each event involving a source of radiation possessed by the licensee or registrant that may have caused or threatens to cause any of the following conditions:

1. An individual to receive:

a. A total effective dose equivalent of 0.25 Sv (25 rem) or more; or

b. An eye dose equivalent of 0.75 Sv (75 rem) or more; or

c. A shallow dose equivalent to the skin or extremities or a total organ dose equivalent of 2.5 Gy (250 rad) or more; or

2. The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake five times the occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.

B. Twenty-four hour notification. Each licensee or registrant shall, within 24 hours of discovery of the event, report to the agency each event involving loss of control of a licensed or registered source of radiation possessed by the licensee or registrant that may have caused, or threatens to cause, any of the following conditions:

1. An individual to receive, in a period of 24 hours:

a. A total effective dose equivalent exceeding 0.05 Sv (5 rem); or

b. An eye dose equivalent exceeding 0.15 Sv (15 rem); or

c. A shallow dose equivalent to the skin or extremities or a total organ dose equivalent exceeding 0.5 Sv (50 rem); or

2. The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake in excess of one occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.

C. Licensees or registrants shall make the reports required by 12 VAC 5-481-1100 A and B by initial contact by telephone to the agency and shall confirm the initial contact by telegram, mailgram, or facsimile to the agency.

D. The licensee or registrant shall prepare each report filed with the agency pursuant to 12 VAC 5-481-1100 so that names of individuals who have received exposure to sources of radiation are stated in a separate and detachable portion of the report.

E. The provisions of 12 VAC 5-481-1100 do not apply to doses that result from planned special exposures, provided such doses are within the limits for planned special exposures and are reported pursuant to 12 VAC 5-481-1120.

12 VAC 5-481-1110. Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the limits.

A. Reportable events. In addition to the notification required by 12 VAC 5-481-1100, each licensee or registrant shall submit a written report within 30 days after learning of any of the following occurrences:

1. Incidents for which notification is required by 12 VAC 5-481-1100; or

2. Doses in excess of any of the following:

a. The occupational dose limits for adults in 12 VAC 5-481-640; or

b. The occupational dose limits for a minor in 12 VAC 5-481-700; or

c. The limits for an embryo/fetus of a declared pregnant woman in 12 VAC 5-481-710; or

d. The limits for an individual member of the public in 12 VAC 5-481-720; or

e. Any applicable limit in the license or registration; or

3. Levels of radiation or concentrations of radioactive material in:

a. A restricted area in excess of applicable limits in the license or registration; or

b. An unrestricted area in excess of 10 times the applicable limit set forth in Part IV (12 VAC 5-481-600 et seq.) or in the license or registration, whether or not involving exposure of any individual in excess of the limits in 12 VAC 5-481-720; or

4. For licensees subject to the provisions of the Environmental Protection Agency's generally applicable environmental radiation standards in 40 CFR 190, levels of radiation or releases of radioactive material in excess of those standards, or of license conditions related to those standards.

B. Contents of reports.

1. Each report required by 12 VAC 5-481-1110 A shall describe the extent of exposure of individuals to radiation and radioactive material, including, as appropriate:

a. Estimates of each individual's dose; and

b. The levels of radiation and concentrations of radioactive material involved; and

c. The cause of the elevated exposures, dose rates, or concentrations; and

d. Corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, generally applicable environmental standards, and associated license or registration conditions.

2. Each report filed pursuant to 12 VAC 5-481-1110 A shall include for each individual exposed: the name, Social Security account number, and date of birth. With respect to the limit for the embryo/fetus in 12 VAC 5-481-710, the identifiers should be those of the declared pregnant woman. The report shall be prepared so that this information is stated in a separate and detachable portion of the report.

C. All licensees or registrants who make reports pursuant to 12 VAC 5-481-1110 A shall submit the report in writing to the agency.

12 VAC 5-481-1120. Reports of planned special exposures.

The licensee or registrant shall submit a written report to the agency within 30 days following any planned special exposure conducted in accordance with 12 VAC 5-481-690, informing the agency that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by 12 VAC 5-481-1030.

12 VAC 5-481-1130. Reports of individual monitoring.

A. This section applies to each person licensed or registered by the agency to:

1. Possess or use sources of radiation for purposes of industrial radiography pursuant to Parts III (12 VAC 5-481-380 et seq.) and V (12 VAC 5-481-1170 et seq.) of these regulations; or

2. Receive radioactive waste from other persons for disposal pursuant to Part XI (12 VAC 5-481-2660 et seq.) of these regulations; or

3. Possess or use at any time, for processing or manufacturing for distribution pursuant to Part III (12 VAC 5-481-380 et seq.) or VII (12 VAC 5-481-1660 et seq.) of these regulations, radioactive material in quantities exceeding any one of the following quantities:

Radionuclide	Activity[a]	
	Ci	GBq
Cesium-137	1	37
Cobalt-60	1	37
Gold-198	100	3,700
Iodine-131	1	37
Iridium-192	10	370
Krypton-85	1,000	37,000

Promethium-147	10	370
Technetium-99m	1,000	37,000

[a] *The agency may require as a license condition, or by rule, regulation, or order pursuant to 12 VAC 5-481-190 of these regulations, reports from licensees or registrants who are licensed or registered to use radionuclides not on this list, in quantities sufficient to cause comparable radiation levels.*

B. Each licensee or registrant in a category listed in 12 VAC 5-481-1130 A shall submit an annual report of the results of individual monitoring carried out by the licensee or registrant for each individual for whom monitoring was required by 12 VAC 5-481-760 during that year. The licensee or registrant may include additional data for individuals for whom monitoring was provided but not required. The licensee or registrant shall use agency form Z or equivalent or electronic media containing all the information required by agency form Z.

C. The licensee or registrant shall file the report required by 12 VAC 5-481-1130 B, covering the preceding year, on or before April 30 of each year. The licensee or registrant shall submit the report to the agency.

12 VAC 5-481-1140. Notifications and reports to individuals.

A. Requirements for notification and reports to individuals of exposure to radiation or radioactive material are specified in 12 VAC 5-481-2610 of these regulations.

B. When a licensee or registrant is required pursuant to 12 VAC 5-481-1110 to report to the agency any exposure of an individual to radiation or radioactive material, the licensee or registrant shall also notify the individual. Such notice shall be transmitted at a time not later than the transmittal to the agency, and shall comply with the provisions of 12 VAC 5-481-2610 A of these regulations.

12 VAC 5-481-1150. Reports of leaking or contaminated sealed sources.

The licensee or registrant shall file a report within five days with the agency if the test for leakage or contamination required pursuant to 12 VAC 5-481-740 indicates a sealed source is leaking or contaminated. The report shall include the equipment involved, the test results and the corrective action taken.

ARTICLE 14.

ADDITIONAL REQUIREMENTS.

12 VAC 5-481-1160. Vacating premises

12 VAC 5-481-1160. Vacating premises.

Each specific licensee or registrant shall, no less than 30 days before vacating or relinquishing possession or control of premises which may have been contaminated with radioactive material as a result of his activities, notify the agency in writing of intent to vacate. When deemed necessary by the agency, the licensee shall decontaminate the premises in such a manner as the agency may specify.

PART V.

RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS.

ARTICLE 1.

GENERAL REQUIREMENTS.

12 VAC 5-481-1230. Locking of sources of radiation, storage containers and source changers.

12 VAC 5-481-1240. Radiation survey instruments.

12 VAC 5-481-1250. Leak testing and replacement of sealed sources.

12 VAC 5-481-1260. Quarterly inventory.

12 VAC 5-481-1270. Inspection and maintenance of radiation machines, radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments.

12 VAC 5-481-1280. Permanent radiographic installations.

12 VAC 5-481-1290. Labeling, storage, and transportation.

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12 VAC 5-481-1170. Purpose.

This Part prescribes requirements for the issuance of licenses or registrations for the industrial use of sources of radiation and radiation safety requirements for persons using these sources of radiation in industrial radiography.

12 VAC 5-481-1180. Scope.

The provisions and requirements of this Part are in addition to, and not in substitution for, other requirements of these regulations. In particular, the general requirements and provisions of Parts I (12 VAC 5-481- 10 et seq.); II (12 VAC 5-481-260 ET SEQ.); III (12 VAC 5-481-380 et seq.); IV (12 VAC 5-481-600 et seq.); X (12 VAC 5-481-2580 et seq.) and XIII (12 VAC 5-481-3280 et seq.), of these regulations apply to applicants, licensees and registrants subject to this Part. Parts III (12 VAC 5-481-380 et seq.) and

XIII (12 VAC 5-481-3280 et seq.) of these regulations apply to licensing and transportation of radioactive material and Part II (12 VAC 5-481-260 et seq.) of these regulations applies to the registration of radiation machines. Except for sections which are applicable only to sealed radioactive sources, radiation machines and sealed radioactive sources are both covered by this Part. This regulation does not apply to medical uses of sources of radiation which are addressed in Parts VII (12 VAC 5-481-1660 et seq.) and XV (12 VAC 5-481-3710 et seq.) of these regulations.

12 VAC 5-481-1190. Exemptions.

A. Uses of certified and certifiable cabinet X-ray systems are exempt from the requirements of this Part except for the following:

1. For certified and certifiable cabinet X-ray systems, including those designed to allow admittance of individuals:

a. No registrant shall permit any individual to operate a cabinet X-ray system until the individual has received a copy of and instruction in the operating procedures for the unit. Records that demonstrate compliance with this subparagraph shall be maintained for agency inspection until disposal is authorized by the agency.

b. Tests for proper operation of interlocks must be conducted and recorded at intervals not to exceed six months. Records of these tests shall be maintained for agency inspection until disposal is authorized by the agency.

c. The registrant shall perform an evaluation of the radiation dose limits to determine compliance with Parts 12 VAC 5-481-720 A through 12 VAC 5-481-720 C of these regulations, and 21 CFR 1020.40, Cabinet X-ray Systems (39 Federal Register 12986, April 10, 1974), at intervals not to exceed one year. Records of these evaluations shall be maintained for agency inspection for two years after the evaluation.

2. Certified cabinet X-ray systems shall be maintained in compliance with 21 CFR 1020.40, Cabinet X-ray Systems (39 Federal Register 12986, April 10, 1974), and no modification shall be made to the system unless prior agency approval has been granted.

B. Industrial uses of hand-held light intensified imaging devices are exempt from the requirements of exceed two millirem per hour. Devices which exceed this limit shall meet the applicable requirements of this Part and the licensing or registration requirements of Part II (12 VAC 5-481-260 et seq.) or Part III (12 VAC 5-481-380 et seq.) of these regulations, as applicable.

12 VAC 5-481-1200. Licensing and registration requirements for industrial radiography operations.

The agency will approve an application for a specific license for the use of licensed material or a registration for use of radiation machines if the applicant meets the following requirements:

A. The applicant satisfies the general requirements specified in Part II (12 VAC 5-481-260 et seq.) for radiation machine facilities or Part III (12 VAC 5-481-380 et seq.) for radioactive material, as applicable, and any special requirements contained in this Part;

B. The applicant submits an adequate program for training radiographers and radiographer's assistants that meets the requirements of 12 VAC 5-481-1320:

1. After two years after the effective date of these regulations, the applicant need not describe the initial training and examination program for radiographers in the subjects outlined in 12 VAC 5-481-1320 G.

2. From the effective date of these regulations to two years after the effective date of these regulations, the applicant may affirm that all individuals acting as industrial radiographers will be certified in radiation safety by a certifying entity before commencing duty as radiographers. This affirmation substitutes for a description of its initial training and examination program for radiographers in the subjects outlined in 12 VAC 5-481-1320 G.

C. The applicant submits procedures for verifying and documenting the certification status of radiographers and for ensuring that the certification of individuals acting as radiographers remains valid;

D. The applicant submits written operating and emergency procedures as described in 12 VAC 5-481-1330;

E. The applicant submits a description of a program for inspections of the job performance of each radiographer and radiographer's assistant at intervals not to exceed six months as described in 12 VAC 5-481-1320 E;

F. The applicant submits a description of the applicant's overall organizational structure as it applies to the radiation safety responsibilities in industrial radiography, including specified delegation of authority and responsibility;

G. The applicant submits the qualifications of the individual(s) designated as the radiation safety officer as described in 12 VAC 5-481-1310 A;

H. If an applicant intends to perform leak testing of sealed sources or exposure devices containing depleted uranium (DU) shielding, the applicant must describe the procedures for performing the test. The description must include the:

1. Methods of collecting the samples;

2. Qualifications of the individual who analyzes the samples;

3. Instruments to be used; and

4. Methods of analyzing the samples.

I. If the applicant intends to perform calibrations of survey instruments and alarming ratemeters, the applicant must describe methods to be used and the experience of the person(s) who will perform the calibrations. All calibrations must be performed according to the procedures described and at the intervals prescribed in 12 VAC 5-481-1240 and 12 VAC 5-481-1350 G 4;

J. The applicant identifies and describes the location(s) of all field stations and permanent radiographic installations;

K. The applicant identifies the location(s) where all records required by this and other Parts of these regulations will be maintained;

L. If a license application includes underwater radiography, a description of:

1. Radiation safety procedures and radiographer responsibilities unique to the performance of underwater radiography;

2. Radiographic equipment and radiation safety equipment unique to underwater radiography; and

3. Methods for gas-tight encapsulation of equipment; and

M. If an application includes offshore platform and/or lay-barge radiography, a description of:

1. Transport procedures for radioactive material to be used in industrial radiographic operations;

2. Storage facilities for radioactive material; and

3. Methods for restricting access to radiation areas.

N. A license or registration will be issued if 12 VAC 5-481-1200 A through 12 VAC 5-481-1200 M, as applicable, are met.

12 VAC 5-481-1210. Performance requirements for industrial radiography equipment.

Equipment used in industrial radiographic operations must meet the following minimum criteria:

A. Each radiographic exposure device, source assembly or sealed source, and all associated equipment must meet the requirements specified in American National Standard Institute, N432-1980 "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography," (published as NBS Handbook 136, issued January 1981);

B. In addition to the requirements specified in 12 VAC 5-481-1210, the following requirements apply to radiographic exposure devices, source changers, source assemblies and sealed sources;

1. The licensee shall ensure that each radiographic exposure device has attached to it a durable, legible, clearly visible label bearing the:

a. Chemical symbol and mass number of the radionuclide in the device;

b. Activity and the date on which this activity was last measured;

c. Model or product code and serial number of the sealed source;

d. Name of the manufacturer of the sealed source; and

e. Licensee's name, address, and telephone number.

2. Radiographic exposure devices intended for use as Type B packages must meet the applicable transportation requirements of Part XIII (12 VAC 5-481-3280 et seq.) of these regulations.

3. Modification of radiographic exposure devices, source changers, and source assemblies and associated equipment is prohibited, unless approved by the agency or other approval body.

C. In addition to the requirements specified in 12 VAC 5-481-1210 A and 12 VAC 5-481-1210 B, the following requirements apply to radiographic exposure devices, source assemblies, and associated equipment that allow the source to be moved out of the device for radiographic operations or to source changers;

1. The coupling between the source assembly and the control cable must be designed in such a manner that the source assembly will not become disconnected if cranked outside the guide tube. The coupling must be such that it cannot be unintentionally disconnected under normal and reasonably foreseeable abnormal conditions.

2. The device must automatically secure the source assembly when it is cranked back into the

fully shielded position within the device. This securing system may only be released by means of a deliberate operation on the exposure device.

3. The outlet fittings, lock box, and drive cable fittings on each radiographic exposure device must be equipped with safety plugs or covers which must be installed during storage and transportation to protect the source assembly from water, mud, sand or other foreign matter.

4. Each sealed source or source assembly must have attached to it or engraved on it, a durable, legible, visible label with the words:

"DANGER --RADIOACTIVE."

The label may not interfere with the safe operation of the exposure device or associated equipment.

5. The guide tube must be able to withstand a crushing test that closely approximates the crushing forces that are likely to be encountered during use, and be able to withstand a kinking resistance test that closely approximates the kinking forces that are likely to be encountered during use.

6. Guide tubes must be used when moving the source out of the device.

7. An exposure head or similar device designed to prevent the source assembly from passing out of the end of the guide tube must be attached to the outermost end of the guide tube

during industrial radiography operations.

8. The guide tube exposure head connection must be able to withstand the tensile test for control units specified in ANSI N432-1980.

9. Source changers must provide a system for ensuring that the source will not be accidentally withdrawn from the changer when connecting or disconnecting the drive cable to or from a source assembly.

D. All radiographic exposure devices and associated equipment in use after January 10, 1996, must comply with the requirements of this section; and

E. As an exception to 12 VAC 5-481-1210 A, equipment used in industrial radiographic operations need not comply with 8.9.2(c) of the Endurance Test in American National Standards Institute N432-1980, if the prototype equipment has been tested using a torque value representative of the torque that an individual using the radiography equipment can reasonably exert on the lever or crankshaft of the drive mechanism.

12 VAC 5-481-1220. Limits on external radiation levels from storage containers and source changers.

The maximum exposure rate limits for storage containers and source changers are two millisieverts (200 mrem) per hour at any exterior surface, and 0.1 millisieverts (10 mrem) per hour at one meter from any exterior surface with the sealed source in the shielded position.

12 VAC 5-481-1230. Locking of sources of radiation, storage containers and source changers.

A. Each radiographic exposure device must have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. The exposure device and/or its container must be kept locked when not under the direct surveillance of a radiographer or a radiographer's assistant except at permanent radiographic installations as stated in 12 VAC 5-481-1370. In addition, during radiographic operations the sealed source assembly must be secured in the shielded position each time the source is returned to that position.

B. Each sealed source storage container and source changer must have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. Storage containers and source changers must be kept locked when containing sealed sources except when under the direct surveillance of a radiographer or a radiographer's assistant.

C. The control panel of each radiation machine shall be equipped with a lock that will prevent the unauthorized use of an X-ray system or the accidental production of radiation. The radiation machine shall be kept locked and the key removed at all times except when under the direct visual surveillance of a radiographer or a radiographer's assistant.

12 VAC 5-481-1240. Radiation survey instruments.

A. The licensee or registrant shall keep sufficient calibrated and operable radiation survey instruments at each location where sources of radiation are present to make the radiation surveys required by this Part and by Part IV (12 VAC 5-481-600 et seq.) of these regulations. Instrumentation required by

this section must be capable of measuring a range from 0.02 millisieverts (2 mrem) per hour through 0.01 sievert (1 rem) per hour.

B. The licensee or registrant shall have each radiation survey instrument required under 12 VAC 5-481-1240 A calibrated:

1. At energies appropriate for use and at intervals not to exceed six months or after instrument servicing, except for battery changes;

2. For linear scale instruments, at two points located approximately one-third and two-thirds of full-scale on each scale; for logarithmic scale instruments, at mid-range of each decade, and at two points of at least one decade; and for digital instruments, at three points between 0.02 and 10 millisieverts (2 and 1000 mrem) per hour; and

3. So that an accuracy within plus or minus 20% of the true radiation dose rate can be demonstrated at each point checked.

C. The licensee or registrant shall maintain records of the results of the instrument calibrations in accordance with 12 VAC 5-481-1410.

12 VAC 5-481-1250. Leak testing and replacement of sealed sources.

A. The replacement of any sealed source fastened to or contained in a radiographic exposure device and leak testing of any sealed source must be performed by persons authorized to do so by the agency,

the Nuclear Regulatory Commission, or another Agreement State.

B. The opening, repair, or modification of any sealed source must be performed by persons specifically authorized to do so by the agency, the Nuclear Regulatory Commission, or another Agreement State.

C. Testing and recordkeeping requirements.

1. Each licensee who uses a sealed source shall have the source tested for leakage at intervals not to exceed six months. The leak testing of the source must be performed using a method approved by the agency, the Nuclear Regulatory Commission, or by another Agreement State. The wipe sample should be taken from the nearest accessible point to the sealed source where contamination might accumulate. The wipe sample must be analyzed for radioactive contamination. The analysis must be capable of detecting the presence of 185 becquerel (0.005 Ci) of radioactive material on the test sample and must be performed by a person specifically authorized by the agency, the Nuclear Regulatory Commission, or another Agreement State to perform the analysis.

2. The licensee shall maintain records of the leak tests in accordance with 12 VAC 5-481-1420.

3. Unless a sealed source is accompanied by a certificate from the transferor that shows that it has been leak tested within six months before the transfer, it may not be used by the licensee until tested for leakage. Sealed sources that are in storage and not in use do not require leak testing, but must be tested before use or transfer to another person if the interval of storage exceeds six months.

D. Any test conducted pursuant to 12 VAC 5-481-1250 B and 12 VAC 5-481-1250 C that reveals the presence of 185 becquerel (0.005 Ci) or more of removable radioactive material must be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the equipment involved from use and shall have it decontaminated and repaired or disposed of in accordance with agency regulations. A report must be filed with the agency within five days of any test with results that exceed the threshold in this paragraph, describing the equipment involved, the test results, and the corrective action taken.

E. Each exposure device using depleted uranium (DU) shielding and an "S" tube configuration must be tested for DU contamination at intervals not to exceed 12 months. The analysis must be capable of detecting the presence of 185 becquerel (0.005 Ci) of radioactive material on the test sample and must be performed by a person specifically authorized by the agency, the Nuclear Regulatory Commission, or another Agreement State to perform the analysis. Should such testing reveal the presence of DU contamination, the exposure device must be removed from use until an evaluation of the wear of the S-tube has been made. Should the evaluation reveal that the S-tube is worn through, the device may not be used again. DU shielded devices do not have to be tested for DU contamination while not in use and in storage. Before using or transferring such a device, however, the device must be tested for DU contamination, if the interval of storage exceeds 12 months. A record of the DU leak-test must be made in accordance with 12 VAC 5-481-1420.

12 VAC 5-481-1260. Quarterly inventory.

A. Each licensee or registrant shall conduct a quarterly physical inventory to account for all sources of

radiation, and for devices containing depleted uranium received and possessed under the license.

B. The licensee or registrant shall maintain records of the quarterly inventory in accordance with 12 VAC 5-481-1430.

12 VAC 5-481-1270. Inspection and maintenance of radiation machines, radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments.

A. The licensee or registrant shall perform visual and operability checks on survey meters, radiation machines, radiographic exposure devices, transport and storage containers, associated equipment and source changers before each day's use, or work shift, to ensure that:

1. The equipment is in good working condition;

2. The sources are adequately shielded; and

3. Required labeling is present.

B. Survey instrument operability must be performed using check sources or other appropriate means.

C. If equipment problems are found, the equipment must be removed from service until repaired.

D. Each licensee or registrant shall have written procedures for and perform inspection and routine

maintenance of radiation machines, radiographic exposure devices, source changers, associated equipment, transport and storage containers, and survey instruments at intervals not to exceed three months or before the first use thereafter to ensure the proper functioning of components important to safety. If equipment problems are found, the equipment must be removed from service until repaired.

E. The licensee's inspection and maintenance program must include procedures to assure that Type B packages are shipped and maintained in accordance with the certificate of compliance or other approval.

F. Records of equipment problems and of any maintenance performed under 12 VAC 5-481-1270 must be made in accordance with 12 VAC 5-481-1450.

12 VAC 5-481-1280. Permanent radiographic installations.

A. Each entrance that is used for personnel access to the high radiation area in a permanent radiographic installation must have either:

1. An entrance control of the type described in 12 VAC 5-481-780 of these regulations that causes the radiation level upon entry into the area to be reduced; or

2. Both conspicuous visible and audible warning signals to warn of the presence of radiation. The visible signal must be actuated by radiation whenever the source is exposed or the machine is energized. The audible signal must be actuated when an attempt is made to enter

the installation while the source is exposed or the machine is energized.

B. The alarm system must be tested for proper operation with a radiation source each day before the installation is used for radiographic operations. The test must include a check of both the visible and audible signals. Entrance control devices that reduce the radiation level upon entry as designated in 12 VAC 5-481-1280 A 1 must be tested monthly. If an entrance control device or an alarm is operating improperly, it must be immediately labeled as defective and repaired within seven calendar days. The facility may continue to be used during this 7-day period, provided the licensee or registrant implements the continuous surveillance requirements of 12 VAC 5-481-1370 and uses an alarming ratemeter. Test records for entrance controls and audible and visual alarms must be maintained in accordance with 12 VAC 5-481-1460.

12 VAC 5-481-1290. Labeling, storage, and transportation.

A. The licensee may not use a source changer or a container to store radioactive material unless the source changer or the storage container has securely attached to it a durable, legible, and clearly visible label bearing the standard trefoil radiation caution symbol conventional colors, i.e., magenta, purple or black on a yellow background, having a minimum diameter of 25 mm, and the wording:

CAUTION *

RADIOACTIVE MATERIAL

NOTIFY CIVIL AUTHORITIES (or " NAME OF COMPANY")

* --- or "DANGER"

B. The licensee may not transport radioactive material unless the material is packaged, and the package is labeled, marked, and accompanied with appropriate shipping papers in accordance with regulations set out in Part XIII (12 VAC 5-481-3280 et seq.).

C. Radiographic exposure devices, source changers, storage containers, and radiation machines, must be physically secured to prevent tampering or removal by unauthorized personnel. The licensee shall store radioactive material in a manner that will minimize danger from explosion or fire.

D. The licensee shall lock and physically secure the transport package containing radioactive material in the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal.

E. The licensee's or registrant's name and city or town where the main business office is located shall be prominently displayed with a durable, clearly visible label(s) on both sides of all vehicles used to transport radioactive material or radiation machines for temporary job site use.

ARTICLE 2.

RADIATION SAFETY REQUIREMENTS.

12 VAC 5-481-1300. Conducting industrial radiographic operations.

12 VAC 5-481-1310. Radiation safety officer.

12 VAC 5-481-1320. Training.

12 VAC 5-481-1330. Operating and emergency procedures.

12 VAC 5-481-1340. Supervision of radiographer's assistants.

12 VAC 5-481-1350. Personnel monitoring.

12 VAC 5-481-1360. Radiation surveys.

12 VAC 5-481-1370. Surveillance.

12 VAC 5-481-1380. Posting.

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12 VAC 5-481-1300. Conducting industrial radiographic operations.

A. Whenever radiography is performed at a location other than a permanent radiographic installation, the radiographer must be accompanied by at least one other qualified radiographer or an individual who has at a minimum met the requirements of 12 VAC 5-481-1320 C. The additional qualified individual shall observe the operations and be capable of providing immediate assistance to prevent unauthorized entry. Radiography may not be performed if only one qualified individual is present.

B. All radiographic operations must be conducted in a permanent radiographic installation unless otherwise specifically authorized by the agency.

C. Except when physically impossible, collimators shall be used in industrial radiographic operations that use radiographic exposure devices that allow the source to be moved out of the device.

D. A licensee or registrant may conduct lay-barge, offshore platform, or underwater radiography only if procedures have been approved by the agency, the Nuclear Regulatory Commission, or by another Agreement State.

12 VAC 5-481-1310. Radiation safety officer.

The radiation safety officer shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's or registrant's program.

A. The minimum qualifications, training, and experience for radiation safety officers for industrial radiography are as follows:

1. Completion of the training and testing requirements of 12 VAC 5-481-1320 A;

2. 2000 hours of hands-on experience as a qualified radiographer in industrial radiographic operations; and

3. Formal training in the establishment and maintenance of a radiation protection program.

B. The agency will consider alternatives when the radiation safety officer has appropriate training and experience in the field of ionizing radiation, and in addition, has adequate formal training with respect to the establishment and maintenance of a radiation safety protection program.

C. The specific duties and authorities of the radiation safety officer include:

1. Establishing and overseeing all operating, emergency, and ALARA procedures as required

by Part IV (12 VAC 5-481-600 et seq.) of these regulations and reviewing them regularly to ensure that they conform to agency regulations and to the license or registration conditions;

2. Overseeing and approving the training program for radiographic personnel to ensure that appropriate and effective radiation protection practices are taught;

3. Ensuring that required radiation surveys and leak tests are performed and documented in accordance with the regulations, including any corrective measures when levels of radiation exceed established limits;

4. Ensuring that personnel monitoring devices are calibrated, if applicable, and used properly; that records are kept of the monitoring results; and that timely notifications are made as required by Part IV (12 VAC 5-481-600 et seq.) of these regulations; and

5. Ensuring that operations are conducted safely and for implementing corrective actions including terminating operations.

D. Licensees and registrants will have two years from the effective date of this rule to meet the requirements of 12 VAC 5-481-1310 A and 12 VAC 5-481-1310 B.

12 VAC 5-481-1320. Training.

A. The licensee or registrant may not permit any individual to act as a radiographer until the individual:

1. Has received at least 40 hours of training in the subjects outlined in 12 VAC 5-481-1320 G, in addition to on the job training consisting of hands-on experience under the supervision of a radiographer and is certified through a radiographer certification program by a certifying entity in accordance with the criteria specified in Appendix M of this Part. The on the job training shall include a minimum of two months (320 hours) of active participation in the performance of industrial radiography utilizing radioactive material and/or one month (160 hours) of active participation in the performance of industrial radiography utilizing radiation machines. Individuals performing industrial radiography utilizing radioactive materials and radiation machines must complete both segments of the on the job training (3 months or 480 hours); or

2. The licensee or registrant may, until two years after the effective date of these regulations, allow an individual who has not met the requirements of 12 VAC 5-481-1320 A 1, to act as a radiographer after the individual has received at least 40 hours of training in the subjects outlined in 12 VAC 5-481-1320 G and demonstrated an understanding of these subjects by successful completion of a written examination that was previously submitted to and approved by the agency, the Nuclear Regulatory Commission, or another Agreement State, in addition to on the job training consisting of hands-on experience under the supervision of a radiographer. The on the job training shall include a minimum of two months (320 hours) of active participation in the performance of industrial radiography utilizing radioactive material and/or one month (160 hours) of active participation in the performance of industrial radiography utilizing radiation machines. Individuals performing industrial radiography utilizing radioactive materials and radiation machines must complete both segments of the on the job training (3 months or 480 hours).

B. In addition, the licensee or registrant may not permit any individual to act as a radiographer until the individual:

1. Has received copies of and instruction in the requirements described in the regulations contained in this Part, and applicable sections of Parts IV (12 VAC 5-481-600 et seq.), X (12 VAC 5-481-2580 et seq.), and XIII (12 VAC 5-481-3280 et seq.) of these regulations, in the license or registration under which the radiographer will perform industrial radiography, and the licensee's or registrant's operating and emergency procedures;

2. Has demonstrated an understanding of items in 12 VAC 5-481-1320 B 1 by successful completion of a written or oral examination;.

3. Has received training in the use of the registrant's radiation machines, or the licensee's radiographic exposure devices, sealed sources, in the daily inspection of devices and associated equipment, and in the use of radiation survey instruments; and

4. Has demonstrated understanding of the use of the equipment described in 12 VAC 5-481-1320 B 3 by successful completion of a practical examination.

C. The licensee or registrant may not permit any individual to act as a radiographer's assistant until the individual:

1. Has received copies of and instruction in the requirements described in the regulations

contained in this Part, and applicable sections of Parts IV (12 VAC 5-481-600 et seq.), X (12 VAC 5-481-2580 et seq.), and XIII (12 VAC 5-481-3280 et seq.) of these regulations, in the license or registration under which the radiographer's assistant will perform industrial radiography, and the licensee's or registrant's operating and emergency procedures;

2. Has demonstrated an understanding of items in 12 VAC 5-481-1320 C 1 by successful completion of a written or oral examination;

3. Under the personal supervision of a radiographer, has received training in the use of the registrant's radiation machines, or the licensee's radiographic exposure devices and sealed sources, in the daily inspection of devices and associated equipment, and in the use of radiation survey instruments; and

4. Has demonstrated understanding of the use of the equipment described in 12 VAC 5-481-1320 C 3 by successful completion of a practical examination.

D. The licensee or registrant shall provide annual refresher safety training for each radiographer and radiographer's assistant at intervals not to exceed 12 months.

E. Except as provided in 12 VAC 5-481-1320 E 4, the radiation safety officer or designee shall conduct an inspection program of the job performance of each radiographer and radiographer's assistant to ensure that the agency's regulations, license or registration requirements, and operating and emergency procedures are followed. The inspection program must:

1. Include observation of the performance of each radiographer and radiographer's assistant during an actual industrial radiographic operation, at intervals not to exceed six months; and

2. Provide that, if a radiographer or a radiographer's assistant has not participated in an industrial radiographic operation for more than six months since the last inspection, the radiographer must demonstrate knowledge of the training requirements of 12 VAC 5-481-1320 B 3 and the radiographer's assistant must demonstrate knowledge of the training requirements of 12 VAC 5-481-1320 C 3 by a practical examination before these individuals can next participate in a radiographic operation.

3. The agency may consider alternatives in those situations where the individual serves as both radiographer and radiation safety officer.

4. In those operations where a single individual serves as both radiographer and radiation safety officer, and performs all radiography operations, an inspection program is not required.

F. The licensee or registrant shall maintain records of the above training to include certification documents, written, oral and practical examinations, refresher safety training and inspections of job performance in accordance with 12 VAC 5-481-1470.

G. The licensee or registrant shall include the following subjects required in 12 VAC 5-481-1320 A:

1. Fundamentals of radiation safety including:

a. Characteristics of gamma and x-radiation;

b. Units of radiation dose and quantity of radioactivity;

c. Hazards of exposure to radiation;

d. Levels of radiation from sources of radiation; and

e. Methods of controlling radiation dose (time, distance, and shielding);

2. Radiation detection instruments including:

a. Use, operation, calibration, and limitations of radiation survey instruments;

b. Survey techniques; and

c. Use of personnel monitoring equipment;

3. Equipment to be used including:

a. Operation and control of radiographic exposure equipment, remote handling equipment, and storage containers, including pictures or models of source assemblies (pigtails);

b. Operation and control of radiation machines;

c. Storage, control, and disposal of sources of radiation; and

d. Inspection and maintenance of equipment.

4. The requirements of pertinent state and federal regulations; and

5. Case histories of accidents in radiography.

H. Licensees and registrants will have one year from the effective date of this rule to comply with the additional training requirements specified in 12 VAC 5-481-1320 B 1. And 12 VAC 5-481-1320 C 1.

12 VAC 5-481-1330. Operating and emergency procedures.

A. Operating and emergency procedures must include, as a minimum, instructions in the following:

1. Appropriate handling and use of sources of radiation so that no person is likely to be exposed to radiation doses in excess of the limits established in Part IV (12 VAC 5-481-600 et seq.) of these regulations;

2. Methods and occasions for conducting radiation surveys;

3. Methods for posting and controlling access to radiographic areas;

4. Methods and occasions for locking and securing sources of radiation;

5. Personnel monitoring and the use of personnel monitoring equipment;

6. Transporting equipment to field locations, including packing of radiographic exposure devices and storage containers in the vehicles, placarding of vehicles when required, and control of the equipment during transportation as described in Part XIII (12 VAC 5-481-3280 et seq.) of these regulations;

7. The inspection, maintenance, and operability checks of radiographic exposure devices, radiation machines, survey instruments, alarming ratemeters, transport containers, and storage containers;

8. Steps that must be taken immediately by radiography personnel in the event a pocket dosimeter is found to be off-scale or an alarming ratemeter alarms unexpectedly;

9. The procedure(s) for identifying and reporting defects and noncompliance, as required by 12 VAC 5-481-1530;

10. The procedure for notifying proper persons in the event of an accident or incident;

11. Minimizing exposure of persons in the event of an accident or incident, including a source

disconnect, a transport accident, or loss of a source of radiation;

12. Source recovery procedure if licensee will perform source recoveries; and

13. Maintenance of records.

B. The licensee or registrant shall maintain copies of current operating and emergency procedures in accordance with 12 VAC 5-481-1480 and 12 VAC 5-481-1520.

12 VAC 5-481-1340. Supervision of radiographer's assistants.

The radiographer's assistant shall be under the personal supervision of a radiographer when using sources of radiation or conducting radiation surveys required by 12 VAC 5-481-1360 B to determine that the sealed source has returned to the shielded position or the radiation machine is off after an exposure. The personal supervision must include:

A. The radiographer's physical presence at the site where the sources of radiation are being used;

B. The availability of the radiographer to give immediate assistance if required; and

C. The radiographer's direct observation of the assistant's performance of the operations referred to in this section.

12 VAC 5-481-1350. 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 alarming ratemeter, and either a film badge or a TLD. At permanent radiographic installations where other appropriate alarming or warning devices are in routine use, or during radiographic operations using radiation machines, the use of an alarming ratemeter is not required.

1. Pocket dosimeters must have a range from zero to two millisieverts (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 and TLD must be assigned to and worn by only one individual.

3. Film badges and TLD's must be exchanged at periods not to exceed one month.

4. After replacement, each film badge 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 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 12 VAC 5-481-1490.

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 12 VAC 5-481-1490. 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 two millisieverts (200 mrem), the individual's film badge or TLD must be sent for processing 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 12 VAC 5-481-1490.

E. If a film badge or TLD is lost or damaged, the worker shall cease work immediately until a replacement film badge or TLD is provided and the exposure is calculated for the time period from issuance to loss or damage of the film badge or TLD. The results of the calculated exposure and the time period for which the film badge or TLD was lost or damaged must be included in the records maintained in accordance with 12 VAC 5-481-1490.

F. Reports received from the film badge or TLD processor must be retained in accordance with 12 VAC 5-481-1490.

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 five millisieverts (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 12 VAC 5-481-1490.

12 VAC 5-481-1360. Radiation surveys.

The licensee or registrant shall:

A. Conduct all surveys with a calibrated and operable radiation survey instrument that meets the requirements of 12 VAC 5-481-1240;

B. Conduct a survey of the radiographic exposure device and the guide tube after each exposure when approaching the device or the guide tube. The survey must determine that the sealed source has returned to its shielded position before exchanging films, repositioning the exposure head, or dismantling equipment. Radiation machines shall be surveyed after each exposure to determine that the machine is off;

C. Conduct a survey of the radiographic exposure device whenever the source is exchanged and whenever a radiographic exposure device is placed in a storage area, as defined in 12 VAC 5-481-10, to ensure that the sealed source is in its shielded position; and

D. Maintain records in accordance with 12 VAC 5-481-1500.

12 VAC 5-481-1370. Surveillance.

During each radiographic operation, the radiographer shall ensure continuous direct visual surveillance of the operation to protect against unauthorized entry into a radiation area or a high radiation area, as defined in Part I (12 VAC 5-481-10 et seq.) of these regulations, except at permanent radiographic installations where all entryways are locked and the requirements of 12 VAC 5-481-1280 are met.

12 VAC 5-481-1380. Posting.

All areas in which industrial radiography is being performed must be conspicuously posted as required by 12 VAC 5-481-860 of these regulations. The exceptions listed in 12 VAC 5-481-880 of these regulation do not apply to industrial radiographic operations.

ARTICLE 3.

RECORDKEEPING REQUIREMENTS.

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12 VAC 5-481-1390. Records for industrial radiography.

Each licensee or registrant shall maintain a copy of its license or registration, documents incorporated by reference, and amendments to each of these items until superseded by new documents approved by the agency, or until the agency terminates the license or registration.

12 VAC 5-481-1400. Records of receipt and transfer of sources of radiation.

A. Each licensee or registrant shall maintain records showing the receipts and transfers of sealed sources, devices using DU for shielding, and radiation machines, and retain each record for three years after it is made.

B. These records must include the date, the name of the individual making the record, radionuclide, number of becquerels (curies) or mass (for DU), and manufacturer, model, and serial number of each source of radiation and/or device, as appropriate.

12 VAC 5-481-1410. Records of radiation survey instruments.

Each licensee or registrant shall maintain records of the calibrations of its radiation survey instruments that are required under 12 VAC 5-481-1240 and retain each record for three years after it is made.

12 VAC 5-481-1420. Records of leak testing of sealed sources and devices containing DU.

Each licensee shall maintain records of leak test results for sealed sources and for devices containing DU. The results must be stated in units of becquerels (Ci). The licensee shall retain each record for three years after it is made or until the source in storage is removed.

12 VAC 5-481-1430. Records of quarterly inventory.

A. Each licensee or registrant shall maintain records of the quarterly inventory of sources of radiation, including devices containing depleted uranium as required by 12 VAC 5-481-1260, and retain each record for three years.

B. The record must include the date of the inventory, name of the individual conducting the inventory, radionuclide, number of becquerels (curies) or mass (for DU) in each device, location of sources of radiation and/or devices, and manufacturer, model, and serial number of each source of radiation and/or device, as appropriate.

12 VAC 5-481-1440. Utilization logs.

A. Each licensee or registrant shall maintain utilization logs showing for each source of radiation the following information:

1. A description, including the make, model, and serial number of the radiation machine or the radiographic exposure device, transport, or storage container in which the sealed source is located;

2. The identity or signature of the radiographer to whom assigned;

3. The location and dates of use, including the dates removed and returned to storage; and

4. For permanent radiographic installations, the dates each radiation machine is energized.

B. The licensee or registrant shall retain the logs required by 12 VAC 5-481-1440 A for three years.

12 VAC 5-481-1450. Records of inspection and maintenance of radiation machines, radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments.

A. Each licensee or registrant shall maintain records specified in 12 VAC 5-481-1270 of equipment problems found in daily checks and quarterly inspections of radiation machines, radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments, and retain each record for three years after it is made.

B. The record must include the date of check or inspection, name of inspector, equipment involved, any problems found, and what repair and/or maintenance, if any, was performed.

12 VAC 5-481-1460. Records of alarm system and entrance control checks at permanent radiographic installations.

Each licensee or registrant shall maintain records of alarm system and entrance control tests required by 12 VAC 5-481-1280 and retain each record for three years after it is made.

12 VAC 5-481-1470. Records of training and certification.

Each licensee or registrant shall maintain the following records for three years:

A. Records of training of each radiographer and each radiographer's assistant. The record must include radiographer certification documents and verification of certification status, copies of written tests, dates of oral and practical examinations, the names of individuals conducting and receiving the oral and practical examinations, and a list of items tested and the results of the oral and practical examinations; and

B. Records of annual refresher safety training and semi-annual inspections of job performance for each radiographer and each radiographer's assistant. The records must list the topics discussed during the refresher safety training, the dates the annual refresher safety training was conducted, and names of the instructors and attendees. For inspections of job performance, the records must also include a list showing the items checked and any non-compliance observed by the radiation safety officer or designee.

12 VAC 5-481-1480. Copies of operating and emergency procedures.

Each licensee or registrant shall maintain a copy of current operating and emergency procedures until the agency terminates the license or registration. Superseded material must be retained for three years after the change is made.

12 VAC 5-481-1490. Records of personnel monitoring.

Each licensee or registrant shall maintain the following exposure records specified in 12 VAC 5-481-1270:

A. Direct reading dosimeter readings and yearly operability checks required by 12 VAC 5-481-1350 B

and 12 VAC 5-481-1350 C for three years after the record is made;

B. Records of alarming ratemeter calibrations for three years after the record is made;

C. Reports received from the film badge or TLD processor until the agency terminates the license or registration; and

D. Records of estimates of exposures as a result of off-scale personal direct reading dosimeters, or lost or damaged film badges or TLD's, until the agency terminates the license or registration.

12 VAC 5-481-1500. Records of radiation surveys.

Each licensee shall maintain a record of each exposure device survey conducted before the device is placed in storage as specified in 12 VAC 5-481-1360 C. Each record must be maintained for three years after it is made.

12 VAC 5-481-1510. Form of records.

Each record required by this Part must be legible throughout the specified retention period. 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 reproducing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, must include all pertinent information, such as stamps, initials, and signatures.

The licensee or registrant shall maintain adequate safeguards against tampering with and loss of records.

12 VAC 5-481-1520. Location of documents and records.

A. Each licensee or registrant shall maintain copies of records required by this Part and other applicable Parts of these regulations at the location specified in 12 VAC 5-481-1200 K.

B. Each licensee or registrant shall also maintain current copies of the following documents and records sufficient to demonstrate compliance at each applicable field station and each temporary jobsite;

1. The license or registration authorizing the use of sources of radiation;

2. A copy of Parts I (12 VAC 5-481-10 et seq.); IV (12 VAC 5-481-600 et seq.); V (12 VAC 5-481-1170 et seq.); and X (12 VAC 5-481-2580 et seq.) of these regulations;

3. Utilization logs for each source of radiation dispatched from that location as required by 12 VAC 5-481-1440.

4. Records of equipment problems identified in daily checks of equipment as required by 12 VAC 5-481-1450 A;

5. Records of alarm system and entrance control checks required by 12 VAC 5-481-1460, if applicable;

6. Records of dosimeter readings as required by 12 VAC 5-481-1490;

7. Operating and emergency procedures as required by 12 VAC 5-481-1480;

8. Evidence of the latest calibration of the radiation survey instruments in use at the site, as required by 12 VAC 5-481-1410;

9. Evidence of the latest calibrations of alarming ratemeters and operability checks of dosimeters as required by 12 VAC 5-481-1490;

10. Survey records as required by 12 VAC 5-481-1500 and 12 VAC 5-481-1000 of these regulations as applicable, for the period of operation at the site;

11. The shipping papers for the transportation of radioactive materials required by Part XIII (12 VAC 5-481-3280 et seq.) of these regulations; and

12. When operating under reciprocity pursuant to Part III (12 VAC 5-481-380 et seq.) of these regulations, a copy of the applicable state license or registration, or Nuclear Regulatory Commission license authorizing the use of sources of radiation.

ARTICLE 4.

NOTIFICATIONS.

12 VAC 5-481-1530. Notifications.

12 VAC 5-481-1530. Notifications.

A. In addition to the reporting requirements specified in 10 CFR 30.50 and in Part IV (12 VAC 5-481-600 et seq.) of these regulations, each licensee or registrant shall provide a written report to the agency within 30 days of the occurrence of any of the following incidents involving radiographic equipment:

1. Unintentional disconnection of the source assembly from the control cable;

2. Inability to retract the source assembly to its fully shielded position and secure it in this position;

3. Failure of any component, which is critical to safe operation of the device, to properly perform its intended function; or

4. An indicator on a radiation machine fails to show that radiation is being produced, an exposure switch fails to terminate production of radiation when turned to the off position, or a safety interlock fails to terminate X-ray production.

B. The licensee or registrant shall include the following information in each report submitted under 12 VAC 5-481-1530 A, and in each report of overexposure submitted under 12 VAC 5-481-1110 of

these regulations which involves failure of safety components of radiography equipment:

1. Description of the equipment problem;

2. Cause of each incident, if known;

3. Name of the manufacturer and model number of equipment involved in the incident;

4. Place, date, and time of the incident;

5. Actions taken to establish normal operations;

6. Corrective actions taken or planned to prevent recurrence; and

7. Names and qualifications of personnel involved in the incident.

C. Any licensee or registrant conducting radiographic operations or storing sources of radiation at any location not listed on the license or registration for a period in excess of 180 days in a calendar year, shall notify the agency prior to exceeding the 180 days.

ARTICLE 5.

RADIOGRAPHER CERTIFICATION.

12 VAC 5-481-1540. Application and examinations.

12 VAC 5-481-1550. Certification identification (ID) Card.

12 VAC 5-481-1560. Reciprocity.

12 VAC 5-481-1570. Specific requirements for radiographic personnel performing industrial radiography.

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12 VAC 5-481-1540. Application and examinations.

A. Application

1. An application for taking the examination shall be on forms prescribed and furnished by the agency.

2. A non-refundable fee of $50/00 shall be submitted with the application to cover certification administrative costs, such as the examination, training documentation review, and issuance of certification.

3. The application and the non-refundable fee shall be submitted to the agency on or before the dates specified by the agency.

4. An individual whose certification ID card has been suspended or revoked shall obtain written approval from the agency to apply to retake the examination.

B. Examination. The examination shall be given for the purpose of determining the qualifications of applicants.

1. A written examination shall be held at times and places determined by the agency. The scope of the examination and the methods of procedure, including determination of the passing score, shall be prescribed by the agency. The examination will assess the applicant's knowledge to safely use sources of radiation and related equipment and the applicant's knowledge of Parts IV (12 VAC 5-481-600 et seq.), V (12 VAC 5-481-1170 et seq.), and XIII (12 VAC 5-481-3280 et seq.) of these regulations.

2. The examination will be administered by the agency or persons authorized by the agency.

3. A candidate failing an examination may apply for re-examination in accordance with 12 VAC 5-481-1540 A and will be re-examined. A candidate shall not retake the same version of the examination.

4. The examination will be held at dates, times and locations designated by the agency.

5. The examination will be in English.

6. To take the examination, an individual shall have a picture identification card, such as a driver's license, at the time of the examination.

7. Calculators will be permitted during the examination. However, calculators or computers

with preprogrammed data or formulas, including exposure calculators, will not be permitted during the examination.

8. The examination will be a 'closed book' examination.

9. Any individual observed by an agency proctor to be compromising the integrity of the examination shall be required to surrender the examination, the answer sheet, and any work paper. Such individual will not be allowed to complete the examination, will forfeit the examination fee, and will leave the examination site to avoid disturbing other examinees. Such individual must wait 90 days and must resubmit a new application and an additional $50.00 fee before taking a new examination.

10. Examination material shall be returned to the agency at the end of the examination. No photographic or other copying of examination questions or materials shall be permitted. Disclosure by any individual of the contents of any examination prior to its administration is prohibited.

11. The names and scores of individuals taking the examination shall be a public record.

12 VAC 5-481-1550. Certification identification (ID) card.

A. A certification ID card shall be issued to each person who successfully completes the requirements of 12 VAC 5-481-1320 A 1 and the examination prescribed in 12 VAC 5-481-1540 B.

1. Each person's certification ID card shall contain their photograph. The agency will take the photograph at the time the examination is administered.

2. The certification ID card remains the property of the agency and may be revoked or suspended.

3. Any individual who wishes to replace their certification ID card shall submit to the agency a written request for a replacement certification ID card, stating the reason a replacement certification ID card is needed. A non-refundable fee of $50.00 shall be paid to the agency for each replacement of a certification ID card. The prescribed fee shall be submitted with the written request for a replacement certification ID card. The individual shall maintain a copy of the request in their possession while performing industrial radiographic operations until a replacement certification ID card is received from the agency.

B. Each certification ID card is valid for a period of five years, unless revoked or suspended in accordance with 12 VAC 5-481-1550 D. Each certification ID card expires at the end of the day, in the month and year stated on the certification ID card.

C. Renewal of certification ID card.

1. Applications for examination to renew a certification ID card shall be filed in accordance with 12 VAC 5-481-1540 A.

2. The examination for renewal of a certification ID card shall be administered in accordance

with 12 VAC 5-481-1540 B.

3. A renewal certification ID card shall be issued in accordance with 12 VAC 5-481-1550 A.

D. Revocation or suspension of a certification ID card.

1. Any radiographer who violates these regulations, equivalent state or Nuclear Regulatory Commission regulations, or any applicable statutory requirements may be required to show cause at a formal hearing why their certification ID card should not be revoked or suspended in accordance with 12 VAC 5-481-1550 D 2 of these regulations.

2. When an agency order has been issued for an industrial radiographer to cease and desist from the use of sources of radiation or the agency revokes or suspends their certification ID card, the industrial radiographer shall surrender the certification ID card to the agency until the order is changed or the suspension expires.

12 VAC 5-481-1560. Reciprocity.

A. All reciprocal recognition of licenses and registrations by the agency will be granted in accordance with Part III (12 VAC 5-481-380 et seq.) of these regulations.

B. Reciprocal recognition by the agency of an individual radiographer certification will be granted provided that:

1. The individual holds a valid certification in the appropriate category issued by a certifying entity, as defined in 12 VAC 5-481-10;

2. The requirements and procedures of the certifying entity issuing the certification affords the same or comparable certification standards as those afforded by 12 VAC 5-481-1320 A;

3. The applicant presents the certification to the agency prior to entry into the state; and

4. No escalated enforcement action is pending with the Nuclear Regulatory Commission or in any other state.

C. Certified individuals who are granted reciprocity by the agency shall maintain the certification upon which the reciprocal recognition was granted, or prior to the expiration of such certification, shall meet the requirements of 12 VAC 5-481-1320 A.

12 VAC 5-481-1570. Specific requirements for radiographic personnel performing industrial radiography.

A. At a job site, the following shall be supplied by the licensee or registrant:

1. At least one operable, calibrated survey instrument for each exposure device or radiation machine in use;

2. A current whole body personnel monitor (TLD or film badge) for each person performing

radiographic operations;

3. An operable, calibrated pocket dosimeter with a range of zero to 200 milliroentgens for each person performing radiographic operations;

4. An operable, calibrated, alarming ratemeter for each person performing radiographic operations using a radiographic exposure device; and

5. The appropriate barrier ropes and signs.

B. Each radiographer at a job site shall have on their person a valid certification ID card issued by a certifying entity.

C. Industrial radiographic operations shall not be performed if any of the items in 12 VAC 5-481-1570 A and 12 VAC 5-481-1570 B are not available at the job site or are inoperable.

D. During an inspection, the agency may terminate an operation if any of the items in 12 VAC 5-481-1570 A and 12 VAC 5-481-1570 B are not available or operable, or if the required number of radiographic personnel are not present. Operations shall not be resumed until all required conditions are met.

PART VI.

USE OF DIAGNOSTIC X-RAYS IN THE HEALING ARTS.

12 VAC 5-481-1580. Purpose and scope.

This Part establishes requirements, for which a registrant is responsible, for use of diagnostic X-ray equipment by, or under the supervision of, an individual authorized by and licensed in accordance with state statutes to engage in the healing arts or veterinary medicine. The provisions of this Part are in addition to, and not in substitution for, other applicable provisions of Parts I (12 VAC 5-481-10 et seq.); II (12 VAC 5-481-260 ET SEQ.); IV (12 VAC 5-481-600 et seq.); and X (12 VAC 5-481-2580 et seq.)

of these regulations. Some registrants may also be subject to the requirements of Parts IX (12 VAC 5-481-2470 et seq.) and XV (12 VAC 5-481-3710 et seq.) of these regulations.

12 VAC 5-481-1590. General and administrative requirements.

A. Radiation safety requirements. The registrant shall be responsible for directing the operation of the X-ray system(s) under his administrative control. The registrant or the registrant's agent shall assure that the requirements of these regulations are met in the operation of the X-ray system(s).

1. An X-ray system which does not meet the provisions of these regulations shall not be operated for diagnostic purposes.

2. Individuals who will be operating the X-ray systems shall be adequately instructed in the safe operating procedures and be competent in the safe use of the equipment. The agency may use interview, observation and/or testing to determine compliance. The following are areas in which the agency considers it important that an individual have expertise for the competent operation of X-ray equipment:

a. Familiarization with equipment

(1) Identification of controls

(2) Function of each control

(3) How to use a technique chart

b. Radiation protection

(1) Collimation

(2) Filtration

(3) Gonad shielding and other patient protection devices, if used

(4) Restriction of X-ray tube radiation to the image receptor

(5) Personnel protection

(6) Grids

c. Film processing

(1) Film speed as related to patient exposure

(2) Film processing parameters

(3) Quality assurance program

d. Emergency procedures - Termination of exposure in event of automatic timing device failure

e. Proper use of personnel dosimetry, if required

f. Understanding units of radiation

3. A chart shall be provided in the vicinity of the diagnostic X-ray system's control panel which specifies, for all examinations performed with that system, the following information:

a. Patient's body part and anatomical size, or body part thickness, or age (for pediatrics), versus technique factors to be utilized;

b. Type and size of the film or film-screen combination to be used;

c. Type and focal distance of the grid to be used, if any;

d. Source to image receptor distance to be used (except for dental intra-oral radiography);

e. Type and location of placement of patient shielding (e.g., gonad, etc.) to be used; and

f. For mammography, indication of kVp/target/filter combination.

4. The registrant of a facility shall create and make available to X-ray operators written safety procedures, including patient holding and any restrictions of the operating technique required for the safe operation of the particular X-ray system. The operator shall be able to demonstrate familiarity with these procedures. A copy of the written safety procedures shall be posted near each X-ray machine.

5. Except for patients who cannot be moved out of the room, only the staff, ancillary personnel or other persons required for the medical procedure or training shall be in the room during the radiographic exposure. Other than the patient being examined:

a. All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by not less than 0.5 millimeter lead equivalent material;

b. The X-ray operator, other staff, ancillary personnel, and other persons required for the medical procedure shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent material;

c. Human patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of not less than 0.25 millimeter lead equivalent material or shall be so positioned that the nearest portion of the body is at least two meters from both the tube head and the nearest edge of the image receptor.

6. Gonad shielding of not less than 0.5 millimeter lead equivalent material shall be used for human patients, who have not passed the reproductive age, during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.

7. Individuals shall not be exposed to the useful beam except for healing arts purposes and unless such exposure has been authorized by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure for the following purposes:

a. Exposure of an individual for training, demonstration, or other non-healing arts purposes; and

b. Exposure of an individual for the purpose of healing arts screening except as authorized by 12 VAC 5-481-1590 A 11.

8. When a patient or film must be provided with auxiliary support during a radiation exposure:

a. Mechanical holding devices shall be used when the technique permits. The written safety procedures, required by 12 VAC 5-481-1590 A 4, shall list individual projections where holding devices cannot be utilized;

b. Written safety procedures, as required by 12 VAC 5-481-1590 A 4, shall indicate the requirements for selecting a holder and the procedure the holder shall follow;

c. The human holder shall be instructed in personal radiation safety and protected as required by 12 VAC 5-481-1590 A 5;

d. No individual shall be used routinely to hold film or patients;

e. In those cases where the patient must hold the film, except during intraoral examinations, any portion of the body other than the area of clinical interest

struck by the useful beam shall be protected by not less than 0.5 millimeter lead equivalent material; and

f. Each facility shall have leaded aprons and gloves available in sufficient numbers to provide protection to all personnel who are involved with X-ray operations and who are otherwise not shielded.

g. When an animal must be held in position during radiography, mechanical supporting or restraining devices should be used. If the animal must be held by an individual, that individual shall be protected by appropriate shielding devices, such as protective glove and apron, and he shall be so positioned that no part of his body will be struck by the useful beam. The radiation exposure of and individual used for this purpose shall be monitored and recorded. These records of radiation exposure must be maintained indefinitely for inspection by the agency.

9. Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized.

a. The speed of the screen and film combinations used shall be the fastest speed consistent with the diagnostic objective of the examinations. Film cassettes without intensifying screens shall not be used for any routine diagnostic radiological imaging, with the exception of veterinary radiography and standard film packets for intra-oral use in dental radiography.

b. The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality and, where applicable, shall not exceed the following standards:

EXPOSURE LIMITS FOR SELECTED PROJECTIONS

Using a method acceptable to the agency, the exposure measurement shall be determined in the center of the X-ray field at the location of the entrance skin of a standard patient, except for dental intraoral X-ray machines in which case the measurement shall be determined at the conetip. The technique factors selected shall be those used for routine radiography for an average size adult patient at that facility for that X-ray machine. At least one projection must be tested for each X-ray machine unless none of the projections listed are used. If an X-ray machine is used in both the manual and phototimed modes, then only the manual mode shall be tested. If the machine is used only in the phototimed mode, then this test is not required. An average size adult, for purposes of these regulations, is defined as a 5'8", 164 lb. adult male meeting the following anthropometric guidelines for the radiographic examination projection specified: PA Chest - Thorax - 23 cm thickness; AP Abdomen and AP Lumbar Spine - Abdomen - 23 cm thickness.

The exposure shall not exceed the following maximum exposure limits for the projections below:

Projection	Maximum Exposure

PA Chest	50 mR
AP Lumbar Spine	1400 mR
AP Abdomen	1100 mR

Dental Bitewing

A. Using D Speed Film

50 kVp	575 mR
55 kVp	500 mR
60 kVp	440 mR
65 kVp	400 mR
70 kVp	350 mR
75 kVp	260 mR
80 kVp	230 mR
85 kVp	200 mR
90 kVp	180 mR
95 kVp	160 mR
100 kVp	140 mR

B. Using E Speed Film

50 kVp	320 mR

55 kVp	270 mR
60 kVp	230 mR
65 kVp	200 mR
70 kVp	170 mR
75 kVp	140 mR
80 kVp	120 mR
85 kVp	105 mR
90 kVp	90 mR
95 kVp	80 mR
100 kVp	70 mR

c. Portable or mobile X-ray equipment shall be used only for examinations where it is impractical to transfer the patient(s) to a stationary X-ray installation.

d. X-ray systems subject to 12 VAC 5-481-1620 shall not be utilized in procedures where the source to patient distance is less than 30 centimeters, except for veterinary systems.

e. If grids are used between the patient and the image receptor to decrease scatter to the film and improve contrast, the grid shall:

(1) Be positioned properly, i.e., tube side facing the right direction, and grid centered to the central ray;

(2) If of the focused type, be of the proper focal distance for the SID's being used.

10. All individuals who are associated with the operation of an X-ray system are subject to the requirements of 12 VAC 5-481-640; 12 VAC 5-481-680; 12 VAC 5-481-700 and 12 VAC 5-481-710 of these regulations.

11. Healing arts screening. Any person proposing to conduct a healing arts screening program shall not initiate such a program without prior approval of the agency. When requesting such approval, that person shall submit the following information. If any information submitted to the agency becomes invalid or outdated, the agency shall be immediately notified.

INFORMATION TO BE SUBMITTED BY PERSONS

PROPOSING TO CONDUCT HEALING ARTS SCREENING

Persons requesting that the agency approve a healing arts screening program shall submit the following information and evaluation:

Name and address of the applicant and, where applicable, the names and addresses of agents within this state;

Diseases or conditions for which the X-ray examinations are to be used in

diagnoses;

A detailed description of the X-ray examinations proposed in the screening program;

Description of the population to be examined in the screening program, i.e., age, sex, physical condition, and other appropriate information;

An evaluation of any known alternate methods not involving ionizing radiation which could achieve the goals of the screening program and why these methods are not used instead of the X-ray examinations;

An evaluation by a private inspector of the X-ray system(s) to be used in the screening program. The evaluation by the private inspector shall show that such system(s) do satisfy all requirements of these regulations. The evaluation shall include a measurement of patient exposures from the X-ray examinations to be performed;

A description of the diagnostic X-ray quality control program;

A copy of the technique chart for the X-ray examination procedures to be used;

The qualifications of each individual who will be operating the X-ray system(s);

The qualifications of the individual who will be supervising the operators of the X-ray system(s). The extent of supervision and the method of work performance evaluation shall be specified;

The name and address of the individual who will interpret the radiograph(s);

A description of the procedures to be used in advising the individuals screened and their private practitioners of the healing arts of the results of the screening procedure and any further medical needs indicated;

A description of the procedures for the retention or disposition of the radiographs and other records pertaining to the X-ray examinations;

An indication of the frequency of screening and the duration of the entire screening program.

12. Information and maintenance record and associated information. The registrant shall maintain the following information for each X-ray system for inspection by the agency:

a. Model and serial numbers of all major components, and user's manuals for those components;

b. Tube rating charts and cooling curves;

c. Records of surveys, calibrations, maintenance, and modifications performed on the X-ray system(s); and

d. A copy of all correspondence with this agency regarding that X-ray system.

13. X-ray utilization log. Except for veterinary facilities, each facility shall maintain a record containing the patient's name, the type of examinations, and the dates the examinations were performed. When the patient or film must be provided with human auxiliary support, the name of the human holder shall be recorded.

14. The registrant shall maintain a list of X-ray machine operators for each facility. The following information will be maintained on the list:

a. The name of the X-ray machine operator. Operators must be licensed by the Department of Health Professions where X-rays are used within the scope of practice or be certified by the ARRT.

B. X-ray film processing facilities and practices.

1. Each installation using a radiographic X-ray system and using analog image receptors (e.g. radiographic film) shall have available suitable equipment for handling and processing radiographic film in accordance with the following provisions:

a. Manually developed film:

(1) Processing tanks shall be constructed of mechanically rigid, corrosion resistant material; and

(2) The temperature of solutions in the tanks shall be maintained within the range of 60°F to 80°F (16°C to 27°C). Film shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer, or, in the absence of such recommendations, with the following time-temperature chart which must be posted in the darkroom:

Thermometer Reading (Degrees)		Minimum Developing Time (Minutes)
°C	°F	
26.7	80	2
26.1	79	2
25.6	78	2½
25.0	77	2½
24.4	76	3
23.9	75	3
23.3	74	3½
22.8	73	3½

22.2	72	4
21.7	71	4
21.1	70	4½
20.6	69	4½
20.0	68	5
19.4	67	5½
18.9	66	5½
18.3	65	6
17.8	64	6½
17.2	63	7
16.7	62	8

16.1	61	8½
15.6	60	9½

(3) Devices shall be utilized which will indicate the actual temperature of the developer and signal the passage of a preset time appropriate to the developing time required.

b. Automatic processors and other closed processing systems:

(1) Films shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer; in the absence of such recommendations, the film shall be developed using the following chart:

Developer Temperature		Minimum Immersion Time[a]
°C	°F	Seconds

35.5	96	19
35	95	20
34.5	94	21
34	93	22
33.5	92	23
33	91	24
32	90	25
31.5	89	26
31	88	27
30.5	87	28
30	86	29
29.5	85	30

[a] *Immersion time only, no crossover time included.*

(2) The specified developer temperature and immersion time shall be posted in the darkroom or on the automatic processor.

c. Processing deviations from the requirements of 12 VAC 5-481-1590 B 1 shall be documented by the registrant in such manner that the requirements are shown to be met or exceeded (e.g., extended processing, and special rapid chemistry).

2. Other requirements.

a. Pass boxes, if provided, shall be so constructed as to exclude light from the darkroom when cassettes are placed in or removed from the boxes, and shall incorporate adequate shielding from stray radiation to prevent exposure of undeveloped film.

b. The darkroom shall be light tight and use proper safelighting such that any film type in use exposed in a cassette to x-radiation sufficient to produce an optical density from one to two when processed shall not suffer an increase in density greater than 0.1 (0.05 for mammography) when exposed in the darkroom for

2 minutes with all safelights on. If used, daylight film handling boxes shall preclude fogging of the film.

c. Darkrooms typically used by more than one individual shall be provided a method to prevent accidental entry while undeveloped films are being handled or processed.

d. Film shall be stored in a cool, dry place and shall be protected from exposure to stray radiation. Film in open packages shall be stored in a light tight container.

e. Film cassettes and intensifying screens shall be inspected periodically and shall be cleaned and replaced as necessary to best assure radiographs of good diagnostic quality.

f. Outdated X-ray film shall not be used for diagnostic radiographs, unless the film has been stored in accordance with the manufacturer's recommendations and a sample of the film passes a sensitometric test for normal ranges of base plus fog and speed.

g. Film developing solutions shall be prepared in accordance with the directions given by the manufacturer, and shall be maintained in strength by replenishment or renewal so that full development is accomplished within the time specified by the manufacturer.

h. Film Retention. Living and deceased patient's films (diagnostic images) shall be maintained for a minimum of five years. Films for minors shall be maintained for a minimum of five years beyond their 18th birthday.

C. Information to be submitted to the agency. The registrant shall submit to the agency a copy of all surveys, calibrations and inspections performed by a private inspector within 30 days of completion of the survey or calibration.

D. Information to be submitted by the private inspector to the registrant. The private inspector shall provide the inspection report to the registrant within 14 days of the completion of the inspection. A summary and/or recommendations shall be included with this report. The private inspector shall notify the registrant of any non-compliances that need corrective action.

12 VAC 5-481-1600. General requirements for all diagnostic X-ray systems.

In addition to other requirements of this Part, all diagnostic X-ray systems shall meet the following requirements:

A. Warning label. The control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "WARNING: This X-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

B. Battery charge indicator. On battery-powered X-ray generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

C. Leakage radiation from the diagnostic source assembly. The leakage radiation from the diagnostic source assembly measured at a distance of one meter in any direction from the source shall not exceed 25.8 μC/kg (100 milliroentgens) in one hour when the X-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

D. Radiation from components other than the diagnostic source assembly. The radiation emitted by a component other than the diagnostic source assembly shall not exceed 0.5 μC/kg (2 milliroentgens) in one hour at five centimeters from any accessible surface of the component when it is operated in an assembled X-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

E. Beam quality.

1. Half-value layer.

a. The half-value layer of the useful beam for a given X-ray tube potential shall not be less than the values shown in Table I. If it is necessary to determine such half-

value layer at an X-ray tube potential which is not listed in Table I, linear interpolation or extrapolation may be made.

TABLE I

Design Operating Range (kVp)	Measured Potential (kVp)	Half-Value Layer In mm Aluminum	
		Dental Intra-Oral Manufactured Before Aug. 1, 1974 and On or After Dec. 1, 1980	All Other Diagnostic X-ray Systems
Below 51	30	N/A	0.3
	40	N/A	0.4
	50	1.5	0.5
51 to 70	51	1.5	1.2
	60	1.5	1.3

	70	1.5	1.5
Above 70	71	2.1	2.1
	80	2.3	2.3
	90	2.5	2.5
	100	2.7	2.7
	110	3.0	3.0
	120	3.2	3.2
	130	3.5	3.5
	140	3.8	3.8
	150	4.1	4.1

b. For capacitor energy storage equipment, compliance with the requirements of 12 VAC 5-481-1600 E 1 shall be determined with the system fully charged and a setting of 10 mAs for each exposure.

c. The required minimal half-value layer of the useful beam shall include the filtration contributed by all materials which are permanently between the source and the patient.

2. Filtration controls. For X-ray systems which have variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filter(s) and shall prevent an exposure unless the minimum amount of filtration necessary to produce the HVL required by 12 VAC 5-481-1600 E 1 is in the useful beam for the given kVp which has been selected.

F. Multiple tubes. Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the X-ray control panel and at or near the tube housing assembly which has been selected.

G. Mechanical support of tube head. The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless tube housing movement is a designed function of the X-ray system.

H. Technique indicators.

1. The technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors which are set prior to the exposure shall be indicated.

2. The requirement of 12 VAC 5-481-1600 H 1 may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

I. Maintaining compliance. Diagnostic X-ray systems and their associated components used on humans and certified pursuant to the Federal X-ray Equipment Performance Standard (21 CFR Part 1020) shall be maintained in compliance with applicable requirements of that standard.

J. Locks. All position locking, holding, and centering devices on X-ray system components and systems shall function as intended.

K. Mechanical timers. The use of a mechanical timer is prohibited.

12 VAC 5-481-1610. Fluoroscopic X-ray systems.

All fluoroscopic X-ray systems used shall be image intensified and meet the following requirements:

A. Limitation of useful beam.

1. Primary barrier.

a. The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID.

b. The X-ray tube used for fluoroscopy shall not produce X-rays unless the barrier is in position to intercept the entire useful beam.

2. Fluoroscopic beam limitation.

a. For certified fluoroscopic systems with or without a spot film device, neither the length nor the width of the X-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3% of the SID. The sum of the excess length and the excess width shall be no greater than 4% of the SID.

b. For uncertified fluoroscopic systems with a spot film device, the X-ray beam with the shutters fully opened (during fluoroscopy or spot filming) shall be no larger than the largest spot film size for which the device is designed. Measurements shall be made at the minimum SID available but at no less than 20 centimeters table top to the film plane distance.

c. For uncertified fluoroscopic systems without a spot film device, the requirements of 12 VAC 5-481-1610 A 2 a apply.

d. Other requirements for fluoroscopic beam limitation:

(1) Means shall be provided to permit further limitation of the field. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID and/or a visible area of greater than 300 square centimeters shall be provided with means for stepless adjustment of the X-ray field;

(2) All equipment with a fixed SID and a visible area of 300 square centimeters or less shall be provided with either stepless adjustment of the X-ray field or with means to further limit the X-ray field size at the plane of the image receptor to 125 square centimeters or less;

(3) If provided, stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum attainable to a field size of five centimeters by five centimeters or less;

(4) For equipment manufactured after February 25, 1978, when the angle between the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor;

(5) For non-circular X-ray fields used with circular image receptors, the error in alignment shall be determined along the length and width dimensions of the X-ray field which pass through the center of the visible area of the image receptor.

3. Spot-film beam limitation. Spot-film devices shall meet the following requirements:

a. Means shall be provided between the source and the patient for adjustment of the X-ray field size in the plane of the film to the size of that portion of the film which has been selected on the spot film selector. Such adjustment shall be automatically accomplished except when the X-ray field size in the plane of the film is smaller than that of the selected portion of the film. For spot film devices manufactured after June 21, 1979, if the X-ray field size is less than the size of the selected portion of the film, the means for adjustment of the field size shall be only at the operator's option;

b. Neither the length nor the width of the X-ray field in the plane of the image receptor shall differ from the corresponding dimensions of the selected portion of the image receptor by more than 3% of the SID when adjusted for full coverage of the selected portion of the image receptor. The sum, without regard to sign, of the length and width differences shall not exceed 4% of the SID;

c. It shall be possible to adjust the X-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID shall be equal to, or less than, five centimeters by five centimeters;

d. The center of the X-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within 2% of the SID; and

e. On spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

4. Override. If a means exists to override any of the automatic X-ray field size adjustments required in 12 VAC 5-481-1610 A 2 and 12 VAC 5-481-1610 A 3, that means:

a. Shall be designed for use only in the event of system failure;

b. Shall incorporate a signal visible at the fluoroscopist's position which will indicate whenever the automatic field size adjustment is overridden; and

c. Shall be clearly and durably labeled as follows:

B. Activation of the fluoroscopic tube. X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the X-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

C. Exposure rate limits.

1. Entrance exposure rate allowable limits.

a. Fluoroscopic equipment which is provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 2.6 mC/kg (10 roentgens) per minute at the point where the center of the useful beam enters the patient, except:

(1) During recording of fluoroscopic images; or

(2) When an optional high level control is provided. When so provided, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 1.3 mC/kg (5 roentgens) per minute at the point where the center of the useful beam enters the patient unless the high level control is activated. Special means

of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

b. Fluoroscopic equipment which is not provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in a exposure rate in excess of 1.3 mC/kg (5 roentgens) per minute at the point where the center of the useful beam enters the patient, except:

(1) During recording of fluoroscopic images; or

(2) When an optional high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

c. Compliance with the requirements of 12 VAC 5-481-1610 C shall be determined as follows:

(1) If the source is below the X-ray table, the exposure rate shall be measured one centimeter above the tabletop or cradle;

(2) If the source is above the X-ray table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement;

(3) For a C-arm type of fluoroscope, the exposure rate shall be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly, with the source positioned at any available SID, provided that the end of the beam-limiting device or spacer is no closer than 30 centimeters from the input surface of the fluoroscopic imaging assembly;

(4) For a lateral type fluoroscope, the exposure rate shall be measured at a point 15 centimeters from the centerline of the X-ray table and in the direction of the X-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral X-ray source, with the end of the beam-limiting device or spacer no closer than 15 centimeters to the centerline of the X-ray table.

2. Periodic measurement of entrance exposure rate shall be performed by a private inspector for both typical and maximum values as follows:

a. Such measurements shall be made annually or after any maintenance of the system which might affect the exposure rate;

b. Results of these measurements shall be posted where any fluoroscopist may have ready access to such results while using the fluoroscope and in the record required in 12 VAC 5-481-1590 A 12 c. The measurement results shall be stated in coulombs per kilogram (roentgens) per minute and include the technique factors used in determining such results. The name of the individual performing the measurements and the date the measurements were performed shall be included in the results;

c. Conditions of periodic measurement of typical entrance exposure rate are as follows:

(1) The measurement shall be made under the conditions that satisfy the requirements of 12 VAC 5-481-1610 C 1 c;

(2) The kVp, mA, and/or other selectable parameters shall be adjusted to those settings typical of clinical use on a 23 cm thick abdominal patient;

(3) The X-ray system that incorporates automatic exposure rate control shall have sufficient attenuative material placed in the useful beam to produce a milliamperage and/or kilovoltage to satisfy the conditions of 12 VAC 5-481-1610 C 2 c (2).

d. Conditions of periodic measurement of maximum entrance exposure rate are as follows:

(1) The measurement shall be made under the conditions that satisfy the requirements of 12 VAC 5-481-1610 C 1 c;

(2) The kVp, mA and/or other selectable parameters shall be adjusted to those settings which give the maximum entrance exposure rate;

(3) The X-ray system(s) that incorporates automatic exposure rate control shall have sufficient attenuative material placed in the useful beam to produce the maximum entrance exposure rate of the system.

D. Barrier transmitted radiation rate limits.

1. The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, shall not exceed 0.5 μC/kg (2 milliroentgens) per hour at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each mC/kg (roentgen) per minute of entrance exposure rate.

2. Measuring compliance of barrier transmission.

a. The exposure rate due to transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

b. If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop.

c. If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters.

d. Movable grids and compression devices shall be removed from the useful beam during the measurement.

E. Indication of potential and current. During fluoroscopy and cinefluorography, the kV and the mA shall be continuously indicated.

F. Source-to-skin distance. The SSD shall not be less than:

1. 38 centimeters on stationary fluoroscopic systems manufactured on or after August 1, 1974;

2. 35.5 centimeters on stationary fluoroscopic systems manufactured prior to August 1, 1974;

3. 30 centimeters on all mobile fluoroscopes; or

4. 20 centimeters for all mobile fluoroscopes when used for specific surgical applications.

G. Fluoroscopic timer.

1. Means shall be provided to preset the cumulative on-time of the fluoroscopic X-ray tube. The maximum cumulative time of the timing device shall not exceed five minutes without resetting.

2. A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on-time. Such signal shall continue to sound while X-rays are produced until the timing device is reset.

H. Control of scattered radiation.

1. Fluoroscopic table designs when combined with procedures utilized shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to

unattenuated scattered radiation which originates from under the table. The attenuation required shall be not less than 0.25 millimeter lead equivalent.

2. Equipment configuration when combined with procedures shall be such that no portion of any staff or ancillary individual's body, except the extremities, shall be exposed to the unattenuated scattered radiation emanating from above the tabletop unless that individual:

a. Is at least 120 centimeters from the center of the useful beam; or

b. The radiation has passed through not less than 0.25 millimeter lead equivalent material including, but not limited to, drapes, Bucky-slot cover panel, or self-supporting curtains, in addition to any lead equivalency provided by the protective apron referred to in 12 VAC 5-481-1590 A 5.

3. The agency may grant exemptions to 12 VAC 5-481-1610 H 2 where a sterile field will not permit the use of the normal protective barriers. Where the use of prefitted sterilized covers for the barriers is practical, the agency shall not permit such exemption. The following is a suggested list of fluoroscopic procedures where such exemptions will be automatically granted: angiograms, arthrograms, biliary drainage procedures, fluoroscopic biopsy procedures, myelograms, percutaneous cholangiograms, percutaneous nephrostomies, sinograms or fistulograms, t-tube cholangiograms.

I. Spot film exposure reproducibility. Fluoroscopic systems equipped with spot film (radiographic) mode shall meet the exposure reproducibility requirements of 12 VAC 5-481-1620 D when operating in the spot film mode.

J. Radiation therapy simulation systems. Radiation therapy simulation systems shall be exempt from all the requirements of 12 VAC 5-481-1610 C. In addition, these systems shall be exempt from:

1. The requirements of 12 VAC 5-481-1610 A and 12 VAC 5-481-1610 D provided such systems are designed and used in such a manner that no individual other than the patient is in the X-ray room during periods of time when the system is producing X-rays; and

2. The requirements of 12 VAC 5-481-1610 G if such systems are provided with a means of indicating the cumulative time that an individual patient has been exposed to X-rays. Procedures shall require in such cases that the timer be reset between examinations.

K. Surveys. Radiation safety and equipment performance surveys shall be performed annually on all fluoroscopic X-ray systems by or under the direct supervision of a private or state inspector who is physically present at the facility during the inspection in order to assure compliance with these regulations.

12 VAC 5-481-1620. Radiographic systems other than fluoroscopic, dental intraoral, or computed tomography X-ray systems.

A. Beam limitation, except mammographic systems. The useful beam shall be limited to the area of clinical interest. This shall be deemed to have been met if a positive beam limiting device meeting manufacturer's specifications and the requirements of 12 VAC 5-481-1620 H 2 has been properly used or if evidence of collimation is shown on at least three sides or three corners of the film (for example, projections from the shutters of the collimator, cone cutting at the corners, or borders at the film's edge).

1. General purpose stationary and mobile X-ray systems, including veterinary systems (other than portable) installed after the effective date of these regulations.

a. Only X-ray systems provided with means for independent stepless adjustment of at least two dimensions of the X-ray field shall be used.

b. A method shall be provided for visually defining the perimeter of the X-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the X-ray field along either the length or width of the visually defined field shall not exceed 2% of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the X-ray beam.

c. The agency may grant an exemption on non-certified X-ray systems to 12 VAC 5-481-1620 A 1 a and b provided the registrant makes a written application for such exemption and in that application:

(1) Demonstrates it is impractical to comply with 12 VAC 5-481-1620 A 1 a and b; and

(2) The purpose of 12 VAC 5-481-1620 A 1 a and b will be met by other methods.

2. Additional requirements for stationary general purpose X-ray systems. In addition to the requirements of 12 VAC 5-481-1620 A 1, stationary general purpose X-ray systems, both certified and non-certified, shall meet the following requirements:

a. A method shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor, to align the center of the X-ray field with respect to the center of the image receptor to within 2% of the SID, and to indicate the SID to within 2%;

b. The beam-limiting device shall indicate numerically the field size in the plane of the image receptor to which it is adjusted; and

c. Indication of field size dimensions and SID's shall be specified in inches and/or centimeters, and shall be such that aperture adjustments result in X-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within 2% of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.

3. X-ray systems designed for one image receptor size. Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the X-ray field with the center of the image receptor to within 2% of the SID, or shall be provided with means to both size and align the X-ray field such that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

4. X-ray systems other than those described in 12 VAC 5-481-1620 A 1 through 3, and veterinary systems installed prior to the effective date of these regulations and all portable veterinary X-ray systems.

a. Means shall be provided to limit the X-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than 2% of the SID when the axis of the X-ray beam is perpendicular to the plane of the image receptor.

b. Means shall be provided to align the center of the X-ray field with the center of the image receptor to within 2% of the SID, or means shall be provided to both size and align the X-ray field such that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. Compliance shall be determined with the axis of the X-ray beam perpendicular to the plane of the image receptor.

c. 12 VAC 5-481-1620 A 4 a and b may be met with a system that meets the requirements for a general purpose X-ray system as specified in 12 VAC 5-481-1620 A 1 or, when alignment means are also provided, may be met with either:

(1) An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed with each such device having clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

(2) A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

B. Radiation exposure control.

1. Exposure initiation. Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action. In addition, it shall not be possible to initiate an exposure when the timer is set to a "zero" or "off" position if either position is provided.

2. Exposure indication. Means shall be provided for visual indication observable at or from the operator's protected position whenever X-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

3. Exposure termination. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. Except for dental panoramic systems, termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "zero."

a. Manual exposure control. An X-ray control shall be incorporated into each X-ray system such that an exposure can be terminated by the operator at any time except for:

(1) Exposure of ½ second or less; or

(2) During serial radiography when means shall be provided to permit completion of any single exposure of the series in process.

b. Automatic exposure controls. When an automatic exposure control is provided:

(1) Indication shall be made on the control panel when this mode of operation is selected;

(2) If the X-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to 2 pulses;

(3) The minimum exposure time for all equipment other than that specified in 12 VAC 5-481-1620 B 3 b (2) shall be equal to or less than one-sixtieth (1/60) second or a time interval required to deliver five mAs, whichever is greater;

(4) Either the product of peak X-ray tube potential, current, and exposure time shall be limited to not more than 60 kWs per exposure, or the product of X-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure except that, when the X-ray tube potential is less than 50 kVp, the product of X-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure; and

(5) A visible signal shall indicate when an exposure has been terminated at the limits required by 12 VAC 5-481-1620 B 3 b (4), and manual resetting shall be required before further automatically timed exposures can be made.

4. Exposure duration (timer) linearity. For systems having independent selection of exposure time settings, the average ratios (X_i) of exposure to the indicated timer setting, in units of C $kg^{-1}s^{-1}$ (mR/s), obtained at any two clinically used timer settings shall not differ by more than 0.10 times their sum. This is written as:

$$(X_1 - X_2) \leq 0.1 (X_1 + X_2)$$

where X_1 and X_2 are the average C $kg^{-1}s^{-1}$ (mR/s) values.

5. Exposure control location. The X-ray exposure control shall be so placed that the operator can view the patient while making any exposure.

6. Operator protection, except veterinary systems.

a. Stationary systems. Stationary X-ray systems shall be required to have the X-ray exposure control permanently mounted behind a protected barrier so that the operator can remain behind that protected barrier during the entire exposure. Where it is impractical to stand behind a protected barrier, dental panographic and podiatry X-ray systems may, as an alternative, be provided with means to allow the operator to be at least nine feet from the tube housing assembly during exposures.

b. Mobile and portable systems. Mobile and portable X-ray systems which are:

(1) Used continuously for greater than one week in the same location, i.e., a room or suite, shall meet the requirements of 12 VAC 5-481-1620 B 6 a ;

(2) Used for less than one week at the same location shall be provided with either a protective barrier at least two meters (6.5 feet) high for operator protection during exposures, or means shall be provided to allow the operator to be at least 2.7 meters (9 feet) from the tube housing assembly during the exposure.

7. Operator protection for veterinary systems. All stationary, mobile or portable X-ray systems used for veterinary work shall be provided with either a two meter (6.5 feet) high protective barrier for operator protection during exposures, or shall be provided with means to allow the operator to be at least 2.7 meters (9 feet) from the tube housing assembly during exposures.

C. Source-to-skin distance. All mobile or portable radiographic systems shall be provided with means to limit the source-to-skin distance to equal to or greater than 30 centimeters, except for veterinary systems.

D. Reproducibility for Exposure and Time. When all technique factors are held constant, including control panel selections associated with automatic exposure control systems, the coefficient of variation of exposure for both manual and automatic exposure control systems shall not exceed 0.10. This requirement applies to clinically used techniques.

E. Radiation from capacitor energy storage equipment in standby status. Radiation emitted from the X-ray tube when the system is fully charged and the exposure switch or timer is not activated shall not exceed a rate of 0.5 μC/kg (2 milliroentgens) per hour at five centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.

F. Accuracy. Deviation of measured technique factors from indicated values of kVp and exposure time shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications, the deviation shall not exceed 10% of the indicated value for kVp and 10% for time.

G. mA/mAs linearity. The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for any fixed X-ray tube potential within the range of 40% to 100% of the maximum rated:

1. Equipment having independent selection of X-ray tube current (mA). The average ratios (X_i) of exposure to the indicated milliampere-seconds product (C kg^{-1} mAs^{-1} (or mR/mAs)) obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$X_1 - X_2 < 0.10 (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at each of two consecutive tube current settings, or at two settings differing by no more than a factor of two where the tube current selection is continuous.

2. Equipment having a combined X-ray tube current-exposure time product (mAs) selector, but not a separate tube current (mA) selector. The average ratios (X_i) of exposure to the indicated milliampere-seconds product, in units of C kg^{-1} mAs^{-1} (or mR/mAs), obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum:

$$X_1 - X_2 < 0.10 (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at any two mAs selector settings, or at two settings differing by no more than a factor of two where the mAs selector provides continuous selection.

3. Measuring compliance. Determination of compliance shall be based on four exposures taken within a time period of one hour, at each of the two settings. These two settings may include any two focal spot sizes except where one is equal to or less than 0.45 millimeters and the other is greater than 0.45 millimeters. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the X-ray tube manufacturer.

H. Additional requirements. Diagnostic X-ray systems shall be required to comply with the following additional requirements.

1. Beam limitation for stationary and mobile general purpose X-ray systems.

a. There shall be provided a means of stepless adjustment of the size of the X-ray field. The minimum field size at an SID of 100 centimeters shall be equal to or less than five centimeters by five centimeters.

b. When a light localizer is used to define the X-ray field, it shall provide an average illumination of not less than 120 lux or 10 footcandles at 100 centimeters or at the maximum SID, whichever is less. The average illumination shall be based upon measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems manufactured on and after May 27, 1980, are exempt from this requirement.

2. Beam limitation and alignment on stationary general purpose X-ray systems equipped with PBL. If PBL is being used, the following requirements shall be met:

a. PBL shall prevent the production of X-rays when:

(1) Either the length or width of the X-ray field in the plane of the image receptor differs, except as permitted by 12 VAC 5-481-1620 H 2 c, from the corresponding image receptor dimensions by more than 3% of the SID; or

(2) The sum of the length and width differences as stated in 12 VAC 5-481-1620 H 2 a (1) without regard to sign exceeds 4% of the SID;

b. Compliance with 12 VAC 5-481-1620 H 2 a shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor. Compliance shall be determined no sooner than five seconds after insertion of the image receptor;

c. The PBL system shall be capable of operation, at the discretion of the operator, such that the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. The minimum field size at an SID of 100 centimeters shall be equal to or less than five centimeters by five centimeters;

d. The PBL system shall be designed such that if a change in image receptor does not cause an automatic return to PBL function as described in 12 VAC 5-481-1620 H 2 a, then any change of image receptor size or SID must cause the automatic return.

3. Beam limitation for portable X-ray systems. Beam limitation for portable X-ray systems shall meet the beam limitation requirements of 12 VAC 5-481-1620 A 1 or 12 VAC 5-481-1620 H 2.

I. Tube stands for portable X-ray systems. A tube stand or other mechanical support shall be used for portable X-ray systems, so that the X-ray tube housing assembly need not be hand-held during exposures unless the system is specifically designed to be hand-held.

J. Surveys. Radiation safety and equipment performance surveys shall be performed annually on all X-ray machines covered by this section in order to assure compliance with the regulations, except that bone densitometers and X-ray machines used in the practice of podiatry or dentistry shall be surveyed every three years. The surveys shall be performed by or under the direct supervision of a private or state inspector who is physically present at the facility during the inspection.

12 VAC 5-481-1630. Intraoral dental radiographic systems.

In addition to the provisions of 12 VAC 5-481-1590 and 12 VAC 5-481-1600, the requirements of 12 VAC 5-481-1630 apply to X-ray equipment and associated facilities used for dental radiography. Requirements for extraoral dental radiographic systems are covered in 12 VAC 5-481-1620. Only systems meeting the requirements of 12 VAC 5-481-1630 shall be used.

A. Source-to-skin distance (SSD). X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit SSD, to not less than:

1. 18 centimeters if operable above 50 kVp; or

2. 10 centimeters if operable at 50 kVp only.

B. Beam limitation. Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the X-ray beam such that the beam at the minimum SSD shall be containable in a circle having a diameter of no more than seven centimeters.

C. Radiation exposure control.

1. Exposure initiation.

a. Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action; and

b. It shall not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided.

2. Exposure indication. Means shall be provided for visual indication observable at or from the operator's protected position whenever X-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

3. Exposure termination.

a. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor.

b. An X-ray exposure control shall be incorporated into each X-ray system such that an exposure can be terminated by the operator at any time, except for exposures of ½ second or less.

c. Termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "zero."

4. Exposure duration (timer) linearity. For systems having independent selection of exposure time settings, the average ratios (X_i) of exposure to the indicated timer setting, in units of C kg^{-1} s^{-1} (mR/s), obtained at any two clinically used timer settings shall not differ by more than 0.10 times their sum. This is written as:

$$(X_1 - X_2) \leq 0.1 (X_1 + X_2)$$

where X_1 and X_2 are the average values.

5. Exposure control location and operator protection.

a. After the effective date of these regulations, stationary X-ray systems shall be required to have the X-ray exposure control permanently mounted behind a protected barrier, so that the operator can remain behind that protected barrier during the entire exposure. Where it is impractical to stand behind a protected barrier, the X-ray exposure shall be permanently mounted at least 2.7 meters (9

feet) from the tube housing assembly while making exposures. If an X-ray machine was installed prior to the effective date of these regulations and if the X-ray exposure control is not permanently mounted behind a protected barrier, so that the operator can remain behind that protected barrier during the entire exposure, then dosimetry shall be required by all operators of the X-ray system.

b. Mobile and portable X-ray systems which are:

(1) Used for greater than one week in the same location, i.e., a room or suite, shall meet the requirements of 12 VAC 5-481-1630 C 5 1;

(2) Used for less than one week in the same location shall be provided with either a protective barrier at least two meters (6.5 feet) high for operator protection, or means shall be provided to allow the operator to be at least 2.7 meters (9 feet) from the tube housing assembly while making exposures.

D. Reproducibility for Exposure and Time. When the equipment is operated on an adequate power supply as specified by the manufacturer, the estimated coefficient of variation of radiation exposures and times shall be no greater than 0.10, for any specific combination of selected technique factors.

E. mA/mAs linearity. The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for any fixed X-ray tube potential within the range of 40% to 100% of the maximum rated.

1. Equipment having independent selection of X-ray tube current (mA). The average ratios (X_i) of exposure to the indicated milliampere-seconds product, in units of C kg^{-1} mAs^{-1} (or mR/mAs), obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$X_1 - X_2 < 0.10 (X_1+X_2)$$

where X_1 and X_2 are the average values obtained at each of two consecutive tube current settings, or at two settings differing by no more than a factor of two where the tube current selection is continuous.

2. Equipment having a combined X-ray tube current-exposure time product (mAs) selector, but not a separate tube current (mA) selector. The average ratios (X_i) of exposure to the indicated milliampere-seconds product, in units of C kg^{-1} mAs^{-1} (or mR/mAs), obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum:

$$X_1 - X_2 < 0.10 (X_1 +X_2)$$

where X_1 and X_2 are the average values obtained at any two mAs selector settings, or at two settings differing by no more than a factor of two where the mAs selector provides continuous selection.

3. Measuring compliance. Determination of compliance shall be based on four exposures taken within a time period of one hour, at each of the two settings. These two settings may include any two focal spot sizes except where one is equal to or less than 0.45 millimeters and the other is greater than 0.45 millimeters. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the X-ray tube manufacturer.

F. Accuracy. Deviation of technique factors from indicated values for kVp and exposure time (if time is independently selectable) shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications the deviation shall not exceed 10% of the indicated value for kVp and 10% for time.

G. kVp limitations. Dental X-ray machines with a nominal fixed kVp of less than 50 kVp shall not be used to make diagnostic dental radiographs of humans.

H. Administrative controls.

1. Patient and film holding devices shall be used when the techniques permit.

2. The tube housing and the PID shall not be hand-held during an exposure.

3. The X-ray system shall be operated in such a manner that the useful beam at the patient's skin does not exceed the requirements of 12 VAC 5-481-1630 B.

4. Dental fluoroscopy without image intensification shall not be used.

I. Radiation safety and equipment performance surveys shall be performed every three years on all dental X-ray systems by or under the direct supervision of a private or state inspector who is physically present at the facility during the inspection in order to assure compliance with these regulations.

12 VAC 5-481-1640. Computed tomography X-ray systems.

A. Reserved.

B. Requirements for equipment.

1. Termination of exposure.

a. Means shall be provided to terminate the X-ray exposure automatically by either de-energizing the X-ray source or shuttering the X-ray beam in the event of equipment failure affecting data collection. Such termination shall occur within an interval that limits the total scan time to no more than 110% of its preset value

through the use of either a backup timer or devices which monitor equipment function.

b. A visible signal shall indicate when the X-ray exposure has been terminated through the means required by 12 VAC 5-481-1640 B 1 a.

c. The operator shall be able to terminate the X-ray exposure at any time during a scan, or series of scans under CT X-ray system control, of greater than one-half second duration.

2. Tomographic plane indication and alignment.

a. For any single tomogram system, means shall be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane.

b. For any multiple tomogram system, means shall be provided to permit visual determination of the location of a reference plane. This reference plane can be offset from the location of the tomographic planes.

c. If a device using a light source is used to satisfy the requirements of 12 VAC 5-481-1640 B 2 a or b, the light source shall provide illumination levels sufficient to permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux.

3. Beam-on and shutter status indicators and control switches.

a. The CT X-ray control and gantry shall provide visual indication whenever X-rays are produced and, if applicable, whether the shutter is open or closed.

b. Each emergency button or switch shall be clearly labeled as to its function.

4. Indication of CT conditions of operation. The CT X-ray system shall be designed such that the CT conditions of operation to be used during a scan or a scan sequence shall be indicated prior to the initiation of a scan or a scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible.

5. Extraneous radiation. When data are not being collected for image production, the radiation adjacent to the tube port shall not exceed that permitted by 12 VAC 5-481-1600 C.

6. Maximum surface CTDI identification. The angular position where the maximum surface CTDI occurs shall be identified to allow for reproducible positioning of a CT dosimetry phantom.

7. Additional requirements applicable to CT X-ray Systems containing a gantry manufactured after September 3, 1985.

a. The total error in the indicated location of the tomographic plane or reference plane shall not exceed five millimeters.

b. If the X-ray production period is less than one-half second, the indication of X-ray production shall be actuated for at least one-half second. Indicators at or near the gantry shall be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible.

c. The deviation of indicated scan increment versus actual increment shall not exceed plus or minus one millimeter with any mass from 0 to 100 kilograms resting on the support device. The patient support device shall be incremented from a typical starting position to the maximum incremented distance or 30 centimeters, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment may be taken anywhere along this travel.

d. Premature termination of the X-ray exposure by the operator shall necessitate resetting of the CT conditions of operation prior to the initiation of another scan.

C. Facility design requirements.

1. Aural communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel.

2. Viewing systems.

a. Windows, mirrors, closed-circuit television, or an equivalent shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.

b. When the primary viewing system is by electronic means, an alternate viewing system (which may be electronic) shall be available for use in the event of failure of the primary viewing system.

D. Surveys, calibrations, spot checks, and operating procedures.

1. Surveys.

a. All CT X-ray systems installed after the effective date of these regulations and those systems not previously surveyed shall have a survey made by, or under the direct supervision of a private inspector who is physically present at the facility during the inspection. In addition, such surveys shall be done at least annually or after any change in the facility or equipment which might cause a significant increase in radiation hazard, whichever occurs first.

b. The registrant shall obtain a written report of the survey from the private inspector, and a copy of the report shall be sent to the agency within 60 days of the date of the survey.

2. Radiation calibrations.

a. The calibration of the radiation output of the CT X-ray system shall be performed by, or under the direction of, a private inspector who is physically present at the facility during such calibration.

b. The calibration of a CT X-ray system shall be performed at intervals specified by a private inspector and after any change or replacement of components which, in the opinion of the private inspector, could cause a change in the radiation output.

c. The calibration of the radiation output of a CT X-ray system shall be performed with a calibrated dosimetry system. The calibration of such system shall be traceable to a national standard. The dosimetry system shall have been calibrated within the preceding two years.

d. CT dosimetry phantom(s) shall be used in determining the radiation output of a CT X-ray system. Such phantom(s) shall meet the following specifications and conditions of use:

(1) CT dosimetry phantom(s) shall be right circular cylinders of polymethyl methacrylate of density 1.19 plus or minus 0.01 grams per cubic centimeter. The phantom(s) shall be at least 14 centimeters in length and shall have diameters of 32.0 centimeters for testing CT X-ray systems designed to image any section of the body and 16.0 centimeters for systems designed to image the head or for whole body scanners operated in the head scanning mode;

(2) CT dosimetry phantom(s) shall provide means for the placement of a dosimeter(s) along the axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom. Means for the placement of dosimeters or alignment devices at other locations may be provided;

(3) Any effects on the doses measured due to the removal of phantom material to accommodate dosimeters shall be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom;

(4) All dose measurements shall be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuation materials present.

e. The calibration shall be required for each type of head, body, or whole-body scan performed at the facility.

f. Calibration shall meet the following requirements:

(1) The dose profile along the center axis of the CT dosimetry phantom for the minimum, maximum, and midrange values of the nominal tomographic section thickness used by the registrant shall be measurable. Where less than three nominal tomographic thicknesses can be selected, the dose profile determination shall be performed for each available nominal tomographic section thickness;

(2) The CTDI along the two axes specified in 12 VAC 5-481-1640 D 2 d (2) shall be measured. The CT dosimetry phantom shall be oriented so that the measurement point 1.0 centimeter from the outer surface and within the phantom is in the same angular position within the gantry as the point of maximum surface CTDI identified. The CT conditions of operation shall correspond to typical values used by the registrant;

(3) The spot checks specified in 12 VAC 5-481-1640 D 3 shall be made.

g. Calibration procedures shall be in writing. Records of calibrations performed shall be maintained for inspection by the agency.

3. Spot checks.

a. The spot-check procedures shall be in writing and shall have been developed by a private inspector.

b. The spot-check procedures shall incorporate the use of a CT dosimetry phantom which has a capability of providing an indication of contrast scale, noise, nominal tomographic section thickness, the resolution capability of the system for low and high contrast objects, and measuring the mean CTN for water or other reference material.

c. All spot checks shall be included in the calibration required by 12 VAC 5-481-1640 D 2 and at time intervals and under system conditions specified by a private inspector.

d. Spot checks shall include acquisition of images obtained with the CT dosimetry phantom(s) using the same processing mode and CT conditions of operation as are used to perform calibrations required by 12 VAC 5-481-1640 D 2. The images shall be retained, until a new calibration is performed, in two forms as follows:

(1) Photographic copies of the images obtained from the image display device; and

(2) Images stored in digital form on a storage medium compatible with the CT X-ray system.

e. Written records of the spot checks performed shall be maintained for inspection by the agency.

4. Operating procedures.

a. The CT X-ray system shall not be operated except by an individual who has been specifically trained in its operation.

b. Information shall be available at the control panel regarding the operation and calibration of the system. Such information shall include the following:

(1) Dates of the latest calibration and spot checks and the location within the facility where the results of those tests may be obtained;

(2) Instructions on the use of the CT dosimetry phantom(s) including a schedule of spot checks appropriate for the system, allowable variations for the indicated parameters, and the results of at least the most recent spot checks conducted on the system;

(3) The distance in millimeters between the tomographic plane and the reference plane if a reference plane is utilized; and

(4) A current technique chart available at the control panel which specifies for each routine examination the CT conditions of operation and the number of scans per examination.

c. If the calibration or spot check of the CT X-ray system identifies that a system operating parameter has exceeded a tolerance established by the private inspector, use of the CT X-ray system on patients shall be limited to those uses permitted by established written instructions of the private inspector.

12 VAC 5-481-1650. Mammography.

A. Equipment standards. Only X-ray systems meeting the following standards shall be used.

1. System design. The X-ray system shall be specifically designed for mammography.

2. Image receptor. The image receptor systems and their individual components shall be specifically designed for or appropriate for mammography.

3. kVp/target/filter. The X-ray system shall have the capability of providing kVp/target/filter combinations compatible with the selected image receptor system.

4. Beam quality.

a. When used with screen-film image receptors, and when the contribution to filtration made by the compression device is included, the useful beam shall have a half-value layer (HVL):

(1) Between the values of: ((measured kVp)/100) and ((measured kVp)/100 + 0.1) millimeters aluminum for molybdenum targets;

(2) At least the value of ((measured kVp)/100) millimeters aluminum for rhodium alloy targets.

b. For xeroradiography, the HVL of the useful beam with the compression device in place shall be at least 1.0 and not greater than 1.6 mm aluminum, measured at 49 kVp with a tungsten target tube.

5. Resolution. The combination of focal spot size, source-to-image receptor distance and magnification shall result in a resolution of at least 12 line pairs per millimeter (cycles/mm) measured when a resolution pattern is positioned 4.2 cm above all breast supports and when the resolution pattern is either perpendicular to or parallel with the chest wall edge of the image receptor support. The measurement shall be made with the kVp in the range of 25-30 and the mA shall be the highest available for the focal spot size selected.

6. Compression.

a. The X-ray system shall be capable of compressing the breast with a force of at least 25 pounds and shall be capable of maintaining this compression for at least three minutes. The maximum force shall be no greater than 40 pounds.

b. The chest wall edge of the compression paddle shall extend beyond the chest wall edge of the image receptor by no more than 2% of the Source-to-Image Receptor Distance with the compression paddle placed 4.2 cm above the breast support device. With the compression paddle in this position, the chest wall edge of the compression paddle shall not be visible in the acquired image.

7. System capabilities. A mammographic X-ray system utilizing screen-film image receptors shall have:

a. The capability of using anti-scatter grids which are:

(1) Integral to the X-ray system;

(2) Available for all image receptor sizes used;

b. The capability of automatic exposure control, for systems installed after the effective date of these regulations; and

c. The capability of displaying post-exposure mAs after an exposure made using an automatic exposure control device, for systems installed after the effective date of these regulations.

8. Milliampere-second read-out accuracy. For those mammographic X-ray systems equipped with automatic exposure control and post-exposure mAs read-out, the indicated mAs read-out shall be within ±10% of the actual mAs delivered.

9. Transmission. For X-ray systems manufactured after September 5, 1978, the transmission of the primary beam through any image receptor support provided with the system shall be limited such that the exposure five centimeters from any accessible surface beyond the plane of the image receptor supporting device does not exceed 25.8 nC/kg (0.1 milliroentgen) for each activation of the tube. Exposure shall be measured with the system operated at the minimum SID for which it is designed. Compliance shall be determined at the maximum rated peak tube potential for the system and at the maximum rated product of tube current and exposure time (mAs) for that peak tube potential. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

10. Collimation.

a. The mammographic system shall be provided with means to limit the useful beam such that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor at any designated SID except the edge of

the image receptor designed to be adjacent to the chest wall where the X-ray field may not extend beyond this edge by more than 2% of the SID.

b. Means for visually defining the perimeter of the X-ray field shall be provided. The total misalignment of the edges of the visually defined field with the respective edges of the X-ray field along either the length or width of the visually defined field shall not exceed 2% of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the X-ray beam.

11. Accuracy of kVp. Deviation of actual kVp from the indicated kVp shall not exceed the limits specified by the manufacturer of the X-ray system, or, the actual kVp shall be within ±2 kVp of the indicated kVp, whichever limit is more restrictive.

12. Automatic exposure control performance. In addition to 12 VAC 5-481-1620 D, mammographic systems in the AEC mode shall be able to maintain constant film density to within an optical density of ± 0.3 of the average optical density over the kVp range used clinically, using phantoms of BR-12 or other breast equivalent material thicknesses of two centimeters to six centimeters. If the facility has established a technique chart that utilizes varying technical factors for different breast thicknesses, those adjustments in technique may be used when performing this test.

13. Radiation output minimum. At 28 kVp, with a focal spot meeting the requirements of 12 VAC 5-481-1650 A 5, the mammographic system shall be capable of sustaining a

minimum output rate of 130 μC/kg/sec (500 mR/sec) for at least three seconds. This output shall be measured at a point 4.2 centimeters from the surface of the breast support device when the SID is at its maximum and the effect of compression paddle attenuation is included.

14. Screen-film contact. Cassettes shall not be used for mammography if poor contact of two or more large areas (>1 cm in diameter) or a section longer than 1 cm and >2 mm in width along the chest wall edge can be seen in a 40 mesh test.

15. Image quality. The mammographic X-ray imaging system shall be capable of providing an image of a 0.75 mm fiber, 0.32 mm speck group, and a 0.75 mm mass from the Conference of Radiation Control Program Directors NEXT '92 phantom (or equivalent) on the standard mammographic image receptor system in use at a facility. Mammograms shall not be taken on patients if this minimum is not met. Any fibers, speck groups and masses larger than those specified shall also be imaged.

16. Dose. The mean glandular dose for one craniocaudal view, measured with the phantom referenced in 12 VAC 5-481-1650 A 15, based on exposure measured at the breast entrance location, and using dose conversion factors specified by the Health Care Financing Administration in their Medicare Mammography Survey Protocols, shall not exceed the following values:

a. 2.0 mGy (200 millirads) for non-grid screen film systems;

b. 3.0 mGy (300 millirads) for screen-film systems with grid.

17. Technique settings. The technique settings used for 12 VAC 5-481-1650 A 15 and 16 shall be those used by the facility for its clinical images of a 50% adipose, 50% glandular, 4.2 cm compressed breast.

B. Quality assurance.

1. Quality assurance program required. The registrant shall have a written, on-going equipment quality assurance program specific to mammographic imaging, covering all components of the diagnostic X-ray imaging system, to ensure consistently high-quality images with minimum patient exposure. Responsibilities under this requirement include providing qualified individuals who are to:

a. Conduct equipment performance monitoring functions;

b. Analyze the monitoring results to determine if there are problems requiring correction;

c. Carry out or arrange for the necessary corrective actions when results of quality control tests including those specified in 12 VAC 5-481-1650 B III indicate the need; and

d. Maintain records for a minimum of two years documenting that actions required under 12 VAC 5-481-1650 B 1 a through 12 VAC 5-481-1650 B 1 c have been completed.

2. Quality assurance program review. At intervals not to exceed 12 months, the registrant shall:

a. Have the annual quality control tests specified in 12 VAC 5-481-1650 B 3 performed by a qualified individual and obtain the results of those tests, incorporating them into the records specified in 12 VAC 5-481-1650 B 1 d; and

b. Conduct a review of the effectiveness of the quality assurance program required in 12 VAC 5-481-1650 B 1 and maintain a written report of such review. Records of
annual reviews shall be maintained for a minimum of two years and shall be available for agency review.

3. Equipment quality control tests. The registrant shall ensure that the following quality control tests are performed when applicable equipment or components are initially installed, or replaced or serviced (if such servicing affects test results), and performed thereafter at least as often as the frequency specified. If such tests indicate the need for corrective action, based on limits defined here, or in 12 VAC 5-481-1650 A, patient mammography may not be performed until correction is accomplished.

a. Processor performance by sensitometric means - daily, or day of use, prior to the first patient exposure. For any mammography registrant using film processors at multiple locations, such as a mobile service, each processor shall be subject to this requirement. Corrective action shall be taken when:

(1) Deviations of ±0.15 or more in optical density from established operating levels occur for readings of mid-density (MD) and density difference (DD) on the sensitometric control charts;

(2) Base plus fog (B+F) exceeds the established operating level by more than 0.03 in optical density.

b. Resolution - upon tube installation or replacement and every 12 months.

c. Focal spot size - upon tube installation or tube replacement only or at least every 12 months, whichever occurs first.

d. Half-value layer - 12 months.

e. kVp accuracy and reproducibility - 12 months.

f. Output reproducibility, mA linearity, and mR/mAs - 12 months.

g. Automatic exposure control reproducibility and performance (response to kVp and phantom thickness variations) - 12 months.

h. Screen-film contact and screen artifact detection - six months.

i. Compression device performance (releases, level of force, etc) - six months.

j. Collimator alignment - 12 months.

k. Primary/secondary barrier transmission - upon initial X-ray system installation and significant modification of the system or the facility.

l. Image quality (using a test "phantom," which simulates the composition of the breast and includes simulations of breast structures) - weekly for stationary systems, on each day of use for mobile systems, and upon significant service or modification of any mammographic system.

m. Densitometer accuracy check - every 12 months.

n. Glandular dose - every 12 months.

o. Image quality - every 12 months.

p. Artifacts - every 12 months.

4. Additional quality control requirements. The registrant shall perform the following observations and procedures according to the frequency noted and record the results. Corrections of problems noted shall be made and recorded. Records shall be maintained over the most recent two year period.

a. Retake Analysis - three months.

b. Viewbox uniformity - six months.

c. Darkroom integrity (safelight condition, light leaks, etc.) - six months.

d. Screen cleaning - weekly.

e. Fixer retention - three months.

C. Additional facility requirements.

1. Masks. Masks shall be provided on the viewboxes to block extraneous light from the viewer's eye when the illuminated surface of the viewbox is larger than the exposed area of the film.

2. Film processing.

a. Film processors utilized for mammography shall be adjusted to and operated at the specifications recommended by the mammographic film manufacturer, or at other settings such that the sensitometric performance is at least equivalent.

b. Clinical films and phantom image quality films shall be processed within 10 hours of exposure.

c. Facilities shall offer to process films before the patient leaves the facility. If the patient chooses not to wait; of there is not developing capabilities, the patient will be notified within two business days if additional films are necessary.

3. Instruments and devices. An image quality phantom, sensitometer, and a calibrated densitometer shall be available to each facility in order to comply with the quality control test frequencies specified in 12 VAC 5-481-1650 B 3.

4. Operator qualifications. The operator of the X-ray machine shall be certified by the American Registry of Radiologic Technologists and shall have had specialized training in mammography meeting the requirements set forth by the FDA under the MQSA of 1992.

5. Physician qualifications. The physician interpreting the mammograms shall be certified by the American Board of Radiology, the American Osteopathic Board of Radiology, or Board eligible, or equivalent, and shall have had specialized training in mammography and image interpretation.

6. Physicist qualifications. The person performing evaluation of mammographic system performance in accordance with these regulations shall meet the requirements set forth in Appendix A.

7. Image retention. Clinical images shall be retained for a minimum of five years or 10 years if no other clinical images are obtained.

8. Retake rate. Corrective action shall be taken if the retake rate exceeds 5%. The retake rate shall be calculated as (repeated + rejected films)/ total number of clinical films.

9. Darkroom fog. Darkroom fog levels shall not exceed 0.05 in optical density when sensitized mammographic film of the type used in the facility is exposed to darkroom conditions with safelight on for two minutes. Film shall be sensitized by exposing it to sufficient light from an appropriate intensifying screen or sensitometer so that after processing an optical density of at least 1.0 is achieved.

10. Facility qualifications. The registrant performing mammography shall be accredited by the American College of Radiology or another agency recognized as a certifying body or have their application pending. The registrant shall also be certified by the FDA or another agency recognized as an accrediting body under the MQSA of 1992 or have a provisional/interim certificate.

PART VII.

USE OF RADIONUCLIDES IN THE HEALING ARTS.

ARTICLE 1.

PURPOSE AND SCOPE.

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12 VAC 5-481-1660. Purpose and scope.

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12 VAC 5-481-1660. Purpose and scope.

Part VII (12 VAC 5-481-1660 et seq.) establishes requirements and provisions for the production, preparation, compounding and use of radionuclides in the healing arts and for issuance of licenses authorizing the medical use of this material. These requirements and provisions provide for the protection of the public health and safety. The requirements and provisions of Part VII (12 VAC 5-481-1660 et seq.) are in addition to, and not in substitution for, others in these regulations. The requirements and provisions of these regulations apply to applicants and licensees subject to Part VII (12 VAC 5-481-1660 et seq.) unless specifically exempted.

ARTICLE 2.

GENERAL REGULATORY REQUIREMENTS.

12 VAC 5-481-1670. License required.

12 VAC 5-481-1680. License amendments.

12 VAC 5-481-1690. Notifications.

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12 VAC 5-481-1670. License required.

A. No person shall manufacture, produce, prepare, compound, acquire, receive, possess, use, or transfer radioactive material for medical use except in accordance with a specific license issued pursuant to these regulations.

B. Unless prohibited by license condition, an individual may receive, possess, use, or transfer radioactive material in accordance with the regulations in Part XII (12 VAC 5-481-2990 et seq.) under the supervision of an authorized user as provided in 12 VAC 5-481-1740.

12 VAC 5-481-1680. License amendments.

A licensee shall apply for and receive a license amendment:

A. Before using radioactive material for a method or type of medical use not permitted by the license issued under Part XII (12 VAC 5-481-2990 et seq.);

B. Before permitting anyone, except a visiting authorized user described in 12 VAC 5-481-1750, to work as an authorized user under the license;

C. Before changing a radiation safety officer or teletherapy physicist;

D. Before receiving radioactive material in excess of the amount authorized on the license;

E. Before adding to or changing the areas of use or address or addresses of use identified in the application or on the license; and

F. Before changing statements, representations, and procedures which are incorporated into the license.

12 VAC 5-481-1690. Notifications.

A licensee shall notify the agency in writing within 30 days when an authorized user, radiation safety officer, or teletherapy physicist, permanently discontinues performance of duties under the license.

ARTICLE 3.

ADDITIONAL REQUIREMENTS.

12 VAC 5-481-1700. ALARA program.

12 VAC 5-481-1710. Radiation safety officer.

12 VAC 5-481-1720. Radiation safety committee.

12 VAC 5-481-1730. Statement of authorities and responsibilities.

12 VAC 5-481-1740. Supervision.

12 VAC 5-481-1750. Visiting authorized user.

12 VAC 5-481-1760. Mobile nuclear medicine service administrative requirements.

12 VAC 5-481-1770. Quality management program.

12 VAC 5-481-1780. Records, notifications, and reports of misadministrations.

12 VAC 5-481-1790. Suppliers.

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12 VAC 5-481-1700. ALARA program.

A. Each licensee shall develop and implement a written program to maintain radiation doses and releases of radioactive material in effluents to unrestricted areas as low as reasonably achievable (ALARA) as defined in Part I (12 VAC 5-481-10 et seq.) of these regulations.

B. To satisfy the requirement of 12 VAC 5-481-1700 A:

1. The management, radiation safety officer, and all authorized users shall participate in the establishment, implementation, and operation of the program as required by these regulations or the radiation safety committee; or

2. For licensees that are not medical institutions, management and all authorized users shall participate in the program as required by the radiation safety officer.

C. The ALARA program shall include an annual review by the radiation safety committee for licensees that are medical institutions, or management and the radiation safety officer for licensees that are not medical institutions, of summaries of the types and amounts of radioactive material used, occupational dose reports, and continuing education and training for all personnel who work with or in the vicinity of radioactive material. The purpose of the review is to ensure that individuals make every reasonable effort to maintain occupational doses, doses to the general public, and releases of radioactive material as low as reasonably achievable, taking into account the state of technology, and the cost of improvements in relation to benefits.

D. The licensee shall retain a current written description of the ALARA program for the duration of the license. The written description shall include:

1. A commitment by management to keep occupational doses as low as reasonably achievable;

2. A requirement that the radiation safety officer brief management once each year on the radiation safety program;

3. Personnel exposure investigational levels as established in accordance with 12 VAC 5-481-1720 B 8 that, when exceeded, will initiate an investigation by the radiation safety officer of the cause of the exposure; and

4. Personnel exposure action levels that, when exceeded, will initiate a prompt investigation by the radiation safety officer of the cause of the exposure and a consideration of actions that might be taken to reduce the probability of recurrence.

12 VAC 5-481-1710. Radiation safety officer.

A. A licensee shall appoint a radiation safety officer responsible for implementing the radiation safety program. The licensee, through the radiation safety officer, shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's radioactive material program.

B. The radiation safety officer shall:

1. Investigate overexposures, misadministrations, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, disposals, and other deviations from approved radiation safety practice and implement corrective actions as necessary;

2. Implement written policy and procedures for:

a. Authorizing the purchase of radioactive material;

b. Receiving and opening packages of radioactive material;

c. Storing radioactive material;

d. Keeping an inventory record of radioactive material;

e. Using radioactive material safely;

f. Taking emergency action if control of radioactive material is lost;

g. Performing periodic radiation surveys;

h. Performing checks and calibrations of survey instruments and other safety equipment;

i. Disposing of radioactive material;

j. Training personnel who work in or frequent areas where radioactive material is used or stored; and

k. Keeping a copy of all records and reports required by the agency regulations, a copy of these regulations, a copy of each licensing request and license and amendments, and the written policy and procedures required by the regulations; and

3. For medical use not sited at a medical institution, approve or disapprove radiation safety program changes with the advice and consent of management prior to submittal to the agency for licensing action; or

4. For medical use sited at a medical institution, assist the radiation safety committee in the performance of its duties.

12 VAC 5-481-1720. Radiation safety committee.

Each medical institution licensee shall establish a radiation safety committee to oversee the use of radioactive material.

A. The Committee shall meet the following administrative requirements:

1. Membership must consist of at least three individuals and shall include an authorized user of each type of use permitted by the license, the radiation safety officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a radiation safety officer. Other members may be included as the licensee deems appropriate;

2. The Committee shall meet at least once each calendar quarter;

3. To establish a quorum and to conduct business, one-half of the Committee's membership shall be present, including the radiation safety officer and the management's representative;

4. The minutes of each radiation safety committee meeting shall include:

a. The date of the meeting;

b. Members present;

c. Members absent;

d. Summary of deliberations and discussions;

e. Recommended actions and the numerical results of all ballots; and

f. Documentation of any reviews required in 12 VAC 5-481-1700 C and 12 VAC 5-481-1720 B;

5. The Committee shall provide each member with a copy of the meeting minutes, and retain one copy until the agency authorizes its disposition.

B. To oversee the use of licensed material, the committee shall:

1. Be responsible for monitoring the institutional program to maintain occupational doses as low as reasonably achievable;

2. Review, on the basis of safety and with regard to the training and experience standards of Part XII (12 VAC 5-481-2990 et seq.), and approve or disapprove any individual who is to be listed as an authorized user, the radiation safety officer, or teletherapy physicist before submitting a license application or request for amendment or renewal;

3. Review on the basis of safety and approve or disapprove each proposed method of use of radioactive material;

4. Review on the basis of safety, and approve with the advice and consent of the radiation safety officer and the management representative, or disapprove procedures and radiation safety program changes prior to submittal to the agency for licensing action;

5. Review quarterly, with the assistance of the radiation safety officer, occupational radiation exposure records of all personnel working with radioactive material;

6. Review quarterly, with the assistance of the radiation safety officer, all incidents involving radioactive material with respect to cause and subsequent actions taken;

7. Review annually, with the assistance of the radiation safety officer, the radioactive material program; and

8. Establish a table of investigational and action levels for occupational dose that, when exceeded, will initiate investigations and/or considerations of action by the radiation safety officer.

12 VAC 5-481-1730. Statement of authorities and responsibilities.

A. A licensee shall provide sufficient authority and organizational freedom to the radiation safety officer and the radiation safety committee to:

1. Identify radiation safety problems;

2. Initiate, recommend, or provide solutions; and

3. Verify implementation of corrective actions.

B. A licensee shall establish in writing the authorities, duties, responsibilities, and radiation safety activities of the radiation safety officer and the radiation safety committee.

12 VAC 5-481-1740. Supervision.

A. A licensee who permits the receipt, possession, production, preparation, compounding, use, or transfer of radioactive material by an individual under the supervision of an authorized user as allowed by 12 VAC 5-481-1670 shall:

1. Instruct the supervised individual in the principles of radiation safety appropriate to that individual's use of radioactive material and in the licensee's written quality management program;

2. Periodically review the supervised individual's use of radioactive material, the records kept to reflect this use, and provide reinstruction as needed;

3. Require an authorized user to be immediately available to communicate with the supervised individual; and

4. Require that only those individuals permitted under state and local regulations and specifically trained, and designated by the authorized user, be permitted to administer radionuclides or radiation to patients.

B. A licensee shall require the supervised individual receiving, possessing, producing, preparing, compounding, using or transferring radioactive material under 12 VAC 5-481-1670 to:

1. Follow the instructions of the supervising authorized user;

2. Follow the written radiation safety and quality management procedures established by the licensee; and

3. Comply with these regulations and the license conditions with respect to the use of radioactive material.

12 VAC 5-481-1750. Visiting authorized user.

A. A licensee may permit any visiting authorized user to use licensed material for medical use under the terms of the licensee's license for 60 days each year if:

1. The visiting authorized user has the prior written permission of the licensee's management for licensee's that are not medical institutions and, if the use occurs on behalf of an institution, prior written permission shall occur by the institution's radiation safety committee;

2. The licensee has a copy of an agency, Agreement State, Licensing State or the Nuclear Regulatory Commission license that identifies the visiting authorized user by name as an authorized user for medical use; and

3. Only those procedures for which the visiting authorized user is specifically authorized by an agency, Agreement State, Licensing State or the Nuclear Regulatory Commission license are performed by that individual.

B. A licensee need not apply for a license amendment in order to permit a visiting authorized user to use licensed material as described in 12 VAC 5-481-1750 A.

C. A licensee shall retain copies of the records specified in 12 VAC 5-481-1750 A for three years from the date of the last visit.

12 VAC 5-481-1760. Mobile nuclear medicine service administrative requirements.

A. The agency shall license mobile nuclear medicine services and/or clients of such services. The mobile nuclear medicine service shall be licensed if the service receives, uses or possesses radioactive material. The client of the mobile nuclear medicine service shall be licensed if the client receives or possesses radioactive material to be used by a mobile nuclear medicine service.

B. Mobile nuclear medicine service licensees shall retain for the duration of service a letter signed by the management of each location where services are rendered that authorizes use of radioactive material. If the client is licensed, the letter shall document procedures for notification, receipt, storage and documentation of transfer of radioactive material delivered to the client's location for use by the mobile nuclear medicine service.

C. A mobile nuclear medicine service shall not have radioactive material delivered directly from the manufacturer or the distributor to the client's address of use, unless the client has a license. Radioactive material delivered to the client's address of use shall be received and handled in conformance with the client's license.

D. A mobile nuclear medicine service shall inform a responsible individual, such as a representative of management or a Registered Nurse in charge of the patient or the Registered Nurse in charge of the nursing unit, who is on site at each client's address of use at the time that radiopharmaceuticals are being administered.

12 VAC 5-481-1770. Quality management program.

A. Each licensee shall establish and maintain a written quality management program to provide assurance that radioactive material or radiation therefrom will be administered as directed by the authorized user. The quality management program shall include written policies and procedures to meet the following specific objectives:

1. That, prior to administration, a written directive is prepared for:

a. Any teletherapy radiation dose;

b. Any gamma stereotactic radiosurgery radiation dose;

c. Any brachytherapy radiation dose;

d. Any administration of quantities greater than 1.11 megabecquerels (30 mCi) of either sodium iodide I-125 or I-131; or

e. Any therapeutic administration of a radiopharmaceutical, other than sodium iodide I-125 or I-131;

(NOTE: 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 will be acceptable, provided that the oral revision

is documented immediately in the patient's record and a revised written directive is signed by the authorized user within 48 hours of the oral revision. Also, a written revision to an existing written directive may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next teletherapy fractional dose. 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 will be acceptable, provided that the information contained in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive.)

2. That, prior to each administration, the patient's identity is verified by more than one method as the individual named in the written directive;

3. That final plans of treatment and related calculations for brachytherapy, teletherapy, and gamma stereotactic radiosurgery are in accordance with the respective written directives;

4. That each administration is in accordance with the written directive; and

5. That any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

B. Each licensee shall:

1. Develop procedures for and conduct a review of the quality management program including, since the last review, an evaluation of a representative sample of patient administrations, all recordable events, and all misadministrations to verify compliance with all aspects of the quality management program; these reviews shall be conducted at intervals no greater than 12 months;

2. Evaluate each of these reviews to determine the effectiveness of the quality management program and, if required, make modifications to meet the objectives of 12 VAC 5-481-1770 A; and

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

C. The licensee shall evaluate and respond to each recordable event, within 30 days after discovery of the recordable event, by:

1. Assembling the relevant facts including the cause;

2. Identifying what, if any, corrective action is required to prevent recurrence; and

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

D. Each licensee shall retain:

1. Each written directive; and

2. A record of each administered radiation dose or radiopharmaceutical dosage where a written directive is required in 12 VAC 5-481-1770 A 1, in an auditable form, for three years after the date of administration.

E. The licensee may make modifications to the quality management program to increase the program's efficiency provided the program's effectiveness is not decreased.

12 VAC 5-481-1780. Records, notifications, and reports of misadministrations.

A. For a misadministration:

1. The licensee shall notify the agency by telephone no later than 24 hours after discovery of the misadministration;

2. The licensee shall submit a written report to the agency within 15 days after discovery of the misadministration. The written report must include the licensee's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the patient; what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the licensee notified the patient, or the patient's responsible relative or guardian (this person will be subsequently referred to as "the

patient"), and if not, why not, and if the patient was notified, what information was provided to the patient. The report must not include the patient's name or other information that could lead to identification of the patient;

3. The licensee shall notify the referring physician and also notify the patient of the misadministration not later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the patient or that, based on medical judgement, telling the patient would be harmful. The licensee is not required to notify the patient without first consulting the referring physician. If the referring physician or patient cannot be reached within 24 hours, the licensee shall notify the patient as soon as possible thereafter. The licensee may not delay any appropriate medical care for the patient, including any necessary remedial care as a result of the misadministration, because of any delay in notification;

4. If the patient was notified, the licensee shall also furnish, within 15 days after discovery of the misadministration, a written report to the patient by sending either:

(a) A copy of the report that was submitted to the agency; or

(b) A brief description of both the event and the consequences, as they may affect the patient, provided a statement is included that the report submitted to the agency can be obtained from the licensee.

B. Each licensee shall retain a record of each misadministration for five years. The record shall contain the names of all individuals involved (including the prescribing physician, allied health personnel, the patient, and the patient's referring physician), the patient's social security number or identification number if one has been assigned, a brief description of the misadministration, why it occurred, the effect on the patient, what improvements are needed to prevent recurrence, and the actions taken to prevent recurrence.

C. Aside from the notification requirement, nothing in 12 VAC 5-481-1780 A and 12 VAC 5-481-1780 B shall affect any rights or duties of licensees and physicians in relation to each other, patients, or the patient's responsible relatives or guardians.

12 VAC 5-481-1790. Suppliers.

A licensee shall use for medical use only:

A. Radioactive material manufactured, produced, labeled, prepared, compounded, packaged, and distributed in accordance with a license issued pursuant to these regulations or the equivalent regulations of another Agreement State, a Licensing State or the Nuclear Regulatory Commission; and

B. Reagent kits, radiopharmaceuticals, and/or radiobiologics that have been manufactured, labeled, packaged, and distributed in accordance with an approval issued by the Food and Drug Administration; or

C. Radiopharmaceuticals compounded from a prescription in accordance with the regulations of the State Board of Pharmacy.

D. Teletherapy and brachytherapy sources manufactured and distributed in accordance with a license issued pursuant to these regulations, or the equivalent regulations of another Agreement State, a Licensing State, or the Nuclear Regulatory Commission.

ARTICLE 4.

SPECIFIC REQUIREMENTS.

12 VAC 5-481-1800. Quality control of diagnostic equipment

12 VAC 5-481-1810. Possession, use, calibration, and check of dose calibrators

12 VAC 5-481-1820. Calibration and check of survey instruments

12 VAC 5-481-1830. Assay of radiopharmaceutical dosages

12 VAC 5-481-1840. Authorization for calibration and reference sources

12 VAC 5-481-1850. Requirements for possession of sealed sources and brachytherapy sources

12 VAC 5-481-1860. Syringe shields

12 VAC 5-481-1870. Syringe labels

12 VAC 5-481-1880. Vial shields

12 VAC 5-481-1890. Vial shield labels

12 VAC 5-481-1900. Surveys for ambient radiation dose rate and contamination

12 VAC 5-481-1910. Release of patients containing radiopharmaceuticals or permanent implants

12 VAC 5-481-1920. Mobile nuclear medicine service technical requirements

12 VAC 5-481-1930. Storage of volatiles and gases

12 VAC 5-481-1940. Decay-in-storage

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12 VAC 5-481-1800. Quality control of diagnostic equipment.

Each licensee shall establish written quality control procedures for all diagnostic equipment used for radionuclide studies. As a minimum, quality control procedures and frequencies shall be those recommended by equipment manufacturers or procedures which have been approved by the agency. The licensee shall conduct quality control procedures in accordance with written procedures.

12 VAC 5-481-1810. Possession, use, calibration, and check of dose calibrators.

A. A medical use licensee authorized to administer radiopharmaceuticals shall possess a dose calibrator and use it to measure the amount of activity administered to each patient. In the case where the ionization type dose calibrator cannot be used effectively to verify administered activity, the licensee shall use an alternative method. Any alternative method to the use of a dose calibrator shall be approved by the agency in writing. Any alternative method shall provide for acceptable verification of constancy, accuracy, linearity, and geometry dependence as applicable.

B. Each licensee shall establish written quality control procedures for all dose calibrators used for measuring the amount of activity administered to a patient. As a minimum, quality control

procedures and frequencies shall be those recommended by the American National Standards Institute in ANSI N42.13-1986 or the licensee shall:

1. Check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use. The check shall be done on a frequently used setting with a sealed source of not less than 1.85 megabecquerels (50 mCi) of any photon-emitting radionuclide with a half-life greater than 90 days;

2. Test each dose calibrator for accuracy upon installation and at intervals not to exceed 12 months thereafter by assaying at least two sealed sources containing different radionuclides with activities of at least 1.85 megabecquerels (50 mCi) each. The activity of one source shall be determined by the manufacturer to be within 5% of the stated activity. All other sources used for this test shall be within 10% of the stated activity. All sources used to satisfy the accuracy test shall be calibration sources traceable to the National Institute of Standards and Technology or other standards recognized as being equivalent by the National Institute of Standards and Technology;

3. Test each dose calibrator for linearity upon installation and at intervals not to exceed three months thereafter over the range of use between 370 kilobecquerels (10 mCi) and the highest dosage that will be assayed; and

4. Test each dose calibrator for geometry dependence upon installation over the range of volumes and volume configurations for which it will be used. The licensee shall keep a record of this test for the duration of the use of the dose calibrator.

C. A licensee shall mathematically correct dosage readings for any geometry or linearity error that exceeds 10% if the dosage is greater than 370 kilobecquerels (10 mCi) and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds 10%.

D. A licensee shall also perform checks and tests required by 12 VAC 5-481-1810 B following adjustment or repair of the dose calibrator.

E. A licensee shall retain a record of each check and test required by 12 VAC 5-481-1810 for three years. The records required by 12 VAC 5-481-1810 B shall include:

1. For 12 VAC 5-481-1810 B 1, the model and serial number of the dose calibrator, the identity and calibrated activity of the radionuclide contained in the check source, the date of the check, the activity measured, the instrument settings, and the initials of the individual who performed the check;

2. For 12 VAC 5-481-1810 B 2, the model and serial number of the dose calibrator, the model and serial number of each source used and the identity of the radionuclide contained in the source and its activity, the date of the test, the results of the test, the instrument settings, and the signature of the individual who performed the test;

3. For 12 VAC 5-481-1810 B 3, the model and serial number of the dose calibrator, the calculated activities, the measured activities, the date of the test, and the signature of the individual who performed the test; and

4. For 12 VAC 5-481-1810 B 4, the model and serial number of the dose calibrator, the configuration and calibrated activity of the source measured, the activity of the source, the activity measured and the instrument setting for each volume measured, the date of the test, and the signature of the individual who performed the test.

12 VAC 5-481-1820. Calibration and check of survey instruments.

A. A licensee shall ensure that the survey instruments used to show compliance with Part XII (12 VAC 5-481-2990 et seq.) have been calibrated before first use, annually, and following repair.

B. To satisfy the requirements of 12 VAC 5-481-1820 A, the licensee shall:

1. Calibrate all required scale readings up to 10 millisieverts (1000 mrem) per hour with a radiation source;

2. For each scale that shall be calibrated, calibrate two readings separated by at least 50% of scale rating; and

3. Conspicuously note on the instrument the apparent dose rate from a dedicated check source as determined at the time of calibration, and the date of calibration.

C. To satisfy the requirements of 12 VAC 5-481-1820 B, the licensee shall consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more

than 10%; and consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 20% if a correction chart or graph is conspicuously attached to the instrument.

D. A licensee shall check each survey instrument for proper operation with the dedicated check source before each use. The licensee is not required to keep records of these checks.

E. The licensee shall retain a record of each calibration required in 12 VAC 5-481-1820 A for three years. The record shall include:

1. A description of the calibration procedure; and

2. A description of the source used and the certified dose rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, the signature of the individual who performed the calibration, and the date of calibration.

F. To meet the requirements of 12 VAC 5-481-1820 A through 12 VAC 5-481-1820 C, the licensee may obtain the services of individuals licensed by the agency, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State to perform calibrations of survey instruments. Records of calibrations which contain information required by 12 VAC 5-481-1820 E shall be maintained by the licensee.

12 VAC 5-481-1830. Assay of radiopharmaceutical dosages.

A licensee shall:

A. Assay, within 30 minutes before medical use, the activity of each radiopharmaceutical dosage that contains more than 370 kilobecquerels (10 mCi) of a photon-emitting radionuclide;

B. Assay, before medical use, the activity of each radiopharmaceutical dosage emitting alpha and/or beta radiation as the radiation of principal interest, unless such radiopharmaceutical has been obtained:

1. In unit dose form, calibrated by the supplier for individual patients; and

2. From a supplier which participates in a measurement quality assurance program with the National Institute of Standards and Technology, and which is designed to ensure that unit doses have a calibration traceable to a national standard;

C. Retain a record of the assays or calibrations required by 12 VAC 5-481-1820 A and B for three years. To satisfy this requirement, the record shall contain the:

1. Radiopharmaceutical, or the radionuclide administered;

2. Patient's name, and identification number if one has been assigned;

3. Prescribed dosage and measured activity of the dosage at the time of assay, or a notation that the total activity was determined by a calibration traceable to a national standard;

4. Date and time of the assay or calibration and the date and time of the administration; and

5. Initials of the individual who performed the assay or documentation of the supplier's participation in the measurement quality assurance program specified in 12 VAC 5-481-1820 B.

12 VAC 5-481-1840. Authorization for calibration and reference sources.

Any person authorized by 12 VAC 5-481-1670 for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration and reference use:

A. Sealed sources manufactured and distributed by persons specifically licensed pursuant to Part III (12 VAC 5-481-380 et seq.) of these regulations or equivalent provisions of the Nuclear Regulatory Commission, Agreement State or Licensing State and that do not exceed 555 megabecquerels (15 mCi) each;

B. Any radioactive material listed in 12 VAC 5-481-1950 or 12 VAC 5-481-1970 with a half-life of 100 days or less in individual amounts not to exceed 555 megabecquerels (15 mCi);

C. Any radioactive material listed in 12 VAC 5-481-1950 or 12 VAC 5-481-1970 with a half-life greater than 100 days in individual amounts not to exceed 7.4 megabecquerels (200 mCi) each; and

D. Technetium-99m in individual amounts not to exceed 1.85 gigabecquerels (50 mCi).

12 VAC 5-481-1850. Requirements for possession of sealed sources and brachytherapy sources.

A. A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer or equivalent instructions approved by the agency and shall maintain the instructions for the duration of source use in a legible form convenient to users.

B. A licensee in possession of a sealed source shall assure that:

1. The source is tested for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within six months before transfer to the licensee; and

2. The source is tested for leakage at intervals not to exceed six months or at intervals approved by the agency, another Agreement State, a Licensing State or the Nuclear Regulatory Commission.

C. To satisfy the leak test requirements of 12 VAC 5-481-1850 B, the licensee shall assure that:

1. Leak tests are capable of detecting the presence of 185 becquerels (0.005 mCi) of radioactive material on the test sample, or in the case of radium, the escape of radon at the rate of 37 becquerels (0.001 mCi) per 24 hours;

2. Test samples are taken from the source or from the surfaces of the device in which the source is mounted or stored on which radioactive contamination might be expected to accumulate; and

3. Test samples are taken when the device containing the source is in the "off" position.

D. A licensee shall retain leak test records for five years. The records shall contain the model number, and serial number, if assigned, of each source tested, the identity of each source radionuclide and its estimated activity, the measured activity of each test sample expressed in becquerels (mCi), a description of the method used to measure each test sample, the date of the test, and the signature of the individual who performed the test.

E. If the leak test reveals the presence of 185 becquerels (0.005 mCi) or more of removable contamination, the licensee shall:

1. Immediately withdraw the sealed source from use and store, repair or dispose of it in accordance with the requirements of Part IV (12 VAC 5-481-600 et seq.) of these regulations; and

2. File a report with the agency within five days of receiving the leak test results describing the equipment involved, the test results, and the action taken.

F. A licensee need not perform a leak test on the following sources:

1. Sources containing only radioactive material with a half-life of less than 30 days;

2. Sources containing only radioactive material as a gas;

3. Sources containing 3.7 megabecquerels (100 mCi) or less of beta- or photon-emitting material or 370 kilobecquerels (10 mCi) or less of alpha-emitting material; and

4. Seeds of iridium-192 encased in nylon ribbon; and

5. Sources stored and not being used. The licensee shall, however, test each such source for leakage before any use or transfer unless it has been tested for leakage within six months before the date of use or transfer.

G. A licensee in possession of a sealed source or brachytherapy source shall conduct a physical inventory of all such sources at intervals not to exceed three months. The licensee shall retain each inventory record for five years. The inventory records shall contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its estimated activity, the location of each source, date of the inventory, and the signature of the individual who performed the inventory.

H. A licensee in possession of a sealed source or brachytherapy source shall survey with a radiation survey instrument at intervals not to exceed three months all areas where such sources are stored. This does not apply to teletherapy sources in teletherapy units or sealed sources in diagnostic devices.

I. A licensee shall retain a record of each survey required in 12 VAC 5-481-1850 H for three years. The record shall include the date of the survey, a sketch of each area that was surveyed, the measured dose rate at several points in each area expressed in microsieverts (mrem) per hour, the model number and serial number of the survey instrument used to make the survey, and the signature of the individual who performed the survey.

12 VAC 5-481-1860. Syringe shields.

A. A licensee shall keep syringes that contain radioactive material to be administered in an appropriate radiation shield or shielded area.

B. A licensee shall require each individual who prepares or administers radiopharmaceuticals to use an appropriate syringe radiation shield unless the use of the shield is contraindicated for that patient.

12 VAC 5-481-1870. Syringe labels.

Unless utilized immediately, a licensee shall conspicuously identify each syringe, or syringe radiation shield as to contents or intended patient.

12 VAC 5-481-1880. Vial shields.

A licensee shall require each individual preparing or handling a vial that contains a radiopharmaceutical to keep the vial in a vial radiation shield.

12 VAC 5-481-1890. Vial shield labels.

A licensee shall conspicuously label each vial radiation shield that contains a vial of a radiopharmaceutical with the radiopharmaceutical name or its abbreviation.

12 VAC 5-481-1900. Surveys for ambient radiation dose rate and contamination.

A. A licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are prepared for use or administered.

B. A licensee shall survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceuticals or radioactive wastes are stored.

C. A licensee shall conduct the surveys required by 12 VAC 5-481-626 A and B so as to able to measure dose rates as low as one microsievert (0.1 mrem) per hour.

D. A licensee shall establish dose rate action levels for the surveys required by 12 VAC 5-481-1900 A and B and shall require that the individual performing the survey immediately notify the radiation safety officer if a dose rate exceeds an action level.

E. A licensee shall survey for removable contamination each day of use all areas where radiopharmaceuticals are prepared for use or administered and each week where radioactive materials are stored.

F. A licensee shall conduct the surveys required by 12 VAC 5-481-1900 E so as to be able to detect contamination on each wipe sample of 33.3 becquerels (2000 dpm).

G. A licensee shall establish removable contamination action levels for the surveys required by 12 VAC 5-481-1900 E and shall require that the individual performing the survey immediately notify the radiation safety officer if contamination exceeds action levels.

H. A licensee shall retain a record of each survey required by 12 VAC 5-481-1900 A, 12 VAC 5-481-1900 B and 12 VAC 5-481-1900 E for three years. The record must include the date of the survey, a sketch of each area surveyed, action levels established for each area, the measured dose rate at several points in each area expressed in microsieverts (mrem) per hour or the removable contamination in each area expressed in becquerels (dpm) per 100 square centimeters, the serial number and the model number of the instrument used to make the survey or analyze the samples, and the initials of the individual who performed the survey.

12 VAC 5-481-1910. Release of patients containing radiopharmaceuticals or permanent implants.

A. A licensee shall not authorize release from confinement for medical care any patient administered a radiopharmaceutical until either:

1. The dose rate from the patient is less than 50 mSv (5 millirems) per hour at a distance of one meter; or

2. The activity in the patient is less than 1.11 GBq (30 millicuries).

B. A licensee shall not authorize release from confinement for medical care any patient administered a permanent implant until the dose rate from the patient is less than 50 mSv (5 millirems) per hour at a distance of one meter.

12 VAC 5-481-1920. Mobile nuclear medicine service technical requirements.

A licensee providing mobile nuclear medicine service shall:

A. Transport to each address of use only syringes or vials containing prepared radiopharmaceuticals or radiopharmaceuticals that are intended for reconstitution of radiopharmaceutical kits;

B. Bring into each area of use all radioactive material to be used and, before leaving, remove all unused radioactive material and associated radioactive waste;

C. Secure or keep under constant surveillance and immediate control all radioactive material when in transit or at an area of use;

D. In addition to complying with 12 VAC 5-481-1810 and 12 VAC 5-481-1820, check survey instruments and dose calibrators for constancy and response, and check all other transported equipment for proper function before medical use at each area of use;

E. Carry a survey meter calibrated in accordance with 12 VAC 5-481-1820 in each vehicle that is being used to transport radioactive material, and, before leaving a client area of use, survey all areas of radiopharmaceutical use with a radiation detection survey instrument, including a survey for removable contamination, to ensure that all radiopharmaceuticals and all associated radioactive waste have been removed;

F. Retain a record of each survey required by 12 VAC 5-481-1920 E for three years. The record must include the date of the survey, a plan of each area that was surveyed, the measured dose rate at several points in each area of use expressed in microsieverts (mrem) per hour, the removable contamination in each area expressed in becquerels (dpm) per 100 square centimeters, the model and serial number of the instrument used to make the survey, and the initials of the individual who performed the survey; and

G. Use radioactive gases only in areas of use and under conditions which have been evaluated and approved by the agency for compliance with airborne release standards.

12 VAC 5-481-1930. Storage of volatiles and gases.

A. A licensee shall store volatile radiopharmaceuticals and radioactive gases in the shippers' radiation shield and container.

B. A licensee shall store and use a multidose container in a properly functioning fume hood.

12 VAC 5-481-1940. Decay-in-storage.

A. Before disposal in ordinary trash, a licensee shall hold radioactive material for decay-in-storage and is exempt from the waste disposal requirements of Part IV (12 VAC 5-481-600 et seq.) of these regulations if the licensee:

1. Holds radioactive material for decay a minimum of 10 half-lives;

2. Monitors radioactive material at the container surface before disposal as ordinary trash and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey instrument set on its most sensitive scale and with no interposed shielding;

3. Removes or obliterates all radiation labels; and

4. Separates and monitors each generator column individually with all radiation shielding removed to ensure that its contents have decayed to background radiation level before disposal.

B. For radioactive material disposed in accordance with 12 VAC 5-481-1940 A, the licensee shall retain a record of each disposal for three years. The record must include the date of the disposal, the date on which the radioactive material was placed in storage, the radionuclides disposed, the model and serial number of the survey instrument used, the background dose rate, the radiation dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

ARTICLE 5.

SPECIFIC REQUIREMENTS FOR THE USE OF RADIOPHARMACEUTICALS FOR UPTAKE, DILUTION, OR EXCRETION STUDIES.

12 VAC 5-481-1950. Use of radiopharmaceuticals for uptake, dilution, or excretion studies.

12 VAC 5-481-1960. Possession of survey instrument.

12 VAC 5-481-1950. Use of radiopharmaceuticals for uptake, dilution, or excretion studies.

A licensee may use any radioactive material in a radiopharmaceutical for a diagnostic use involving measurements of uptake, dilution, or excretion:

A. Which has been granted acceptance or approval by the Food and Drug Administration; or

B. Which is prepared and compounded in accordance with the regulations of the State Board of Pharmacy.

12 VAC 5-481-1960. Possession of survey instrument.

A licensee authorized to use radioactive material for uptake, dilution, and excretion studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range one microsievert (0.1 mrem) per hour to 500 microsieverts (50 mrem) per hour. The instrument shall be operable and calibrated in accordance with 12 VAC 5-481-1820.

ARTICLE 6.

SPECIFIC REQUIREMENTS FOR THE USE OF RADIOPHARMACEUTICALS, GENERATORS, AND REAGENT KITS FOR IMAGING AND LOCALIZATION STUDIES.

12 VAC 5-481-1970. Use of radiopharmaceuticals, generators, and reagent kits for imaging and localization studies.

12 VAC 5-481-1980. Radionuclide contaminants.

12 VAC 5-481-1990. Control of aerosols and gases.

12 VAC 5-481-2000. Possession of survey instruments.

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12 VAC 5-481-1970. Use of radiopharmaceuticals, generators, and reagent kits for imaging and localization studies.

A licensee may use any radioactive material in a diagnostic radiopharmaceutical (except aerosol or gaseous forms) or any generator or reagent kit for preparation and diagnostic use of a radiopharmaceutical containing radioactive material:

A. Which has been granted acceptance or approval by the Food and Drug Administration; or

B. Which has been prepared and compounded in accordance with the regulations of the State Board of Pharmacy;

C. A licensee shall elute generators in compliance with 12 VAC 5-481-1980;

D. Provided the conditions of 12 VAC 5-481-1990 are met, a licensee shall use radioactive aerosols or gases only if specific application is made to and approved by the agency.

12 VAC 5-481-1980. Radionuclide contaminants.

A. A licensee shall not administer a radiopharmaceutical containing:

1. More than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 mCi of Mo-99 per mCi of Tc-99m);

2. More than 0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 chloride injection (0.02 mCi of Sr-82 per mCi of Rb-82 chloride);

3. More than 0.2 kilobecquerel of strontium-85 per megabecquerel of rubidium-82 chloride injection (0.2 mCi of Sr-85 per mCi of Rb-82).

B. A licensee preparing radiopharmaceuticals from radionuclide generators shall measure the concentration of radionuclide contaminant in each elute or extract, as appropriate for the generator system, to determine compliance with the limits specified in 12 VAC 5-481-1980 A.

C. A licensee who must measure radionuclide contaminant concentration shall retain a record of each measurement for three years. The record shall include, for each elution or extraction tested, the measured activity of the radiopharmaceutical expressed in megabecquerels (mCi), the measured activity of contaminant expressed in kilobecquerels (mCi), the ratio of the measures expressed as kilobecquerels (mCi) of contaminant per megabecquerel (mCi) of radiopharmaceutical, the date of the test, and the initials of the individual who performed the test.

D. A licensee shall report immediately to the agency each occurrence of radionuclide contaminant concentration exceeding the limits specified in 12 VAC 5-481-1980 A.

12 VAC 5-481-1990. Control of aerosols and gases.

A. A licensee who administers radioactive aerosols or gases shall do so with a system that will keep airborne concentrations within the limits prescribed in Part IV (12 VAC 5-481-600 et seq.) of these regulations.

B. The system shall either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container.

C. A licensee shall only administer radioactive gases in rooms that are at negative pressure with respect to surrounding rooms.

D. Before receiving, using, or storing a radioactive gas, the licensee shall calculate the amount of time needed after a release to reduce the concentration in the area of use to the occupational limit listed in Appendix F. The calculation shall be based on the highest activity of gas handled in a single container and the measured available air exhaust rate.

E. A licensee shall post the time calculated in 12 VAC 5-481-1990 D at the area of use and require that, in case of a gas spill, individuals evacuate the room until the posted time has elapsed.

F. A licensee shall check the operation of collection systems monthly and measure the ventilation rates in areas of use at intervals not to exceed six months. Records of these checks and measurements shall be maintained for three years.

G. A copy of the calculations required in 12 VAC 5-481-1990 D shall be recorded and retained for the duration of the license.

12 VAC 5-481-2000. Possession of survey instruments.

A licensee authorized to use radioactive material for imaging and localization studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of one microsievert (0.1 mrem) per hour to 500 microsieverts (50 mrem) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 microsieverts (1 mrem) per hour to 10 millisieverts (1000 mrem) per hour. The instruments shall be operable and calibrated in accordance with 12 VAC 5-481-1820.

ARTICLE 7.

SPECIFIC REQUIREMENTS FOR THE USE OF RADIOPHARMACEUTICALS FOR THERAPY.

12 VAC 5-481-2010. Use of radiopharmaceuticals for therapy.

A licensee may use any radioactive material in a radiopharmaceutical and for a therapeutic use:

A. Which has been granted acceptance or approval by the Food and Drug Administration; or

B. Which has been prepared and compounded in accordance with the regulations of the State Board of Pharmacy.

12 VAC 5-481-2020. Safety instruction.

A. A licensee shall provide oral and written radiation safety instruction for all personnel caring for patients undergoing radiopharmaceutical therapy. Refresher training shall be provided at intervals not to exceed one year.

B. To satisfy 12 VAC 5-481-2020 A, the instruction shall describe the licensee's procedures for:

1. Patient control;

2. Visitor control;

3. Contamination control;

4. Waste control;

5. Notification of the radiation safety officer or authorized user in case of the patient's death or medical emergency; and

6. Training for workers as required by Part X (12 VAC 5-481-2580 et seq.) of these regulations.

C. A licensee shall keep a record of individuals receiving instruction required by 12 VAC 5-481-2020 A, a description of the instruction, the date of instruction, and the name of the individual who gave the instruction. Such record shall be maintained for inspection by the agency for three years.

12 VAC 5-481-2030. Safety precautions.

A. For each patient receiving radiopharmaceutical therapy and hospitalized for compliance with 12 VAC 5-481-1910, a licensee shall:

1. Provide a private room with a private sanitary facility;

2. Post the patient's door with a "Caution: Radioactive Material" sign and note on the door or on the patient's chart where and how long visitors may stay in the patient's room;

3. Authorize visits by individuals under 18 years of age only on a case-by-case basis with the approval of the authorized user after consultation with the radiation safety officer;

4. Promptly after administration of the dosage, measure the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of Part IV (12 VAC 5-481-600 et seq.) of these regulations and retain for three years a record of each survey that includes the time and date of the survey, a plan of the area or list of points surveyed, the measured dose

rate at several points expressed in microsieverts (mrem) per hour, the instrument used to make the survey, and the initials of the individual who made the survey;

5. Either monitor material and items removed from the patient's room to determine that any contamination cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle these materials and items as radioactive waste;

6. Instruct the patient and, where appropriate, the patient's family, orally and in writing concerning radiation safety precautions that will help to keep radiation dose to household members and the public as low as reasonably achievable before authorizing release of the patient;

7. Survey the patient's room and private sanitary facility for removable contamination with a radiation detection survey instrument before assigning another patient to the room. The room must not be reassigned until removable contamination is less than 3.33 becquerels (200 dpm) per 100 square centimeters; and

8. Measure the thyroid burden of each individual who helped prepare or administer a dosage of I-131 within three days after administering the dosage, and retain for the period required by Part IV (12 VAC 5-481-600 et seq.) of these regulations a record of each thyroid burden measurement, date of measurement, the name of the individual whose thyroid burden was measured, and the initials of the individual who made the

measurements. Other procedures acceptable to the agency may be used for individuals who only prepare, but do not administer, doses of stabilized I-131.

B. For each non-hospitalized patient receiving radiopharmaceutical therapy, the licensee shall instruct the patient and, where appropriate, the patient's family, orally and in writing concerning radiation safety precautions that will help to keep radiation doses to the household members and the public as low as reasonably achievable.

C. The radiation safety officer or the authorized user shall be notified immediately if the hospitalized patient dies or has a medical emergency.

12 VAC 5-481-2040. Possession of survey instruments.

A licensee authorized to use radioactive material for radiopharmaceutical therapy shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range one microsievert (0.1 mrem) per hour to 500 microsieverts (50 mrem) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 microsieverts (1 mrem) per hour to 10 millisieverts (1000 mrem) per hour. The instruments shall be operable and calibrated in accordance with 12 VAC 5-481-1820.

ARTICLE 8.

SPECIFIC REQUIREMENTS FOR THE USE OF SEALED SOURCES FOR DIAGNOSIS.

12 VAC 5-481-2050. Use of sealed sources for diagnosis.

12 VAC 5-481-2060. Availability of survey instrument.

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12 VAC 5-481-2050. Use of sealed sources for diagnosis.

A licensee shall use the following sealed sources in accordance with the manufacturer's radiation safety and handling instructions:

A. Iodine-125 as a sealed source in a device for bone mineral analysis;

B. Americium-241 as a sealed source in a device for bone mineral analysis;

C. Gadolinium-153 as a sealed source in a device for bone mineral analysis or in a portable device for imaging; and

D. Iodine-125 as a sealed source in a portable device for imaging.

12 VAC 5-481-2060. Availability of survey instrument.

A licensee authorized to use radioactive material as a sealed source for diagnostic purposes shall have available for use a portable radiation detection survey instrument capable of detecting dose rates over the range one microsievert (0.1 mrem) per hour to 500 microsieverts (50 mrem) per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range 10

microsieverts (1 mrem) per hour to 10 microsieverts (1000 mrem) per hour. The instrument shall be operable and calibrated in accordance with 12 VAC 5-481-1820.

ARTICLE 9.

SPECIFIC REQUIREMENTS FOR THE USE OF SEALED SOURCES FOR BRACHYTHERAPY.

12 VAC 5-481-2070. Use of sources for brachytherapy.

A licensee shall use the following sources in accordance with the manufacturer's radiation safety and handling instructions:

A. Cesium-137 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;

B. Cobalt-60 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;

C. Gold-198 as a sealed source in seeds for interstitial treatment of cancer;

D. Iodine-125 as a sealed source in seeds for interstitial treatment of cancer;

E. Iridium-192 as seeds encased in nylon ribbon for interstitial treatment of cancer;

F. Strontium-90 as a sealed source in an applicator for treatment of superficial eye conditions; and

G. Palladium-103 as a sealed source in seeds for the interstitial treatment of cancer.

12 VAC 5-481-2080. Safety instruction.

A. The licensee shall provide oral and written radiation safety instruction to all personnel caring for a patient receiving implant therapy. Refresher training shall be provided at intervals not to exceed one year.

B. To satisfy 12 VAC 5-481-2080 A, the instruction shall describe:

1. Size and appearance of the brachytherapy sources;

2. Safe handling and shielding instructions in case of a dislodged source;

3. Procedures for patient control;

4. Procedures for visitor control;

5. Procedures for notification of the radiation safety officer or authorized user if the patient dies or has a medical emergency; and

6. Training for workers as required by Part X (12 VAC 5-481-2580 et seq.) of these regulations.

C. A licensee shall maintain a record of individuals receiving instruction required by 12 VAC 5-481-2080 A, a description of the instruction, the date of instruction, and the name of the individual who gave the instruction for three years.

12 VAC 5-481-2090. Safety precautions.

A. For each patient receiving implant therapy a licensee shall:

1. Not place the patient in the same room with a patient who is not receiving radiation therapy unless the licensee can demonstrate compliance with the radiation dose limits for individual members of the public as specified in Part IV (12 VAC 5-481-600 et seq.) of these regulations at a distance of one meter from the implant;

2. Post the patient's door with a "Caution: Radioactive Materials" sign and note on the door or the patient's chart where and how long visitors may stay in the patient's room;

3. Authorize visits by individuals under 18 years of age only on a case-by-case basis with the approval of the authorized user after consultation with the radiation safety officer;

4. Promptly after implanting the sources, survey the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with Part IV (12 VAC 5-481-600 et seq.) of these regulations and retain for three years a record of each survey that includes the time and date of the survey, a sketch of the area or list of points surveyed, the measured dose rate at several points expressed in microsieverts (mrem) per hour, the instrument used to make the survey, and the initials of the individual who made the survey; and

5. Before authorizing the release of a patient administered a permanent implant, instruct the patient, and where appropriate, the patient's family, orally and in writing concerning radiation safety precautions that will help keep the radiation dose to household members and the public as low as reasonably achievable.

B. The radiation safety officer or authorized user shall be notified immediately if the hospitalized patient dies or has a medical emergency.

12 VAC 5-481-2100. Brachytherapy sources inventory.

A. Each time brachytherapy sources are returned to an area of storage from an area of use, the licensee shall immediately count or otherwise verify the number returned to ensure that all sources taken from the storage area have been returned.

B. A licensee shall make a record of brachytherapy source utilization which includes:

1. The names of the individuals permitted to handle the sources;

2. The number and activity of sources removed from storage, the room number of use and patient's name, the time and date they were removed from storage, the number and activity of sources in storage after the removal, and the initials of the individual who removed the sources from storage; and

3. The number and activity of sources returned to storage, the room number of use and patient's name, the time and date they were returned to storage, the number and activity of sources in storage after the return, and the initials of the individual who returned the sources to storage.

C. Immediately after implanting sources in a patient and immediately after removal of sources from a patient, the licensee shall make a radiation survey of the patient and the area of use to confirm that no sources have been misplaced. The licensee shall make a record of each survey.

D. A licensee shall maintain the records required in 12 VAC 5-481-2100 B and C for three years.

12 VAC 5-481-2110. Release of patients treated with temporary implants.

A. Immediately after removing the last temporary implant source from a patient, the licensee shall perform a radiation survey of the patient with a radiation detection survey instrument to confirm that all sources have been removed. The licensee shall not release from confinement for medical care a patient treated by temporary implant until all sources have been removed.

B. A licensee shall maintain a record of patient surveys which demonstrate compliance with 12 VAC 5-481-2110 A for three years. Each record shall include the date of the survey, the name of the patient, the dose rate from the patient expressed as microsieverts (mrem) per hour and measured within one meter from the patient, and the initials of the individual who made the survey.

12 VAC 5-481-2120. Possession of survey instruments.

A licensee authorized to use radioactive material for implant therapy shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range one microsievert (0.1 mrem) per hour to 500 microsieverts (50 mrem) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 microsieverts (mrem) per hour to 10 millisieverts (1000 mrem) per hour. The instruments shall be operable and calibrated in accordance with 12 VAC 5-481-1820.

ARTICLE 10.

SPECIFIC REQUIREMENTS FOR THE USE OF SEALED SOURCES IN TELETHERAPY.

12 VAC 5-481-2130. Use of a sealed source in a teletherapy unit.

A licensee shall use cobalt-60 or cesium-137 as a sealed source in a teletherapy unit for medical use in accordance with the manufacturer's radiation safety and operating instructions.

12 VAC 5-481-2140. Maintenance and repair restrictions.

Only a person specifically licensed by the agency, the Nuclear Regulatory Commission, or an Agreement State to perform teletherapy unit maintenance and repair shall install, relocate, or remove a teletherapy sealed source or a teletherapy unit that contains a sealed source or maintain, adjust, or repair the source drawer, the shutter or other mechanism of a teletherapy unit that could expose the source, reduce the shielding around the source, or result in increased radiation levels.

12 VAC 5-481-2150. Amendments.

In addition to the requirements specified in 12 VAC 5-481-1680, a licensee shall apply for and receive a license amendment before:

A. Making any change in the treatment room shielding;

B. Making any change in the location of the teletherapy unit within the treatment room;

C. Using the teletherapy unit in a manner that could result in increased radiation levels in areas outside the teletherapy treatment room;

D. Relocating the teletherapy unit; or

E. Allowing an individual not listed on the licensee's license to perform the duties of the teletherapy physicist.

12 VAC 5-481-2160. Safety instruction.

A. A licensee shall conspicuously post written instructions at the teletherapy unit console. These instructions shall inform the operator of:

1. The procedure to be followed to ensure that only the patient is in the treatment room before turning the primary beam of radiation "on" to begin a treatment or after a door interlock interruption;

2. The procedure to be followed if the operator is unable to turn the primary beam of radiation "off" with controls outside the treatment room or any other abnormal operation occurs; and

3. The names and telephone numbers of the authorized users and radiation safety officer to be immediately contacted if the teletherapy unit or console operates abnormally.

B. A licensee shall provide instruction in the topics identified in 12 VAC 5-481-2160 A to all individuals who operate a teletherapy unit and shall provide appropriate refresher training to individuals at intervals not to exceed one year.

C. A licensee shall maintain a record of individuals receiving instruction required by 12 VAC 5-481-2160 B, a description of the instruction, the date of instruction, and the name of the individual who gave the instruction for three years.

12 VAC 5-481-2170. Doors, interlocks, and warning systems.

A. A licensee shall control access to the teletherapy room by a door at each entrance.

B. A licensee shall equip each entrance to the teletherapy room with an electrical interlock system that shall:

1. Prevent the operator from turning the primary beam of radiation "on" unless each treatment room entrance door is closed;

2. Turn the beam of radiation "off" immediately when an entrance door is opened; and

3. Prevent the primary beam of radiation from being turned "on" following an interlock interruption until all treatment room entrance doors are closed and the beam on-off control is reset at the console.

C. A licensee shall equip each entrance to the teletherapy room with a conspicuously visible beam condition indicator light.

12 VAC 5-481-2180. Possession of survey instrument.

A licensee authorized to use radioactive material in a teletherapy unit shall possess either a portable radiation detection survey instrument capable of detecting dose rates over the range one microsievert (0.1 mrem) per hour to 500 microsieverts (50 mrem) per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 microsieverts (1 mrem) per hour to 10 microsieverts (1000 mrem) per hour. The instruments shall be operable and calibrated in accordance with 12 VAC 5-481-1820.

12 VAC 5-481-2190. Radiation monitoring device.

A. A licensee shall have in each teletherapy room a permanent radiation monitor capable of continuously monitoring beam status.

B. Each radiation monitor shall be capable of providing visible notice of a teletherapy unit malfunction that results in an exposed or partially exposed source. The visible indicator of high radiation levels shall be observable by an individual entering the teletherapy room.

C. Each radiation monitor shall be equipped with a backup power supply separate from the power supply to the teletherapy unit. This backup power supply may be a battery system.

D. A radiation monitor shall be checked with a dedicated check source for proper operation each day before the teletherapy unit is used for treatment of patients.

E. A licensee shall maintain a record of the check required by 12 VAC 5-481-2190 D. for three years. The record shall include the date of the check, notation that the monitor indicates when the source is exposed, and the initials of the individual who performed the check.

F. If a radiation monitor is inoperable, the licensee shall require any individual entering the teletherapy room to use a survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the source exposure mechanism. The instrument or dosimeter shall be checked with a dedicated check source for proper operation at the beginning of each day of use. The licensee shall keep a record as described in 12 VAC 5-481-2190 E.

G. A licensee shall promptly repair or replace the radiation monitor if it is inoperable.

12 VAC 5-481-2200. Viewing system.

A licensee shall construct or equip each teletherapy room to permit continuous observation of the patient from the teletherapy unit console during irradiation.

12 VAC 5-481-2210. Dosimetry equipment.

A. A licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions shall be met:

1. The system shall have been calibrated by the National Institute of Standards and Technology or by a calibration laboratory accredited by the American Association of

Physicists in Medicine. The calibration shall have been performed within the previous two years and after any servicing that may have affected system calibration; or

2. The system shall have been calibrated within the previous four years; 18 to 30 months after that calibration, the system shall have been intercompared at an intercomparison meeting with another dosimetry system that was calibrated within the past 24 months by the National Institute of Standards and Technology or by a calibration laboratory accredited by the American Association of Physicists in Medicine. The intercomparison meeting shall be sanctioned by a calibration laboratory or radiologic physics center accredited by the American Association of Physicists in Medicine. The results of the intercomparison meeting must have indicated that the calibration factor of the licensee's system had not changed by more than 2%. The licensee shall not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating cobalt-60 teletherapy units, the licensee shall use a teletherapy unit with a cobalt-60 source. When intercomparing dosimetry systems to be used for calibrating cesium-137 teletherapy units, the licensee shall use a teletherapy unit with a cesium-137 source.

B. The licensee shall have available for use a dosimetry system for spot-check measurements. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with 12 VAC 5-481-2210 A. This comparison shall have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system shall be the same system used to meet the requirement in 12 VAC 5-481-2210 A.

C. The licensee shall maintain a record of each calibration, intercomparison, and comparison for the duration of the license. For each calibration, intercomparison, or comparison, the record shall include the date, the model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by 12 VAC 5-481-2210 A and B, the correction factors that were determined, the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that the intercomparison meeting was sanctioned by a calibration laboratory or radiologic physics center accredited by the American Association of Physicists in Medicine.

12 VAC 5-481-2220. Full calibration measurements.

A. A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit:

1. Before the first medical use of the unit;

2. Before medical use under the following conditions:

a. Whenever spot-check measurements indicate that the output differs by more than 5% from the output obtained at the last full calibration corrected mathematically for radioactive decay;

b. Following replacement of the source or following reinstallation of the teletherapy unit in a new location; and

c. Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

3. At intervals not exceeding one year.

B. To satisfy the requirement of 12 VAC 5-481-2220 A, full calibration measurements shall include determination of:

1. The output within 3% for the range of field sizes and for the distance or range of distances used for medical use;

2. The coincidence of the radiation field and the field indicated by the light beam localizing device;

3. The uniformity of the radiation field and its dependence on the orientation of the useful beam;

4. Timer accuracy, constancy, and linearity;

5. "On-off" error; and

6. The accuracy of all distance measuring and localization devices in medical use.

C. A licensee shall use the dosimetry system described in 12 VAC 5-481-2210 to measure the output for one set of exposure conditions. The remaining radiation measurements required in 12 VAC 5-481-2220 B 1 may then be made using a dosimetry system that indicates relative dose rates.

D. A licensee shall make full calibration measurements required by 12 VAC 5-481-2220 A in accordance with the measurements required for annual calibration by "Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy Committee Task Group 40," Medical Physics, Vol. 21, No. 4, 1994, pp. 581-618.

E. A licensee shall correct mathematically the outputs determined in 12 VAC 5-481-2220 B 1 for physical decay for intervals not exceeding one month for cobalt-60 and intervals not exceeding six months for cesium-137.

F. Full calibration measurements required by 12 VAC 5-481-2220 A and physical decay corrections required by 12 VAC 5-481-2220 E shall be performed by a teletherapy physicist named on the licensee's license or authorized by a license issued by the Nuclear Regulatory Commission or an Agreement State to perform such services.

G. A licensee shall maintain a record of each calibration for the duration of the license. The record shall include the date of the calibration, the manufacturer's name, model number, and serial number for both the teletherapy unit and the source, the model numbers and serial numbers of the instruments used to calibrate the teletherapy unit, tables that describe the output of the unit

over the range of field sizes and for the range of distances used in radiation therapy, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, the measured timer accuracy for a typical treatment time, the calculated "on-off" error, the estimated accuracy of each distance measuring or localization device, and the signature of the teletherapy physicist.

12 VAC 5-481-2230. Periodic spot checks.

A. A licensee authorized to use teletherapy units for medical use shall perform output spot checks on each teletherapy unit at intervals not to exceed one month.

B. To satisfy the requirement of 12 VAC 5-481-2230 A, spot checks shall include determination of:

1. Timer constancy and timer linearity over the range of use;

2. "On-off" error;

3. The coincidence of the radiation field and the field indicated by the light beam localizing device;

4. The accuracy of all distance measuring and localization devices used for medical use;

5. The output for one typical set of operating conditions; and

6. The difference between the measurement made in 12 VAC 5-481-2230 B 5 and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

C. A licensee shall use the dosimetry system described in 12 VAC 5-481-2210 to make the spot check required in 12 VAC 5-481-2230 B 5.

D. A licensee shall perform spot checks required by 12 VAC 5-481-2230 A in accordance with procedures established by the teletherapy physicist. The teletherapy physicist does not need to actually perform the output spot-check measurements.

E. A licensee shall have the teletherapy physicist review the results of each output spot check within 15 days. The teletherapy physicist shall promptly notify the licensee in writing of the results of each output spot check. The licensee shall keep a copy of each written notification for two years.

F. A licensee authorized to use a teletherapy unit for medical use shall perform safety spot checks of each teletherapy facility at intervals not to exceed one month.

G. To satisfy the requirements of 12 VAC 5-481-2230 F, safety spot checks shall assure proper operation of:

1. Electrical interlocks at each teletherapy room entrance;

2. Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation restriction of source housing angulation or elevation, carriage or stand travel, and operation of the beam "on-off" mechanism;

3. Beam condition indicator lights on the teletherapy unit, on the control console, and in the facility;

4. Viewing systems;

5. Treatment room doors from inside and outside the treatment room; and

6. Electrically assisted treatment room doors with the teletherapy unit electrical power turned "off."

H. A licensee shall lock the control console in the "off" position if any door interlock malfunctions. No licensee shall use the unit until the interlock system is repaired unless specifically authorized by the agency.

I. A licensee shall promptly repair any system identified in 12 VAC 5-481-2230 G that is not operating properly. The teletherapy unit shall not be used until all repairs are completed.

J. A licensee shall maintain a record of each spot check required by 12 VAC 5-481-2230 A and F for three years. The record shall include the date of the spot check, the manufacturer's name, model number, and serial number for both the teletherapy unit and source, the manufacturer's

name, model number and serial number of the instrument used to measure the output of the teletherapy unit, the timer constancy and linearity, 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 timer constancy and linearity for a typical treatment time, the calculated "on-off" error, the estimated accuracy of each distance measuring or localization device, the difference between the anticipated output and the measured output, notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system and doors, and the signature of the individual who performed the periodic spot check.

12 VAC 5-481-2240. Radiation surveys for teletherapy facilities.

A. Before medical use, after each installation of a teletherapy source, and after making any change for which an amendment is required by 12 VAC 5-481-2150, the licensee shall perform radiation surveys with an operable radiation measurement survey instrument calibrated in accordance with 12 VAC 5-481-1820 to verify that:

1. The maximum and average radiation levels at one meter from the teletherapy source with the source in the "off" position and the collimators set for a normal treatment field do not exceed 100 microsieverts (10 mrem) per hour and 20 microsieverts (2 mrem) per hour, respectively; and

2. With the teletherapy source in the "on" position with the largest clinically available treatment field and with a scattering phantom in the primary beam of radiation, that:

a. Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in Part IV (12 VAC 5-481-600 et seq.) of these regulations; and

b. Radiation levels in unrestricted areas do not exceed the limits specified in Part IV (12 VAC 5-481-600 et seq.) of these regulations.

B. If the results of the surveys required in 12 VAC 5-481-2240 A indicate any radiation levels in excess of the respective limit specified in that paragraph, the licensee shall lock the control in the "off" position and not use the unit:

1. Except as may be necessary to repair, replace, or test the teletherapy unit, the teletherapy unit shielding, or the treatment room shielding; or

2. Until the licensee has received a specific exemption from the agency.

C. A licensee shall maintain a record of the radiation measurements made following installation of a source for the duration of the license. The record shall include the date of the measurements, the reason the survey is required, the manufacturer's name, model number and serial number of the teletherapy unit, the source, and the instrument used to measure radiation levels, each dose rate measured around the teletherapy source while in the "off" position and the average of all measurements, a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in microsieverts (mrem) per hour, the

calculated maximum level of radiation over a period of one week for each restricted and unrestricted area, and the signature of the radiation safety officer.

12 VAC 5-481-2250. Safety spot checks for teletherapy facilities.

A. A licensee shall promptly check all systems listed in 12 VAC 5-481-2230 G for proper function after each installation of a teletherapy source and after making any change for which an amendment is required by 12 VAC 5-481-2150.

B. If the results of the safety spot checks required in 12 VAC 5-481-2250 A indicate the malfunction of any system specified in 12 VAC 5-481-2230, the licensee shall lock the control console in the "off" position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

C. A licensee shall maintain a record of the safety spot checks following installation of a source for three years. The record shall include notations indicating the operability of each entrance door interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system, doors, and the signature of the radiation safety officer.

12 VAC 5-481-2260. Modification of teletherapy unit or room before beginning a treatment program.

If the survey required by 12 VAC 5-481-2240 indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by Part IV (12 VAC 5-481-600 et seq.) of these regulations, before beginning the treatment program the licensee shall:

A. Either equip the unit with stops or add additional radiation shielding to ensure compliance with Part IV (12 VAC 5-481-600 et seq.) of these regulations;

B. Perform the survey required by 12 VAC 5-481-2240 again; and

C. Include in the report required by 12 VAC 5-481-2270 the results of the initial survey, a description of the modification made to comply with 12 VAC 5-481-2260 A, and the results of the second survey; or

D. Request and receive a license amendment under Part IV (12 VAC 5-481-600 et seq.) of these regulations that authorizes radiation levels in unrestricted areas greater than those permitted by Part IV (12 VAC 5-481-600 et seq.) of these regulations.

12 VAC 5-481-2270. Reports of teletherapy surveys, checks, tests, and measurements.

A licensee shall furnish a copy of the records required in 12 VAC 5-481-2240; 12 VAC 5-481-2250; 12 VAC 5-481-2260 and the output from the teletherapy source expressed as grays (or rads) per hour at one meter from the source as determined during the full calibration required in 12 VAC 5-481-2220 to the agency within 30 days following completion of the action that initiated the record requirement.

12 VAC 5-481-2280. Five-year inspection.

A. A licensee shall have each teletherapy unit fully inspected and serviced during teletherapy source replacement or at intervals not to exceed five years, whichever comes first, to assure proper functioning of the source exposure mechanism.

B. This inspection and servicing shall only be performed by persons specifically licensed to do so by the agency, an Agreement State, or the Nuclear Regulatory Commission.

C. A licensee shall maintain a record of the inspection and servicing for the duration of the license. The record shall contain the inspector's name, the inspector's license number, the date of inspection, the manufacturer's name and model number and serial number for both the teletherapy unit and source, a list of components inspected, a list of components serviced and the type of service, a list of components replaced, and the signature of the inspector.

ARTICLE 11.

SPECIFIC REQUIREMENTS FOR TRAINING.

12 VAC 5-481-2290. Radiation safety officer.

12 VAC 5-481-2300. Training for experienced radiation safety officer.

12 VAC 5-481-2310. Training for uptake, dilution, or excretion studies.

12 VAC 5-481-2320. Training for imaging and localization studies.

12 VAC 5-481-2330. Training for therapeutic use of radiopharmaceuticals.

12 VAC 5-481-2340. Training for therapeutic use of brachytherapy sources.

12 VAC 5-481-2350. Training for ophthalmic use of strontium-90.

12 VAC 5-481-2360. Training for use of sealed sources for diagnosis.

12 VAC 5-481-2370. Training for teletherapy.

12 VAC 5-481-2380. Training for teletherapy physicist.

12 VAC 5-481-2390. Training for experienced authorized users.

12 VAC 5-481-2400. Physician training in a three-month program.

12 VAC 5-481-2410. Recentness of training.

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12 VAC 5-481-2290. Radiation safety officer.

Except as provided in 12 VAC 5-481-2300, an individual fulfilling the responsibilities of the radiation safety officer as provided in 12 VAC 5-481-1710 shall:

A. Be certified by the:

1. American Board of Health Physics in Comprehensive Health Physics; or

2. American Board of Radiology in Radiological Physics, Therapeutic Radiological Physics, or Medical Nuclear Physics; or

3. American Board of Nuclear Medicine; or

4. American Board of Science in Nuclear Medicine; or

5. Board of Pharmaceutical Specialties in Nuclear Pharmacy or Science; or

6. American Board of Medical Physics in Radiation Oncology Physics; or

7. Royal College of Physicians and Surgeons of Canada in Nuclear Medicine; or

8. American Osteopathic Board of Radiology; or

9. American Osteopathic Board of Nuclear Medicine; or

B. Have had 200 hours of classroom and laboratory training covering:

1. Radiation physics and instrumentation;

2. Radiation protection;

3. Mathematics pertaining to the use and measurement of radioactivity;

4. Radiation biology;

5. Radiopharmaceutical chemistry; and

6. Have had one year of full-time experience in radiation safety at a medical institution under the supervision of the individual identified as the radiation safety officer on an agency, Agreement State, Licensing State, or the Nuclear Regulatory Commission license that authorizes the medical use of radioactive material; or

C. Be an authorized user for those radioactive material uses that come within the radiation safety officer's responsibilities.

12 VAC 5-481-2300. Training for experienced radiation safety officer.

An individual identified as a radiation safety officer on an agency, Agreement State, Licensing State, or Nuclear Regulatory Commission license on the effective date of these regulations who oversees only the use of radioactive material for which the licensee was authorized on that date need not comply with the training requirements of 12 VAC 5-481-2290.

12 VAC 5-481-2310. Training for uptake, dilution, or excretion studies.

Except as provided in 12 VAC 5-481-2390 and 12 VAC 5-481-2400, the licensee shall require the authorized user of a radiopharmaceutical listed in 12 VAC 5-481-1950 to be a physician who:

A. Is certified in:

1. Nuclear medicine by the American Board of Nuclear Medicine; or

2. Diagnostic radiology by the American Board of Radiology; or

3. Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or

4. Nuclear medicine by the American Osteopathic Board of Nuclear Medicine; or

5. Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

B. Has completed 40 hours of instruction in basic radionuclide handling techniques applicable to the use of prepared radiopharmaceuticals, and 20 hours of supervised clinical experience.

1. To satisfy the basic instruction requirement, 40 hours of classroom and laboratory instruction shall include:

a. Radiation physics and instrumentation;

b. Radiation protection;

c. Mathematics pertaining to the use and measurement of radioactivity;

d. Radiation biology; and

e. Radiopharmaceutical chemistry.

2. To satisfy the requirement for 20 hours of supervised clinical experience, training must be under the supervision of an authorized user at a medical institution and shall include:

a. Examining patients and reviewing their case histories to determine their suitability for radionuclide diagnosis, limitations, or contraindications;

b. Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

c. Administering dosages to patients and using syringe radiation shields;

d. Collaborating with the authorized user in the interpretation of radionuclide test results; and

e. Patient follow up; or

C. Has successfully completed a six-month training program in nuclear medicine as part of a training program that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in 12 VAC 5-481-2310 B.

12 VAC 5-481-2320. Training for imaging and localization studies.

Except as provided in 12 VAC 5-481-2390 or 12 VAC 5-481-2400, the licensee shall require the authorized user of a radiopharmaceutical, generator, or reagent kit specified in 12 VAC 5-481-1970 to be a physician who:

A. Is certified in:

1. Nuclear medicine by the American Board of Nuclear Medicine; or

2. Diagnostic radiology by the American Board of Radiology; or

3. Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or

4. Nuclear medicine by the American Osteopathic Board of Nuclear Medicine; or

5. Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

B. Has completed 200 hours of instruction in basic radionuclide handling techniques applicable to the use of prepared radiopharmaceuticals, generators, and reagent kits, 500 hours of supervised work experience, and 500 hours of supervised clinical experience.

1. To satisfy the basic instruction requirement, 200 hours of classroom and laboratory training shall include:

a. Radiation physics and instrumentation;

b. Radiation protection;

c. Mathematics pertaining to the use and measurement of radioactivity;

d. Radiopharmaceutical chemistry; and

e. Radiation biology.

2. To satisfy the requirement for 500 hours of supervised work experience, training shall be under the supervision of an authorized user at a medical institution and shall include:

a. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

b. Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;

c. Calculating and safely preparing patient dosages;

d. Using administrative controls to prevent the misadministration of radioactive material;

e. Using emergency procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

f. Eluting technetium-99m from generator systems, assaying and testing the elute for molybdenum-99 and alumina contamination, and processing the elute with reagent kits to prepare technetium-99m labeled radiopharmaceuticals.

3. To satisfy the requirement for 500 hours of supervised clinical experience, training shall be under the supervision of an authorized user at a medical institution and shall include:

a. Examining patients and reviewing their case histories to determine their suitability for radionuclide diagnosis, limitations, or contraindications;

b. Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

c. Administering dosages to patients and using syringe radiation shields;

d. Collaborating with the authorized user in the interpretation of radionuclide test results; and

e. Patient follow up; or

C. Has successfully completed a six-month training program in nuclear medicine as part of a training program that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in 12 VAC 5-481-2320 B.

12 VAC 5-481-2330. Training for therapeutic use of radiopharmaceuticals.

Except as provided in 12 VAC 5-481-2390, the licensee shall require the authorized user of a radiopharmaceutical listed in 12 VAC 5-481-2010 for therapy to be a physician who:

A. Is certified in:

1. Nuclear medicine by the American Board of Nuclear Medicine; or

2. Radiation oncology, therapeutic radiology, or radiology by the American Board of Radiology; or

3. Nuclear medicine or radiation oncology by the American Osteopathic Board of Radiology after 1984; or

4. Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

B. Has completed 80 hours of instruction in basic radionuclide handling techniques applicable to the use of therapeutic radiopharmaceuticals, and has had supervised clinical experience.

1. To satisfy the requirement for instruction, 80 hours of classroom and laboratory 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;

2. To satisfy the requirement for supervised clinical experience, training shall be under the supervision of an authorized user at a medical institution and shall include:

a. Use of iodine-131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in 10 individuals;

b. Use of soluble phosphorus-32 for the treatment of ascites, polycythemia vera, leukemia, or bone metastases in three individuals;

c. Use of iodine-131 for treatment of thyroid carcinoma in three individuals;

d. Use of colloidal chromic phosphorus-32 or of colloidal gold-198 for intracavitary treatment of malignant effusions in three individuals; and

e. Use of strontium-89 as strontium chloride for the treatment of pain associated with bone metastases in three individuals.

12 VAC 5-481-2340. Training for therapeutic use of brachytherapy sources.

Except as provided in 12 VAC 5-481-2390, the licensee shall require the authorized user using a brachytherapy source specified in 12 VAC 5-481-2070 for therapy to be a physician who:

A. Is certified in:

1. Radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; or

2. Radiation oncology by the American Osteopathic Board of Radiology; or

3. Radiology, with a specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

4. Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

B. Is in the active practice of therapeutic radiology, has completed 200 hours of instruction in basic radionuclide handling techniques applicable to the therapeutic use of brachytherapy sources and 500 hours of supervised work experience and a minimum of three years of supervised clinical experience.

1. To satisfy the requirement for instruction, 200 hours of classroom and laboratory 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.

2. To satisfy the requirement for 500 hours of supervised work experience, training shall be under the supervision of an authorized user at a medical institution and shall include:

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 sealed sources;

d. Using administrative controls to prevent the misadministration of radioactive material; and

e. Using emergency procedures to control radioactive material.

3. To satisfy the requirement for a period of supervised clinical experience, training shall include one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association, and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution. The supervised clinical experience shall include:

a. Examining individuals and reviewing their case histories to determine their suitability for brachytherapy treatment, and any limitations or contraindications;

b. Selecting the proper brachytherapy sources, dose, and method of administration;

c. Calculating the dose; and

d. Post-administration follow up and review of case histories in collaboration with the authorized user.

12 VAC 5-481-2350. Training for ophthalmic use of strontium-90.

Except as provided in 12 VAC 5-481-2390, the licensee shall require the authorized user using only strontium-90 for ophthalmic radiotherapy to be a physician who:

A. Is certified in radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; or

B. Is in the active practice of therapeutic radiology or ophthalmology, and has completed 24 hours of instruction in basic radionuclide handling techniques applicable to the use of strontium-90 for ophthalmic radiotherapy, and a period of supervised clinical training in ophthalmic radiotherapy.

1. To satisfy the requirement for instruction, the classroom and laboratory 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.

2. To satisfy the requirement for a period of supervised clinical training in ophthalmic radiotherapy, training shall be under the supervision of an authorized user at a medical institution and shall include the use of strontium-90 for the ophthalmic treatment of five individuals that includes:

a. Examination of each individual to be treated;

b. Calculation of the dose to be administered;

c. Administration of the dose; and

d. Followup and review of each individual's case history.

12 VAC 5-481-2360. Training for use of sealed sources for diagnosis.

Except as provided in 12 VAC 5-481-2390, the licensee shall require the authorized user using a sealed source in a device specified in 12 VAC 5-481-2050 to be a physician, dentist, or podiatrist who:

A. Is certified in:

1. Radiology, diagnostic radiology with special competence in nuclear radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; or

2. Nuclear medicine by the American Board of Nuclear Medicine; or

3. Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or

4. Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

B. Has completed eight hours of classroom and laboratory instruction in basic radionuclide handling techniques specifically applicable to the use of the device.

1. To satisfy the requirement for instruction, the training shall include:

a. Radiation physics, mathematics pertaining to the use and measurement of radioactivity, and instrumentation;

b. Radiation biology; and

c. Radiation protection and training in the use of the device for the purposes authorized by the license.

12 VAC 5-481-2370. Training for teletherapy. Except as provided in 12 VAC 5-481-2390, the licensee shall require the authorized user of a sealed source specified in 12 VAC 5-481-2130 in a teletherapy unit to be a physician who:

A. Is certified in:

1. Radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; or

2. Radiation oncology by the American Osteopathic Board of Radiology; or

3. Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

4. Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

B. Is in the active practice of therapeutic radiology, and has completed 200 hours of instruction in basic radionuclide techniques applicable to the use of a sealed source in a teletherapy unit, 500 hours of supervised work experience, and a minimum of three years of supervised clinical experience.

1. To satisfy the requirement for instruction, the classroom and laboratory 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.

2. To satisfy the requirement for 500 hours of supervised work experience, training shall be under the supervision of an authorized user at an institution and shall include:

a. Review of the full calibration measurements and periodic spot checks;

b. Preparing treatment plans and calculating treatment times;

c. Using administrative controls to prevent misadministrations;

d. Implementing emergency procedures to be followed in the event of the abnormal operation of a teletherapy unit or console; and

e. Checking and using survey meters.

3. To satisfy the requirement for a period of supervised clinical experience, training shall include one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution. The supervised clinical experience shall include:

a. Examining individuals and reviewing their case histories to determine their suitability for teletherapy treatment, and any limitations or contraindications;

b. Selecting the proper dose and how it is to be administered;

c. Calculating the teletherapy doses and collaborating with the authorized user in the review of patients' progress and consideration of the need to modify originally prescribed doses as warranted by patients' reaction to radiation; and

d. Post-administration followup and review of case histories.

12 VAC 5-481-2380. Training for teletherapy physicist.

The licensee shall require the teletherapy physicist to:

A. Be certified by the American Board of Radiology in:

1. Therapeutic radiological physics;

2. Roentgen-ray and gamma-ray physics;

3. X-ray and radium physics; or

4. Radiological physics; or

B. Be certified by the American Board of Medical Physics in radiation oncology physics; or

C. Hold a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and have completed one year of full time training in therapeutic radiological physics and also one year of full time work experience under the supervision of a teletherapy physicist at a medical institution. To meet this requirement, the individual shall have performed the tasks listed in 12 VAC 5-481-1850; 12 VAC 5-481-2220; 12 VAC 5-481-2230; and 12 VAC 5-481-2240 under the supervision of a teletherapy physicist during the year of work experience.

12 VAC 5-481-2390. Training for experienced authorized users.

Practitioners of the healing arts identified as authorized users for the human use of radioactive material on an agency, a Nuclear Regulatory Commission or an Agreement State or a Licensing State license on the effective date of these regulations who perform only those methods of use for which they were authorized on that date need not comply with the training requirements of 12 VAC 5-481-2290 through 12 VAC 5-481-2410.

12 VAC 5-481-2400. Physician training in a three-month program.

A physician who, before July 1, 1984, began a three-month nuclear medicine training program approved by the Accreditation Council for Graduate Medical Education and has successfully completed the program, is exempted from the requirements of 12 VAC 5-481-2310 or 12 VAC 5-481-2320.

12 VAC 5-481-2410. Recentness of training.

The training and experience specified in 12 VAC 5-481-2290 through 12 VAC 5-481-2380 shall have been obtained within the five years proceeding the date of application or the individual shall have had continuing applicable experience since the required training and experience was completed.

PART VIII.

RADIATION SAFETY REQUIREMENTS FOR ANALYTICAL X-RAY EQUIPMENT.

12 VAC 5-481-2420. Purpose and scope.

This Part provides special requirements for analytical X-ray equipment. The requirements of this Part are in addition to, and not in substitution for, applicable requirements in other Parts of these regulations.

12 VAC 5-481-2430. Equipment requirements.

A. Safety device. A device which prevents the entry of any portion of an individual's body into the primary X-ray beam path or which causes the beam to be shut off upon entry into its path shall be provided on all open-beam configurations. A registrant (or licensee) may apply to the agency for an exemption from the requirement of a safety device. Such application shall include:

1. A description of the various safety devices that have been evaluated;

2. The reason each of these devices cannot be used; and

3. A description of the alternative methods that will be employed to minimize the possibility of an accidental exposure, including procedures to assure that operators and others in the area will be informed of the absence of safety devices.

B. Warning devices

1. Open-beam configurations shall be provided with a readily discernible indication of:

a. X-ray tube "on-off" status located near the radiation source housing, if the primary beam is controlled in this manner; and/or

b. Shutter "open-closed" status located near each port on the radiation source housing, if the primary beam is controlled in this manner.

2. An easily visible warning light labeled with the words "X-RAY ON", or words having a similar intent, shall be located:

a. Near any switch that energizes an X-ray tube and shall be illuminated only when the tube is energized; or

b. In the case of a radioactive source, near any switch that opens a housing shutter and shall be illuminated only when the shutter is open.

3. Warning devices shall be labeled so that their purpose is easily identified. On equipment installed after the effective date of these regulations, warning devices shall have fail-safe characteristics.

C. Ports. Unused ports on radiation source housings shall be secured in the closed position in a manner which will prevent casual opening.

D. Labeling. All analytical X-ray equipment shall be labeled with a readily discernible sign or signs bearing the radiation symbol and the words:

1. "CAUTION - HIGH INTENSITY X-RAY BEAM", or words having a similar intent, on the X-ray source housing; and

2. "CAUTION RADIATION - THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED", or words having a similar intent, near any switch that energizes an X-ray tube if the radiation source is an X-ray tube; or

3. "CAUTION - RADIOACTIVE MATERIAL", or words having a similar intent, on the source housing in accordance with 12 VAC 5-481-660 of these regulations if the

radiation source is a radionuclide.

E. Shutters. On open-beam configurations installed after the effective date of these regulations, each port on the radiation source housing shall be equipped with a shutter that cannot be opened unless a collimator or a coupling has been connected to the port.

F. Radiation source housing. Each radiation source housing shall be subject to the following requirements:

1. Each X-ray tube housing shall be equipped with an interlock that shuts off the tube if it is removed from the radiation source housing or if the housing is disassembled.

2. Each radioactive source housing or port cover or each X-ray tube housing shall be so constructed that, with all shutters closed, the radiation measured at a distance of five centimeters from its surface is not capable of producing a dose in excess of 2.5 millirems (0.025 mSv) in one hour. For systems utilizing X-ray tubes, this limit shall be met at any specified tube rating.

G. Generator cabinet. Each X-ray generator shall be supplied with a protective cabinet which limits leakage radiation measured at a distance of five centimeters from its surface such that it is not capable of producing a dose in excess of 0.25 millirem (2.5 μSv) in one hour.

12 VAC 5-481-2440. Area requirements.

A. Radiation Levels. The local components of an analytical X-ray system shall be located and arranged and shall include sufficient shielding or access control such that no radiation levels exist in any area surrounding the local component group which could result in a dose to an individual present therein in excess of the dose limits given in 12 VAC 5-481-640 of these regulations. For systems utilizing X-ray tubes, these levels shall be met at any specified tube rating.

B. Surveys

1. Radiation surveys, as required by 12 VAC 5-481-750 of these regulations, of all analytical X-ray systems sufficient to show compliance with 12 VAC 5-481-2440 A shall be performed:

a. Upon installation of the equipment, and at least once every 12 months thereafter;

b. Following any change in the initial arrangement, number, or type of local components in the system;

c. Following any maintenance requiring the disassembly or removal of a local component in the system;

d. During the performance of maintenance and alignment procedures if the procedures require the presence of a primary X-ray beam when any local component in the system is disassembled or removed;

e. Any time a visual inspection of the local components in the system reveals an abnormal condition; and

f. Whenever personnel monitoring devices show a significant increase over the previous monitoring period or the readings are approaching the limits specified in 12 VAC 5-481-630 of these regulations.

2. Radiation survey measurements shall not be required if a registrant (or licensee) can demonstrate compliance with 12 VAC 5-481-2440 A to the satisfaction of the agency.

C. Posting. Each area or room containing analytical X-ray equipment shall be conspicuously posted with a sign or signs bearing the radiation symbol and the words "CAUTION - X-RAY EQUIPMENT" or words having a similar intent in accordance with 12 VAC 5-481-660 of these regulations.

12 VAC 5-481-2450. Operating requirements.

A. Procedures. Normal operating procedures shall be written and available to all analytical X-ray equipment workers. No individual shall be permitted to operate analytical X-ray equipment in any manner other than that specified in the procedures unless such individual has obtained written approval of the radiation safety officer.

B. Bypassing. No individual shall bypass a safety device or interlock unless such individual has

obtained the approval of the radiation safety officer. Such approval shall be for a specified period of time. When a safety device or interlock has been bypassed, a readily discernible sign bearing the words "SAFETY DEVICE NOT WORKING", or words having a similar intent, shall be placed on the radiation source housing.

C. Repair or modification of X-ray tube systems. Except as specified in 12 VAC 5-481-2450 B, no operation involving removal of covers, shielding materials or tube housings or modifications to shutters, collimators, or beam stops shall be performed without ascertaining that the tube is off and will remain off until safe conditions have been restored. The main switch, rather than interlocks, shall be used for routine shutdown in preparation for repairs.

D. Radioactive source replacement, testing, or repair. Radioactive source housings shall be opened for source replacement, leak testing, or other maintenance or repair procedures only by individuals authorized to specifically conduct such procedures under a license issued by the Nuclear Regulatory Commission, an Agreement State, or a Licensing State.

12 VAC 5-481-2460. Personnel requirements.

A. Instruction. No individual shall be permitted to operate or maintain analytical X-ray equipment unless such individual has received instruction in and demonstrated competence as to:

1. Identification of radiation hazards associated with the use of the equipment;

2. Significance of the various radiation warning, safety devices, and interlocks incorporated

into the equipment, or the reasons they have not been installed on certain pieces of equipment and the extra precautions required in such cases;

3. Proper operating procedures for the equipment;

4. Recognition of symptoms of an acute localized exposure; and

5. Proper procedures for reporting an actual or suspected exposure.

B. Personnel monitoring

1. Finger or wrist dosimetric devices shall be provided to and shall be used by:

a. Analytical X-ray equipment workers using systems having an open-beam configuration and not equipped with a safety device; and

b. Personnel maintaining analytical X-ray equipment if the maintenance procedures require the presence of a primary X-ray beam when any local component in the analytical X-ray system is disassembled or removed.

2. Reported dose values shall not be used for the purpose of determining compliance with 12 VAC 5-481-630 of these regulations unless evaluated by a private inspector.

PART IX.

RADIATION SAFETY REQUIREMENTS FOR PARTICLE ACCELERATORS.

ARTICLE 1.

PURPOSE AND SCOPE

12 VAC 5-481-2470. Purpose and scope.

12 VAC 5-481-2470. Purpose and scope.

A. This Part establishes procedures for the registration and the use of particle accelerators.

B. In addition to the requirements of this Part, all registrants are subject to the requirements of Parts I (12 VAC 5-481-10 et seq.); II (12 VAC 5-481-260 et seq.); III (12 VAC 5-481-380 et seq.); IV

(12 VAC 5-481-600 et seq.); and X (12 VAC 5-481-2580 et seq.) of these regulations. Registrants engaged in industrial radiographic operations are subject to the requirements of Part V (12 VAC 5-481-1170 et seq.) of these regulations, and registrants engaged in the healing arts are subject to the requirements of Parts VI (12 VAC 5-481-1580 et seq.) and VII (12 VAC 5-481-1660 et seq.) of these regulations. Registrants whose operations result in the production of radioactive material are subject to the requirements of Part III (12 VAC 5-481-380 et seq.) of these regulations.

ARTICLE 2.

REGISTRATION PROCEDURES.

12 VAC 5-481-2480. Registration requirements.

12 VAC 5-481-2490. General requirements for the issuance of a registration for particle accelerators.

12 VAC 5-481-2500. Human use of particle accelerators.

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12 VAC 5-481-2480. Registration requirements.

No person shall receive, possess, use, transfer, own, or acquire a particle accelerator except as authorized in a registration issued pursuant to Parts II (12 VAC 5-481-260 et seq.) or III (12 VAC 5-481-380 et seq.) of these regulations.

12 VAC 5-481-2490. General requirements for the issuance of a registration for particle

accelerators.

In addition to the requirements of Part II (12 VAC 5-481-260 et seq.) or III (12 VAC 5-481-380 et seq.) of these regulations, a registration application for use of a particle accelerator will be approved only if the agency determines that:

A. The applicant is qualified by reason of training and experience to use the accelerator in question for the purpose requested in accordance with this Part and Parts IV (12 VAC 5-481-600 et seq.) and X (12 VAC 5-481-2580 et seq.) of these regulations in such a manner as to minimize danger to public health and safety or property;

B. The applicant's proposed or existing equipment, facilities, and operating and emergency procedures are adequate to protect health and minimize danger to public health and safety or property;

C. The issuance of the registration will not be inimical to the health and safety of the public, and the applicant satisfies any applicable special requirement in 12 VAC 5-481-2500;

D. The applicant has appointed a radiation safety officer;

E. The applicant and the applicant's staff have substantial experience in the use of particle accelerators and training sufficient for application to its intended uses;

F. The applicant has established a radiation safety committee to approve, in advance, proposals for

uses of particle accelerators, whenever deemed necessary by the agency; and

G. The applicant has an adequate training program for operators of particle accelerators.

12 VAC 5-481-2500. Human use of particle accelerators.

In addition to the requirements of Part II (12 VAC 5-481-260 et seq.) of these regulations, a registration for use of a particle accelerator in the healing arts will be issued only if:

A. The applicant has appointed a medical committee of at least three members to evaluate all proposals for research, diagnostic, and therapeutic use of a particle accelerator whenever deemed necessary by the agency. Membership of the committee should include physicians expert in internal medicine, hematology, therapeutic radiology, and a person experienced in depth dose calculations and protection against radiation;

B. The individuals designated on the application as the users have substantial training and experience in deep therapy techniques or in the use of particle accelerators to treat humans; and

C. The individual designated on the application as the user is a physician.

ARTICLE 3.

RADIATION SAFETY REQUIREMENTS FOR USE OF PARTICLE ACCELERATORS.

12 VAC 5-481-2510. Limitations.

A. No registrant shall permit any individual to act as an operator of a particle accelerator until such individual:

1. Has been instructed in radiation safety and shall have demonstrated an understanding thereof;

2. Has received copies of and instruction in this Part and the applicable requirements of Parts IV (12 VAC 5-481-600 et seq.) and X (12 VAC 5-481-2580 et seq.) of these regulations, pertinent registration conditions and the registrant's operating and emergency procedures, and shall have demonstrated understanding thereof; and

3. Has demonstrated competence to use the particle accelerator, related equipment, and survey instruments which will be employed.

B. The radiation safety committee or the radiation safety officer shall have the authority to terminate the operations at a particle accelerator facility if such action is deemed necessary to minimize danger to public health and safety or property.

12 VAC 5-481-2520. Shielding and safety design requirements.

A. A private inspector, acceptable to the agency, shall be consulted in the design of a particle accelerator installation and called upon to perform a radiation survey when the accelerator is first capable of producing radiation.

B. Each particle accelerator installation shall be provided with such primary and secondary barriers as are necessary to assure compliance with 12 VAC 5-481-630 of these regulations.

12 VAC 5-481-2530. Particle accelerator controls and interlock systems.

A. Instrumentation, readouts, and controls on the particle accelerator control console shall be clearly identified and easily discernible.

B. Each entrance into a target room or other high radiation area shall be provided with a safety interlock that shuts down the machine under conditions of barrier penetration.

C. Each safety interlock shall be on a circuit which shall allow it to operate independently of all other safety interlocks.

D. All safety interlocks shall be designed so that any defect or component failure in the safety interlock system prevents operation of the accelerator.

E. When a safety interlock system has been tripped, it shall only be possible to resume operation of the accelerator by manually resetting controls at the position where the safety interlock has been tripped and, lastly, at the main control console.

F. A scram button or other emergency power cutoff switch shall be located and easily identifiable in all high radiation areas. Such a cutoff switch shall include a manual reset so that the accelerator cannot be restarted from the accelerator control console without resetting the cutoff switch.

12 VAC 5-481-2540. Warning devices.

A. Each location designated as high radiation area, and each entrance to such location, shall be equipped with easily observable warning lights that operate when, and only when, radiation is being produced.

B. Except in facilities designed for human exposure, each high radiation area shall have an audible warning device which shall be activated for 15 seconds prior to the possible creation of such high radiation area. Such warning device shall be clearly discernible in all high radiation areas.

C. Barriers, temporary or otherwise, and pathways leading to high radiation areas shall be posted in

accordance with 12 VAC 5-481-660 of these regulations.

12 VAC 5-481-2550. Operating procedures.

A. Particle accelerators, when not in operation, shall be secured to prevent unauthorized use.

B. The safety interlock system shall not be used to turn off the accelerator beam except in an emergency.

C. All safety and warning devices, including interlocks, shall be checked for proper operation at intervals not to exceed three months. Results of such tests shall be maintained at the accelerator facility for inspection by the agency.

D. Electrical circuit diagrams of the accelerator and the associated safety interlock systems shall be kept current and maintained for inspection by the agency and shall be available to the operator at each accelerator facility.

E. If, for any reason, it is necessary to intentionally bypass a safety interlock or interlocks, such action shall be:

1. Authorized by the radiation safety committee or radiation safety officer;

2. Recorded in a permanent log and a notice posted at the accelerator control console; and

3. Terminated as soon as possible.

F. A copy of the current operating and the emergency procedures shall be maintained at the accelerator control panel.

12 VAC 5-481-2560. Radiation monitoring requirements.

A. There shall be available at each particle accelerator facility appropriate portable monitoring equipment which is operable and has been appropriately calibrated for the radiations being produced at the facility. Such equipment shall be tested for proper operation daily and calibrated at intervals not to exceed one year and after each servicing and repair.

B. A radiation protection survey shall be performed and documented by a private inspector, acceptable to the agency, when changes have been made in shielding, operation, equipment, or occupancy of adjacent areas.

C. Radiation levels in all high radiation areas shall be continuously monitored. The monitoring devices shall be electrically independent of the accelerator control and safety interlock systems and capable of providing a readout at the control panel.

D. All area monitors shall be calibrated at intervals not to exceed one year and after each servicing and repair.

E. Whenever applicable, periodic surveys shall be made to determine the amount of airborne

particulate radioactivity present.

F. Whenever applicable, periodic smear surveys shall be made to determine the degree of contamination.

G. All surveys shall be made in accordance with the written procedures established by a private inspector, acceptable to the agency, or the radiation safety officer.

H. Records of all radiation protection surveys, calibrations, and instrumentation tests shall be maintained at the accelerator facility for inspection by the agency.

12 VAC 5-481-2570. Ventilation systems.

A. Ventilation systems shall be provided to ensure that personnel entering any area where airborne radioactivity may be produced will not be exposed to airborne radioactive material in excess of those limits specified in Part IV (12 VAC 5-481-600 et seq.), Appendix F, Table I of these regulations.

B. A registrant, as required by Part IV (12 VAC 5-481-600 et seq.) of these regulations, shall not vent, release, or otherwise discharge airborne radioactive material to an unrestricted area which exceeds the limits specified in Part IV (12 VAC 5-481-600 et seq.), Appendix F, Table II of these regulations, except as authorized pursuant to 12 VAC 5-481-730 of these regulations. For purposes of 12 VAC 5-481-2570 B, concentrations may be averaged over a period not greater than one year. Every effort should be made to maintain releases of radioactive material to

unrestricted areas as far below these limits as is reasonably achievable.

PART X.

NOTICES, INSTRUCTIONS, AND REPORTS TO WORKERS; INSPECTIONS.

12 VAC 5-481-2580. Purpose and scope.

This Part establishes requirements for notices, instructions and reports by licensees or registrants to individuals engaged in activities under a license or registration and options available to such individuals in connection with agency inspections of licensees or registrants to ascertain compliance with the provisions of the Act and regulations, orders, and licenses issued thereunder regarding radiological working conditions. The regulations in this Part apply to all persons who receive, possess, use, own, or

transfer sources of radiation registered with or licensed by the agency pursuant to Parts II (12 VAC 5-481-260 et seq.) and III (12 VAC 5-481-380 et seq.) of these regulations.

12 VAC 5-481-2590. Posting of notices to workers.

A. Each licensee or registrant shall post current copies of the following documents:

1. The regulations in this Part and in Part IV (12 VAC 5-481-600 et seq.) of these regulations;

2. The license, certificate of registration, conditions or documents incorporated into the license by reference and amendments thereto;

3. The operating procedures applicable to activities under the license or registration; and

4. Any notice of violation involving radiological working conditions, proposed imposition of civil penalty, or order issued pursuant to Part I (12 VAC 5-481-10 et seq.) of these regulations, and any response from the licensee or registrant.

B. If posting of a document specified in 12 VAC 5-481-2590 A 1; 12 VAC 5-481-2590 A 2; or 12 VAC 5-481-2590 A 3 is not practicable, the licensee or registrant may post a notice which describes the document and states where it may be examined.

C. Agency form X "Notice to Employees" shall be posted by each licensee or registrant as required by these regulations.

D. Agency documents posted pursuant to 12 VAC 5-481-2590 A 4 shall be posted within five working days after receipt of the documents from the agency; the licensee's or registrant's response, if any, shall be posted within five working days after dispatch from the licensee or registrant. Such documents shall remain posted for a minimum of five working days or until action correcting the violation has been completed, whichever is later.

E. Documents, notices, or forms posted pursuant to 12 VAC 5-481-2590 shall appear in a sufficient number of places to permit individuals engaged in work under the license or registration to observe them on the way to or from any particular work location to which the document applies, shall be conspicuous, and shall be replaced if defaced or altered.

12 VAC 5-481-2600. Instructions to workers.

A. All individuals likely to receive an occupational dose:

1. Shall be kept informed of the storage, transfer, or use of sources of radiation in the licensee's or registant's workplace;

2. Shall be instructed in the health protection problems associated with exposure to radiation or radioactive material to the individual and potential offspring, in precautions

or procedures to minimize exposure, and in the purposes and functions of protective devices employed;

3. Shall be instructed in, and instructed to observe, to the extent within the worker's control, the applicable provisions of these regulations and licenses for the protection of personnel from exposures to radiation or radioactive material;

4. Shall be instructed of their responsibility to report promptly to the licensee or registrant any condition which may constitute, lead to, or cause a violation of the Act, these regulations, or license condition, or any unnecessary exposure to radiation or radioactive material;

5. Shall be instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material; and

6. Shall be advised as to the radiation exposure reports which workers shall be furnished pursuant to 12 VAC 5-481-2610.

B. The extent of these instructions shall be commensurate with potential radiological health protection problems present in the workplace.

12 VAC 5-481-2610. Notifications and reports to individuals.

A. Radiation exposure data for an individual and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body of an individual shall be reported to the individual as specified in 12 VAC 5-481-2610. The information reported shall include data and results obtained pursuant to these regulations, orders, or license conditions, as shown in records maintained by the licensee or registrant pursuant to 12 VAC 5-481-1040 of these regulations. Each notification and report shall:

1. Be in writing;

2. Include appropriate identifying data such as the name of the licensee or registrant, the name of the individual, and the individual's identification number, preferably social security number;

3. Include the individual's exposure information; and

4. Contain the following statement:

"This report is furnished to you under the provisions of Part X (12 VAC 5-481-2580 et seq.). You should preserve this report for further reference."

B. Each licensee or registrant shall furnish to each worker annually a written report of the worker's dose as shown in records maintained by the licensee or registrant pursuant to 12 VAC 5-481-1040 of these regulations.

C. Each licensee or registrant shall furnish a written report of the worker's exposure to sources of radiation at the request of a worker formerly engaged in activities controlled by the licensee or registrant. The report shall include the dose record for each year the worker was required to be monitored pursuant to 12 VAC 5-481-760 of these regulations. Such report shall be furnished within 30 days from the date of the request, or within 30 days after the dose of the individual has been determined by the licensee or registrant, whichever is later. The report shall cover the period of time that the worker's activities involved exposure to sources of radiation and shall include the dates and locations of work under the license or registration in which the worker participated during this period.

D. When a licensee or registrant is required pursuant to 12 VAC 5-481-1100; 12 VAC 5-481-1110; or 12 VAC 5-481-1120 of these regulations to report to the agency any exposure of an individual to sources of radiation, the licensee or the registrant shall also provide the individual a written report on the exposure data included therein. Such reports shall be transmitted at a time not later than the transmittal to the agency.

E. At the request of a worker who is terminating employment with the licensee or registrant in work involving exposure to radiation or radioactive material, during the current year, each licensee or registrant shall provide at termination to each such worker, or to the worker's designee, a written report regarding the radiation dose received by that worker from operations of the licensee or registrant during the current year or fraction thereof. If the most recent individual monitoring results are not available at that time, a written estimate of the dose shall be provided together with a clear indication that this is an estimate.

12 VAC 5-481-2620. Presence of representatives of licensees or registrants and workers during inspection.

A. Each licensee or registrant shall afford to the agency at all reasonable times opportunity to inspect materials, machines, activities, facilities, premises, and records pursuant to these regulations.

B. During an inspection, agency inspectors may consult privately with workers as specified in 12 VAC 5-481-2630. The licensee or registrant may accompany agency inspectors during other phases of an inspection.

C. If, at the time of inspection, an individual has been authorized by the workers to represent them during agency inspections, the licensee or registrant shall notify the inspectors of such authorization and shall give the workers' representative an opportunity to accompany the inspectors during the inspection of physical working conditions.

D. Each workers' representative shall be routinely engaged in work under control of the licensee or registrant and shall have received instructions as specified in 12 VAC 5-481-2600.

E. Different representatives of licensees or registrants and workers may accompany the inspectors during different phases of an inspection if there is no resulting interference with the conduct of the inspection. However, only one workers' representative at a time may accompany the inspectors.

F. With the approval of the licensee or registrant and the workers' representative, an individual who is not routinely engaged in work under control of the licensee or registrant, for example, a consultant to the licensee or registrant or to the workers' representative, shall be afforded the opportunity to accompany agency inspectors during the inspection of physical working conditions.

G. Notwithstanding the other provisions of 12 VAC 5-481-2620, agency inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection. With regard to areas containing information classified by an agency of the U.S. Government in the interest of national security, an individual who accompanies an inspector may have access to such information only if authorized to do so. With regard to any area containing proprietary information, the workers' representative for that area shall be an individual previously authorized by the licensee or registrant to enter that area.

12 VAC 5-481-2630. Consultation with workers during inspections.

A. Agency inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of these regulations and licenses to the extent the inspectors deem necessary for the conduct of an effective and thorough inspection.

B. During the course of an inspection, any worker may bring privately to the attention of the inspectors, either orally or in writing, any past or present condition which the worker has reason to believe may have contributed to or caused any violation of the Act, these regulations, or

license condition, or any unnecessary exposure of an individual to sources of radiation under the licensee's or registrant's control. Any such notice in writing shall comply with the requirements of 12 VAC 5-481-2640 A.

C. The provisions of 12 VAC 5-481-2630 B. shall not be interpreted as authorization to disregard instructions pursuant to 12 VAC 5-481-2600.

12 VAC 5-481-2640. Requests by workers for inspections.

A. Any worker or representative of workers believing that a violation of the Act, these regulations, or license conditions exists or has occurred in work under a license or registration with regard to radiological working conditions in which the worker is engaged may request an inspection by giving notice of the alleged violation to the agency. Any such notice shall be in writing, shall set forth the specific grounds for the notice, and shall be signed by the worker or representative of the workers. A copy shall be provided to the licensee or registrant by the agency no later than at the time of inspection except that, upon the request of the worker giving such notice, such worker's name and the name of individuals referred to therein shall not appear in such copy or on any record published, released, or made available by the agency, except for good cause shown.

B. If, upon receipt of such notice, the agency determines that the complaint meets the requirements set forth in 12 VAC 5-481-2640 A., and that there are reasonable grounds to believe that the alleged violation exists or has occurred, an inspection shall be made as soon as practicable to determine if such alleged violation exists or has occurred. Inspections pursuant to 12 VAC 5-481-2640 need not be limited to matters referred to in the complaint.

C. No licensee, registrant, or contractor or subcontractor of a licensee or registrant shall discharge or in any manner discriminate against any worker because such worker has filed any complaint or instituted or caused to be instituted any proceeding under these regulations or has testified or is about to testify in any such proceeding or because of the exercise by such worker on behalf of such worker or others of any option afforded by this Part.

12 VAC 5-481-2650. Inspections not warranted; informal review.

A. Do the following:

1. If the agency determines, with respect to a complaint under 12 VAC 5-481-2640, that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, the agency shall notify the complainant in writing of such determination. The complainant may obtain review of such determination by submitting a written statement of position with the agency. The agency will provide the licensee or registrant with a copy of such statement by certified mail, excluding, at the request of the complainant, the name of the complainant. The licensee or registrant may submit an opposing written statement of position with the agency. The agency will provide the complainant with a copy of such statement by certified mail.

2. Upon the request of the complainant, the agency may hold an informal conference in which the complainant and the licensee or registrant may orally present their views. An informal conference may also be held at the request of the licensee or registrant, but

disclosure of the identity of the complainant will be made only following receipt of written authorization from the complainant. After considering all written and oral views presented, the agency shall affirm, modify, or reverse the determination of the agency and furnish the complainant and the licensee or registrant a written notification of the decision and the reason therefor.

B. If the agency determines that an inspection is not warranted because the requirements of 12 VAC 5-481-2640 A have not been met, the complainant shall be notified in writing of such determination. Such determination shall be without prejudice to the filing of a new complaint meeting the requirements of 12 VAC 5-481-2640 A.

PART XI.

LICENSING REQUIREMENTS FOR LAND DISPOSAL OF RADIOACTIVE WASTE.

ARTICLE 1.

PURPOSE AND SCOPE.

12 VAC 5-481-2660. Purpose and scope.

12 VAC 5-481-2660. Purpose and scope.

A. The regulations in this Part establish procedures, criteria, and terms and conditions upon which the agency issues licenses for the land disposal of wastes received from other persons.

(Applicability of the requirements in this Part to agency licenses for waste disposal facilities in effect on the effective date of this regulation will be determined on a case-by-case basis and implemented through terms and conditions of the license or by orders issued by the agency.) The requirements of this Part are in addition to, and not in substitution for, other applicable requirements of these regulations.

B. The regulations in this Part do not apply to disposal of byproduct material as defined in the definition of "Byproduct material" in these regulations in quantities greater than 10,000 kilograms containing more than five millicuries of radium-226 or disposal of radioactive material as provided for in Part IV (12 VAC 5-481-600 et seq.) of these regulations.

C. This Part establishes procedural requirements and performance objectives applicable to any method of land disposal. It establishes specific technical requirements for near-surface disposal of radioactive waste which involves disposal in the uppermost portion of the earth.

ARTICLE 2.

GENERAL REGULATORY PROVISIONS.

12 VAC 5-481-2670. License required.

12 VAC 5-481-2680. Content of application.

12 VAC 5-481-2690. General information.

12 VAC 5-481-2700. Specific technical information.

12 VAC 5-481-2710. Technical analyses.

12 VAC 5-481-2720. Institutional information.

12 VAC 5-481-2730. Financial information.

12 VAC 5-481-2740. Requirements for issuance of a license.

12 VAC 5-481-2750. Conditions of licenses.

12 VAC 5-481-2760. Application for renewal or closure.

12 VAC 5-481-2770. Contents of application for site closure and stabilization.

12 VAC 5-481-2780. Post-closure observation and maintenance.

12 VAC 5-481-2790. Transfer of license.

12 VAC 5-481-2800. Termination of license.

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12 VAC 5-481-2670. License required.

A. No person may receive, possess, and dispose of waste received from other persons at a land disposal facility unless authorized by a license issued by the agency pursuant to this Part, and Part III (12 VAC 5-481-380 et seq.) of these regulations.

B. Each person shall file an application with the agency pursuant to 12 VAC 5-481-440 of these regulations and obtain a license as provided in this Part before commencement of construction of a land disposal facility. Failure to comply with this requirement may be grounds for denial of a license.

12 VAC 5-481-2680. Content of application.

In addition to the requirements set forth in Section 12 VAC 5-481-450 of these regulations, an application to receive from others, possess, and dispose of wastes shall consist of general information, specific technical information, institutional information, and financial information as set forth in 12 VAC 5-481-2690 through 12 VAC 5-481-2730.

12 VAC 5-481-2690. General information.

The general information shall include each of the following:

A. Identity of the applicant including:

1. The full name, address, telephone number, and description of the business or occupation of the applicant;

2. If the applicant is a partnership, the name and address of each partner and the principal location where the partnership does business;

3. If the applicant is a corporation or an unincorporated association, (a) the state where it is incorporated or organized and the principal location where it does business, and (b) the names and addresses of its directors and principal officers; and

4. If the applicant is acting as an agent or representative of another person in filing the application, all information required under 12 VAC 5-481-2690 A must be supplied with respect to the other person.

B. Qualifications of the applicant:

1. The organizational structure of the applicant, both offsite and onsite, including a description of lines of authority and assignments of responsibilities, whether in the form of administrative directives, contract provisions, or otherwise;

2. The technical qualifications, including training and experience, of the applicant and members of the applicant's staff to engage in the proposed activities. Minimum training and experience requirements for personnel filling key positions described in 12 VAC 5-481-2690 B 1 must be provided.

3. A description of the applicant's personnel training program; and

4. The plan to maintain an adequate complement of trained personnel to carry out waste receipt, handling, and disposal operations in a safe manner.

C. A description of:

1. The location of the proposed disposal site;

2. The general character of the proposed activities;

3. The types and quantities of waste to be received, possessed, and disposed of;

4. Plans for use of the land disposal facility for purposes other than disposal of wastes; and

5 The proposed facilities and equipment.

D. Proposed schedules for construction, receipt of waste, and first emplacement of waste at the proposed land disposal facility.

12 VAC 5-481-2700. Specific technical information.

The specific technical information shall include the following information needed for demonstration that the performance objectives and the applicable technical requirements of this Part will be met:

A. A description of the natural and demographic disposal site characteristics as determined by disposal site selection and characterization activities. The description shall include geologic, geochemical, geotechnical, hydrologic, ecologic, archaelogic, meteorologic, climatologic, and biotic features of the disposal site and vicinity.

B. A description of the design features of the land disposal facility and the disposal units. For near-surface disposal, the description shall include those design features related to infiltration of water; integrity of covers for disposal units; structural stability of backfill, wastes, and covers; contact of wastes with standing water; disposal site drainage; disposal site closure and stabilization; elimination to the extent practicable of long-term disposal site maintenance; inadvertent intrusion; occupational exposures; disposal site monitoring; and adequacy of the size

of the buffer zone for monitoring and potential mitigative measures.

C. A description of the principal design criteria and their relationship to the performance objectives.

D. A description of the design basis natural events or phenomena and their relationship to the principal design criteria.

E. A description of codes and standards which the applicant has applied to the design and which will apply to construction of the land disposal facilities.

F. A description of the construction and operation of the land disposal facility. The description shall include as a minimum the methods of construction of disposal units; waste emplacement; the procedures for and areas of waste segregation; types of intruder barriers; onsite traffic and drainage systems; survey control program; methods and areas of waste storage; and methods to control surface water and groundwater access to the wastes. The description shall also include a description of the methods to be employed in the handling and disposal of wastes containing chelating agents or other non-radiological substances that might affect meeting the performance objectives of this Part.

G. A description of the disposal site closure plan, including those design features which are intended to facilitate disposal site closure and to eliminate the need for ongoing active maintenance.

H. An identification of the known natural resources at the disposal site, whose exploitation could

result in inadvertent intrusion into the wastes after removal of active institutional control.

I. A description of the kind, amount, classification and specifications of the radioactive material proposed to be received, possessed, and disposed of at the land disposal facility.

J. A description of the quality control program for the determination of natural disposal site characteristics and for quality control during the design, construction, operation, and closure of the land disposal facility and the receipt, handling, and emplacement of waste. Audits and managerial controls must be included.

K. A description of the radiation safety program for control and monitoring of radioactive effluents to ensure compliance with the performance objective in 12 VAC 5-481-2820 and occupational radiation exposure to ensure compliance with the requirements of Part IV (12 VAC 5-481-600 et seq.) of these regulations and to control contamination of personnel, vehicles, equipment, buildings, and the disposal site. Both routine operations and accidents shall be addressed. The program description must include procedures, instrumentation, facilities, and equipment.

L. A description of the environmental monitoring program to provide data to evaluate potential health and environmental impacts and the plan for taking corrective measures if migration is indicated.

M. A description of the administrative procedures that the applicant will apply to control activities at the land disposal facility.

12 VAC 5-481-2710. Technical analyses.

The specific technical information shall also include the following analyses needed to demonstrate that the performance objectives of this Part will be met:

A. Pathways analyzed in demonstrating protection of the general population from releases of radioactivity shall include air, soil, groundwater, surface water, plant uptake, and exhumation by burrowing animals. The analyses shall clearly identify and differentiate between the roles performed by the natural disposal site characteristics and design features in isolating and segregating the wastes. The analyses shall clearly demonstrate that there is reasonable assurance that the exposures to humans from the release of radioactivity will not exceed the limits set forth in 12 VAC 5-481-2820.

B. Analyses of the protection of individuals from inadvertent intrusion shall include demonstration that there is reasonable assurance the waste classification and segregation requirements will be met and that adequate barriers to inadvertent intrusion will be provided.

C. Analyses of the protection of individuals during operations shall include assessments of expected exposures due to routine operations and likely accidents during handling, storage, and disposal of waste. The analyses shall provide reasonable assurance that exposures will be controlled to meet the requirements of Part IV (12 VAC 5-481-600 et seq.) of these regulations.

D. Analyses of the long-term stability of the disposal site and the need for ongoing active maintenance after closure shall be based upon analyses of active natural processes such as

erosion, mass wasting, slope failure, settlement of wastes and backfill, infiltration through covers over disposal areas and adjacent soils, and surface drainage of the disposal site. The analyses shall provide reasonable assurance that there will not be a need for ongoing active maintenance of the disposal site following closure.

12 VAC 5-481-2720. Institutional information.

The institutional information submitted by the applicant shall include:

A. A certification by the Federal or state agency which owns the disposal site that the Federal or state agency is prepared to accept transfer of the license when the provisions of 12 VAC 5-481-2790 are met and will assume responsibility for institutional control after site closure and post-closure observation and maintenance.

B. Where the proposed disposal site is on land not owned by the Federal or a state government, the applicant shall submit evidence that arrangements have been made for assumption of ownership in fee by the Federal or a state agency before the agency issues a license.

12 VAC 5-481-2730. Financial information.

The financial information shall be sufficient to demonstrate that the financial qualifications of the applicant are adequate to carry out the activities for which the license is sought and meet other financial assurance requirements of this Part.

12 VAC 5-481-2740. Requirements for issuance of a license.

A license for the receipt, possession, and disposal of waste containing or contaminated with radioactive material will be issued by the agency upon finding that:

A. The issuance of the license will not constitute an unreasonable risk to the health and safety of the public;

B. The applicant is qualified by reason of training and experience to carry out the disposal operations requested in a manner that protects health and minimizes danger to life or property;

C. The applicant's proposed disposal site, disposal design, land disposal facility operations, including equipment, facilities, and procedures, disposal site closure, and post-closure institutional control are adequate to protect the public health and safety in that they provide reasonable assurance that the general population will be protected from releases of radioactivity as specified in the performance objective in 12 VAC 5-481-2820;

D. The applicant's proposed disposal site, disposal site design, land disposal facility operations, including equipment, facilities, and procedures, disposal site closure, and post-closure institutional control are adequate to protect the public health and safety in that they will provide reasonable assurance that individual inadvertent intruders are protected in accordance with the performance objective in 12 VAC 5-481-2850;

E. The applicant's proposed land disposal facility operations, including equipment, facilities, and

procedures, are adequate to protect the public health and safety in that they will provide reasonable assurance that the standards for radiation protection set out in Part IV (12 VAC 5-481-600 et seq.) of these regulations will be met;

F. The applicant's proposed disposal site, disposal site design, land disposal facility operations, disposal site closure, and post-closure institutional control are adequate to protect the public health and safety in that they will provide reasonable assurance that long-term stability of the disposed waste and the disposal site will be achieved and will eliminate to the extent practicable the need for ongoing active maintenance of the disposal site following closure;

G. The applicant's demonstration provides reasonable assurance that the applicable technical requirements of this Part will be met;

H. The applicant's proposal for institutional control provides reasonable assurance that such control will be provided for the length of time found necessary to ensure the findings in 12 VAC 5-481-2740 C through 12 VAC 5-481-2740 F and that the institutional control meets the requirements of 12 VAC 5-481-10328; and

I. The financial or surety arrangements meet the requirements of this Part.

12 VAC 5-481-2750. Conditions of licenses.

A. A license issued under this Part, or any right thereunder, may be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of

control of the license to any person, only if the agency finds, after securing full information, that the transfer is in accordance with the provisions of the Act and gives its consent in writing in the form of a license amendment.

B. The licensee shall submit written statements under oath upon request of the agency, at any time before termination of the license, to enable the agency to determine whether the license should be modified, suspended, or revoked.

C. The license will be terminated only on the full implementation of the final closure plan as approved by the agency, including post-closure observation and maintenance.

D. The licensee shall be subject to the provisions of the Act now or hereafter in effect, and to all rules, regulations, and orders of the agency. The terms and conditions of the license are subject to amendment, revision, or modification, by reason of amendments to, or by reason of rules, regulations, and orders issued in accordance with the terms of the Act.

E. Each person licensed by the agency pursuant to the regulations in this Part shall confine possession and use of materials to the locations and purposes authorized in the license.

F. The licensee shall not dispose of waste until the agency has inspected the land disposal facility and has found it to be in conformance with the description, design, and construction described in the application for a license.

G. The agency may incorporate in any license at the time of issuance, or thereafter, by appropriate

rule, regulation or order, additional requirements and conditions with respect to the licensee's receipt, possession, and disposal of waste as it deems appropriate or necessary in order to:

1. Protect health or to minimize danger to life or property;

2. Require reports and the keeping of records, and to provide for inspections of activities under the license that may be necessary or appropriate to effectuate the purposes of the Act and regulations thereunder.

H. The authority to dispose of wastes expires on the date stated in the license. Any expiration date on a license applies only to the above ground activities and to the authority to dispose of waste. Failure to renew the license shall not relieve the licensee of responsibility for implementing site closure, post-closure observation, and transfer of the license to the site owner.

I. Each licensee shall notify the agency in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against:

1. The licensee;

2. An entity (as that term is defined in 11 U.S.C. 101(14)) controlling the licensee or listing the license or licensee as property of the estate; or

3. An affiliate (as that term is defined in 11 U.S.C. 101(2)) of the licensee.

J. The notification specified in 12 VAC 5-481-2750 I shall indicate the bankruptcy court in which the petition for bankruptcy was filed and the date of the filing of the petition.

12 VAC 5-481-2760. Application for renewal or closure.

A. An application for renewal or an application for closure under 12 VAC 5-481-2770 must be filed at least 90 days prior to license expiration.

B. Applications for renewal of a license must be filed in accordance with 12 VAC 5-481-2680 through 12 VAC 5-481-2730. Applications for closure must be filed in accordance with 12 VAC 5-481-2770 . Information contained in previous applications, statements, or reports filed with the agency under the license may be incorporated by reference if the references are clear and specific.

C. In any case in which a licensee has filed an application in proper form for renewal of a license, the license does not expire until the agency has taken final action on the application for renewal.

D. In determining whether a license will be renewed, the agency will apply the criteria set forth in 12 VAC 5-481-2740.

12 VAC 5-481-2770. Contents of application for site closure and stabilization.

A. Prior to final closure of the disposal site, or as otherwise directed by the agency, the applicant shall submit an application to amend the license for closure. This closure application shall include a final revision and specific details of the disposal site closure plan included as part of the license application submitted under 12 VAC 5-481-2700 G that includes each of the following:

1. Any additional geologic, hydrologic, or other data pertinent to the long-term containment of emplaced wastes obtained during the operational period.

2. The results of tests, experiments, or any other analyses relating to backfill of excavated areas, closure and sealing, waste migration and interaction with emplacement media, or any other tests, experiments, or analysis pertinent to the long-term containment of emplaced waste within the disposal site.

3. Any proposed revision of plans for:

a. Decontamination and/or dismantlement of surface facilities;

b. Backfilling of excavated areas; or

c. Stabilization of the disposal site for post-closure care.

4. Any significant new information regarding the environmental impact of closure activities and long-term performance of the disposal site.

B. Upon review and consideration of an application to amend the license for closure submitted in accordance with 12 VAC 5-481-2770 A, the agency shall issue an amendment authorizing closure if there is reasonable assurance that the long-term performance objectives of this Part will be met.

12 VAC 5-481-2780. Post-closure observation and maintenance.

The licensee shall observe, monitor, and carry out necessary maintenance and repairs at the disposal site until the site closure is complete and the license is transferred by the agency in accordance with 12 VAC 5-481-2790. Responsibility for the disposal site must be maintained by the licensee for five years. A shorter or longer time period for post-closure observation and maintenance may be established and approved as part of the site closure plan, based on site-specific conditions.

12 VAC 5-481-2790. Transfer of license.

Following closure and the period of post-closure observation and maintenance, the licensee may apply for an amendment to transfer the license to the disposal site owner. The license shall be transferred when the agency finds:

A. That the closure of the disposal site has been made in conformance with the licensee's disposal site closure plan, as amended and approved as part of the license;

B. That reasonable assurance has been provided by the licensee that the performance objectives of

this Part are met;

C. That any funds and necessary records for care will be transferred to the disposal site owner;

D. That the post-closure monitoring program is operational for implementation by the disposal site owner; and

E. That the federal or state agency which will assume responsibility for institutional control of the disposal site is prepared to assume responsibility and ensure that the institutional requirements found necessary under 12 VAC 5-481-2740 H will be met.

12 VAC 5-481-2800. Termination of license.

A. Following any period of institutional control needed to meet the requirements found necessary under 12 VAC 5-481-2740, the licensee may apply for an amendment to terminate the license.

B. This application will be reviewed in accordance with the provisions of 12 VAC 5-481-440 of these regulations.

C. A license shall be terminated only when the agency finds:

1. That the institutional control requirements found necessary under 12 VAC 5-481-2740 H have been met;

2. That any additional requirements resulting from new information developed during the institutional control period have been met; and

3. That permanent monuments or markers warning against intrusion have been installed.

ARTICLE 3.

GENERAL PERFORMANCE OBJECTIVES.

12 VAC 5-481-2810. General requirement.

12 VAC 5-481-2820. Protection of the general population from releases of radioactivity.

12 VAC 5-481-2830. Protection of individuals from inadvertent intrusion.

12 VAC 5-481-2840. Protection of individuals during operations.

12 VAC 5-481-2850. Stability of the disposal site after closure.

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12 VAC 5-481-2810. General requirement.

Land disposal facilities shall be sited, designed, operated, closed, and controlled after closure so that reasonable assurance exists that exposures to individuals are within the requirements established in the performance objectives in 12 VAC 5-481-2820 through 12 VAC 5-481-2850.

12 VAC 5-481-2820. Protection of the general population from releases of radioactivity.

Concentrations of radioactive material which may be released to the general environment in ground water, surface water, air, soil, plants, or animals shall not result in an annual dose exceeding an equivalent of 25 millirems (0.25 mSv) to the whole body, 75 millirems (0.75 mSv) to the thyroid, and 25 millirems (0.25 mSv) to any other organ of any member of the public. Reasonable effort should be made to maintain releases of radioactivity in effluents to the general environment as low as is reasonably achievable.

12 VAC 5-481-2830. Protection of individuals from inadvertent intrusion.

Design, operation, and closure of the land disposal facility shall ensure protection of any individual inadvertently intruding into the disposal site and occupying the site or contacting the waste at any time after active institutional controls over the disposal site are removed.

12 VAC 5-481-2840. Protection of individuals during operations.

Operations at the land disposal facility shall be conducted in compliance with the standards for radiation protection set out in Part IV (12 VAC 5-481-600 et seq.) of these regulations, except for releases of radioactivity in effluents from the land disposal facility, which shall be governed by 12 VAC 5-481-2820. Every reasonable effort should be made to maintain radiation exposures as low as is reasonably achievable.

12 VAC 5-481-2850. Stability of the disposal site after closure.

The disposal facility shall be sited, designed, used, operated, and closed to achieve long-term stability of

the disposal site and to eliminate, to the extent practicable, the need for ongoing active maintenance of the disposal site following closure so that only surveillance, monitoring, or minor custodial care are required.

ARTICLE 4.

TECHNICAL REQUIREMENTS FOR LAND DISPOSAL FACILITIES.

12 VAC 5-481-2860. Disposal site suitability requirements for land disposal.

12 VAC 5-481-2870. Disposal site design for land disposal.

12 VAC 5-481-2880. Land disposal facility operation and disposal site closure.

12 VAC 5-481-2890. Environmental monitoring.

12 VAC 5-481-2900. Alternative requirements for design and operations.

12 VAC 5-481-2910. Institutional requirements.

12 VAC 5-481-2920. Alternative requirements for waste classification and characteristics.

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12 VAC 5-481-2860. Disposal site suitability requirements for land disposal.

A. Disposal site suitability for near-surface disposal. The primary emphasis in disposal site suitability is given to isolation of wastes and to disposal site features that ensure that the long-term performance objectives are met.

1. The disposal site shall be capable of being characterized, modeled, analyzed and

monitored.

2. Within the region where the facility is to be located, a disposal site should be selected so that projected population growth and future developments are not likely to affect the ability of the disposal facility to meet the performance objectives of this Part.

3. Areas shall be avoided having known natural resources which, if exploited, would result in failure to meet the performance objectives of this Part.

4. The disposal site shall be generally well drained and free of areas of flooding or frequent ponding. Waste disposal shall not take place in a 100-year flood plain, coastal high-hazard area or wetland, as defined in federal Executive Order 11988, "Floodplain Management Guidelines".

5 Upstream drainage areas shall be minimized to decrease the amount of runoff which could erode or inundate waste disposal units.

6. The disposal site shall provide sufficient depth to the water table that ground water intrusion, perennial or otherwise, into the waste will not occur. The agency will consider an exception to this requirement to allow disposal below the water table if it can be conclusively shown that disposal site characteristics will result in molecular diffusion being the predominant means of radionuclide movement and the rate of movement will result in the performance objectives being met. In no case will waste disposal be permitted in the zone of fluctuation of the water table.

7. The hydrogeologic unit used for disposal shall not discharge ground water to the surface within the disposal site.

8. Areas shall be avoided where tectonic processes such as faulting, folding, seismic activity, or vulcanism may occur with such frequency and extent to significantly affect the ability of the disposal site to meet the performance objectives of this Part or may preclude defensible modeling and prediction of long-term impacts.

9 Areas shall be avoided where surface geologic processes such as mass wasting, erosion, slumping, landsliding, or weathering occur with such frequency and extent to significantly affect the ability of the disposal site to meet the performance objectives of this Part, or may preclude defensible modeling and prediction of long-term impacts.

10. The disposal site must not be located where nearby facilities or activities could adversely impact the ability of the site to meet the performance objectives of this Part or significantly mask the environmental monitoring program.

B. Reserved

12 VAC 5-481-2870. Disposal site design for land disposal.

A. Disposal site design for near-surface disposal

1. Site design features shall be directed toward long-term isolation and avoidance of the need for continuing active maintenance after site closure.

2. The disposal site design and operation shall be compatible with the disposal site closure and stabilization plan and lead to disposal site closure that provides reasonable assurance that the performance objectives will be met.

3. The disposal site shall be designed to complement and improve, where appropriate, the ability of the disposal site's natural characteristics to assure that the performance objectives will be met.

4. Covers shall be designed to minimize to the extent practicable water infiltration, to direct percolating or surface water away from the disposed waste, and to resist degradation by surface geologic processes and biotic activity.

5 Surface features shall direct surface water drainage away from disposal units at velocities and gradients which will not result in erosion that will require ongoing active maintenance in the future.

6. The disposal site shall be designed to minimize to the extent practicable the contact of water with waste during storage, the contact of standing water with waste during disposal, and the contact of percolating or standing water with wastes after disposal.

B. Reserved

12 VAC 5-481-2880. Land disposal facility operation and disposal site closure.

A. Near-Surface disposal facility operation and disposal site closure

1. Wastes designated as Class A pursuant to these regulations shall be segregated from other wastes by placing in disposal units which are sufficiently separated from disposal units for the other waste classes so that any interaction between Class A wastes and other wastes will not result in the failure to meet the performance objectives of this Part. This segregation is not necessary for Class A wastes if they meet the stability requirements of these regulations.

2. Wastes designated as Class C pursuant to these regulations shall be disposed of so that the top of the waste is a minimum of five meters below the top surface of the cover or must be disposed of with intruder barriers that are designed to protect against an inadvertent intrusion for at least 500 years.

3. Except as provided in 12 VAC 5-481-2880 A 12, only waste classified as Class A, B, or C shall be acceptable for near-surface disposal. All waste shall be disposed of in accordance with requirements of 12 VAC 5-481-2880 A 4 through 12 VAC 5-481-2880 A 11.

4. Wastes shall be emplaced in a manner that maintains the package integrity during emplacement, minimizes the void spaces between packages, and permits the void spaces

to be filled.

5 Void spaces between waste packages shall be filled with earth or other material to reduce future subsidence within the fill.

6. Waste shall be placed and covered in a manner that limits the radiation dose rate at the surface of the cover to levels that at a minimum will permit the licensee to comply with all provisions of 12 VAC 5-481-640 of these regulations at the time the license is transferred pursuant to 12 VAC 5-481-2790.

7. The boundaries and locations of each disposal unit shall be accurately located and mapped by means of a land survey. Near-surface disposal units shall be marked in such a way that the boundaries of each unit can be easily defined. Three permanent survey marker control points, referenced to United States Geological Survey (USGS) or National Geodetic Survey (NGS) survey control stations, shall be established on the site to facilitate surveys. The USGS or NGS control stations shall provide horizontal and vertical controls as checked against USGS or NGS record files.

8. A buffer zone of land shall be maintained between any buried waste and the disposal site boundary and beneath the disposed waste. The buffer zone shall be of adequate dimensions to carry out environmental monitoring activities specified in 12 VAC 5-481-2890 C and take mitigative measures if needed.

9 Closure and stabilization measures as set forth in the approved site closure plan shall be

carried out as each disposal unit is filled and covered.

10. Active waste disposal operations shall not have an adverse effect on completed closure and stabilization measures.

11. Only wastes containing or contaminated with radioactive material shall be disposed of at the disposal site.

12. Proposals for disposal of waste that is not generally acceptable for near-surface disposal because the waste form and disposal methods must be different and, in general, more stringent than those specified for Class C waste, may be submitted to the agency for approval.

B. Reserved

12 VAC 5-481-2890. Environmental monitoring.

A. At the time a license application is submitted, the applicant shall have conducted a preoperational monitoring program to provide basic environmental data on the disposal site characteristics. The applicant shall obtain information about the ecology, meteorology, climate, hydrology, geology including geophysics and geotechnical engineering, geochemistry, and seismology of the disposal site. For those characteristics that are subject to seasonal variation, data must cover at least a 12-month period.

B. During the land disposal facility site construction and operation, the licensee shall maintain an environmental monitoring program. Measurements and observations must be made and recorded to provide data to evaluate the potential health and environmental impacts during both the construction and the operation of the facility and to enable the evaluation of long-term effects and the need for mitigative measures. The monitoring system must be capable of providing early warning of releases of waste from the disposal site before they leave the site boundary.

C. After the disposal site is closed, the licensee responsible for post-operational surveillance of the disposal site shall maintain a monitoring system based on the operating history and the closure and stabilization of the disposal site. The monitoring system must be capable of providing early warning of releases of waste from the disposal site before they leave the site boundary.

D. The licensee shall have plans for taking corrective measures if the environmental monitoring program detects migration of waste which would indicate that the performance objectives may not be met.

12 VAC 5-481-2900. Alternative requirements for design and operations.

The agency may, upon request or on its own initiative, authorize provisions other than those set forth in 12 VAC 5-481-2870 through 12 VAC 5-481-2890 for the segregation and disposal of waste and for the design and operation of a land disposal facility on a specific basis, if it finds reasonable assurance of compliance with the performance objectives of this Part.

12 VAC 5-481-2910. Institutional requirements.

A. Land ownership. Disposal of waste received from other persons may be permitted only on land owned in fee by the Federal or a state government.

B. Institutional control. The land owner or custodial agency shall conduct an institutional control program to physically control access to the disposal site following transfer of control of the disposal site from the disposal site operator. The institutional control program shall also include, but not be limited to, conducting an environmental monitoring program at the disposal site, periodic surveillance, minor custodial care, and other requirements as determined by the agency; and administration of funds to cover the costs for these activities. The period of institutional controls will be determined by the agency, but institutional controls may not be relied upon for more than 100 years following transfer of control of the disposal site to the owner.

12 VAC 5-481-2920. Alternative requirements for waste classification and characteristics.

The agency licensing a low-level disposal facility may, upon request or on its own initiative, authorize other provisions for the classification and characteristics of waste on a specific basis, if, after evaluation of the specific characteristics of the waste, disposal site, method of disposal, it finds reasonable assurance of compliance with the performance objectives specified in this Part.

ARTICLE 5.

FINANCIAL ASSURANCES.

12 VAC 5-481-2930. Applicant qualifications and assurances.

12 VAC 5-481-2940. Funding for disposal site closure and stabilization.

12 VAC 5-481-2950. Financial assurances for institutional controls.

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12 VAC 5-481-2930. Applicant qualifications and assurances.

Each applicant shall show that it either possesses the necessary funds or has reasonable assurance of obtaining the necessary funds, or by a combination of the two, to cover the estimated costs of conducting all licensed activities over the planned operating life of the project, including costs of construction and disposal.

12 VAC 5-481-2940. Funding for disposal site closure and stabilization.

A. The applicant shall provide assurances prior to the commencement of operations that sufficient funds will be available to carry out disposal site closure and stabilization, including: (i) decontamination or dismantlement of land disposal facility structures; and (ii) closure and stabilization of the disposal site so that following transfer of the disposal site to the site owner, the need for ongoing active maintenance is eliminated to the extent practicable and only minor custodial care, surveillance, and monitoring are required. These assurances shall be based on agency-approved cost estimates reflecting the agency-approved plan for disposal site closure and stabilization. The applicant's cost estimates must take into account total costs that would be incurred if an independent contractor were hired to perform the closure and stabilization work.

B. In order to avoid unnecessary duplication and expense, the agency will accept financial sureties that have been consolidated with earmarked financial or surety arrangements established to meet requirements of Federal or other state agencies (and/or local governmental bodies} for such decontamination, closure, and stabilization. The agency will accept these arrangements only if they are considered adequate to satisfy the requirements of 12 VAC 5-481-2940 and that the portion of the surety which covers the closure of the disposal site is clearly identified and committed for use in accomplishing these activities.

C. The licensee's financial or surety arrangement shall be submitted annually for review by the agency to assure that sufficient funds will be available for completion of the closure plan.

D. The amount of the licensee's financial or surety arrangement shall change in accordance with changes in the predicted costs of closure and stabilization. Factors affecting closure and stabilization cost estimates include inflation, increases in the amount of disturbed land, changes in engineering plans, closure and stabilization that has already been accomplished, and any other conditions affecting costs. The financial or surety arrangement shall be sufficient at all times to cover the costs of closure and stabilization of the disposal units that are expected to be used before the next license renewal.

E. The financial or surety arrangement shall be either open-ended or be written for a specified period of time and shall be automatically renewed unless the person who issues the surety notifies the agency, the beneficiary (the site owner), and the principal (the licensee) not less than 90 days prior to the renewal date of its intention not to renew. In such a situation, the licensee must submit a replacement surety within 30 days after notification of cancellation. If the

licensee fails to provide a replacement surety acceptable to the agency, the beneficiary may collect on the original surety.

F. Proof of forfeiture shall not be necessary to collect the surety so that, in the event that the licensee could not provide an acceptable replacement surety within the required time, the surety shall be automatically collected prior to its expiration. The conditions described above shall be clearly stated on any surety instrument.

G. Financial or surety arrangements generally acceptable to the agency include surety bonds, cash deposits, certificates of deposit, deposits of government securities, escrow accounts, irrevocable letters or lines of credit, trust funds, and combinations of the above or such other types of arrangements as may be approved by the agency. Self-insurance, or any arrangement which essentially constitutes self-insurance, will not satisfy the surety requirement for private sector applicants.

H. The licensee's financial or surety arrangement shall remain in effect until the closure and stabilization program has been completed and approved by the agency, and the license has been transferred to the site owner.

12 VAC 5-481-2950. Financial assurances for institutional controls.

A. Prior to the issuance of the license, the applicant shall provide for agency approval, a binding arrangement, between the applicant and the disposal site owner that ensures that sufficient funds will be available to cover the costs of monitoring and any required maintenance during the

institutional control period. The binding arrangement shall be reviewed periodically by the agency to ensure that changes in inflation, technology, and disposal facility operations are reflected in the arrangements.

B. Subsequent changes to the binding arrangement specified in 12 VAC 5-481-2950 A relevant to institutional control shall be submitted to the agency for prior approval.

ARTICLE 6.

RECORDS, REPORTS, TESTS, AND INSPECTIONS.

12 VAC 5-481-2960. Maintenance of records, reports, and transfers.

12 VAC 5-481-2970. Tests on land disposal facilities.

12 VAC 5-481-2980. Agency inspections of land disposal facilities.

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12 VAC 5-481-2960. Maintenance of records, reports, and transfers.

A. Each licensee shall maintain any records and make any reports in connection with the licensed activities as may be required by the conditions of the license or by the rules, regulations, and orders of the agency.

B. Records which are required by these regulations or by license conditions shall be maintained for a period specified by the appropriate regulations or by license condition. If a retention period is

not otherwise specified, these records must be maintained and transferred to the officials specified in 12 VAC 5-481-2960 D as a condition of license termination unless the agency otherwise authorizes their disposition.

C. Records which shall be maintained pursuant to this Part may be the original or a reproduced copy or microfilm if this reproduced copy or microfilm is capable of producing copy that is clear and legible at the end of the required retention period.

D. Notwithstanding 12 VAC 5-481-2960 A through 12 VAC 5-481-2960 C, copies of records of the location and the quantity of wastes contained in the disposal site must be transferred upon license termination to the chief executive of the nearest municipality, the chief executive of the county in which the facility is located, the county zoning board or land development and planning agency, the state governor, and other state, local and Federal governmental agencies as designated by the agency at the time of license termination.

E. Following receipt and acceptance of a shipment of waste, the licensee shall record the date of disposal of the waste, the location in the disposal site, the condition of the waste packages as received, any discrepancies between materials listed on the manifest and those received, and any evidence of leaking or damaged packages or radiation or contamination levels in excess of limits specified in U.S. Department of Transportation and agency regulations. The licensee shall briefly describe any repackaging operations of any of the waste packages included in the shipment, plus any other information required by the agency as a license condition.

F. Each licensee authorized to dispose of waste received from other persons shall file a copy of its

financial report or a certified financial statement annually with the agency in order to update the information base for determining financial qualifications.

G. Do the following:

1. Each licensee authorized to dispose of waste received from other persons, pursuant to this Part, shall submit annual reports to the agency. Reports shall be submitted by the end of the first calendar quarter of each year for the preceding year.

2. The reports shall include:

a. Specification of the quantity of each of the principal contaminants released to unrestricted areas in liquid and in airborne effluents during the preceding year,

b. The results of the environmental monitoring program,

c. A summary of licensee disposal unit survey and maintenance activities,

d. A summary, by waste class, of activities and quantities of radionuclides disposed of,

e. Any instances in which observed site characteristics were significantly different from those described in the application for a license, and

f. Any other information the agency may require.

3. If the quantities of waste released during the reporting period, monitoring results, or maintenance performed are significantly different from those predicted, the report must cover this specifically.

12 VAC 5-481-2970. Tests on land disposal facilities.

Each licensee shall perform, or permit the agency to perform, any tests the agency deems appropriate or necessary for the administration of the regulations in this Part, including, but not limited to, tests of:

A. Wastes;

B. Facilities used for the receipt, storage, treatment, handling or disposal of wastes;

C. Radiation detection and monitoring instruments;

D. Other equipment and devices used in connection with the receipt, possession, handling, treatment, storage, or disposal of waste; or

E. Environmental sampling or testing.

12 VAC 5-481-2980. Agency inspections of land disposal facilities.

A. Each licensee shall afford to the agency at all reasonable times opportunity to inspect waste not yet disposed of, and the premises, equipment, operations, and facilities in which wastes are received, possessed, handled, treated, stored, or disposed of.

B. Each licensee shall make available to the agency for inspection, upon reasonable notice, records kept by it pursuant to these regulations. Authorized representatives of the agency may copy and take away copies of, for the agency's use, any record required to be kept pursuant to these regulations.

PART XII.

LICENSING AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS.

12 VAC 5-481-3180 Personnel monitoring.

12 VAC 5-481-3190 Radiation surveys.

12 VAC 5-481-3200 Detection of leaking sources.

12 VAC 5-481-3210 Inspection and maintenance.

12 VAC 5-481-3220 Pool water purity.

12 VAC 5-481-3230 Attendance during operation.

12 VAC 5-481-3240 Entering and leaving the radiation room.

12 VAC 5-481-3250 Irradiation of explosive or flammable materials.

12 VAC 5-481-3260 Records and retention periods.

12 VAC 5-481-3270 Reports.

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12 VAC 5-481-2990. Purpose and scope.

A. Part XII (12 VAC 5-481-2990 et seq.) contains requirements for the issuance of a license authorizing the use of sealed sources containing radioactive material in irradiators used to irradiate objects or materials using gamma radiation. This part also contains radiation safety requirements for operating irradiators. The requirements of this part are in addition to other requirements of these regulations. In particular, the provisions of Parts I (12 VAC 5-481-10 et seq.); III (12 VAC 5-481-380 et seq.); IX (12 VAC 5-481-2470 et seq.); and X (12 VAC 5-481-2580 et seq.) of these regulations apply to applications and licenses subject to this Part. Nothing in this Part relieves the licensee from complying with other applicable federal, state and local regulations governing the siting, zoning, land use, and building code requirements for industrial facilities.

B. The regulations in this Part apply to panoramic irradiators that have either dry or wet storage of the radioactive sealed sources and to underwater irradiators in which both the source and the product being irradiated are under water. Irradiators whose dose rates exceed five grays (500 rads) per hour at one meter from the radioactive sealed sources in air or in water, as applicable for the irradiator type, are covered by this Part.

C. The regulations in this Part do not apply to self-contained dry-source-storage irradiators in which both the source and the area subject to irradiation are contained within a device and are not accessible by personnel; medical radiology or teletherapy; radiography for the irradiation of materials for nondestructive testing purposes; gauging; or open-field, agricultural, irradiations.

12 VAC 5-481-3000. Application for a specific license.

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. In the application, the applicant may incorporate by reference information contained in previous applications, statements, or reports filed with the agency provided such references are clear and specific.

F. Applications and documents submitted to the agency may be made available for public inspection except that the agency may withhold any document or part thereof from public inspection if disclosure of its content is not required in the public interest and would adversely affect the interest of a person concerned.

12 VAC 5-481-3010. Specific licenses for irradiators.

The agency will approve an application for a specific license for the use of licensed material in an irradiator if the applicant meets the requirements contained in this section.

A. The applicant shall satisfy the general requirements specified in Part III (12 VAC 5-481-380 et seq.) of these regulations and the requirements contained in this part.

B. The application must describe the training provided to irradiator operators including:

1. Classroom training;

2. On-the-job or simulator training;

3. Safety reviews;

4. Means employed by the applicant to test each operator's understanding of the agency's regulations and licensing requirements and the irradiator operating, safety, and emergency procedures; and

5 Minimum training and experience of personnel who may provide training.

C. The application must include an outline of the written operating and emergency procedures listed in 12 VAC 5-481-3170 that describes the radiation safety aspects of the procedures.

D. The application must describe the organizational structure for managing the irradiator, specifically the radiation safety responsibilities and authorities of the radiation safety officer and those management personnel who have radiation safety responsibilities or authorities. In particular, the application must specify who, within the management structure, has the authority to stop unsafe operations. The application must also describe the training and experience required for the position of radiation safety officer.

E. The application must include a description of the access control systems required by 12 VAC 5-481-3060, the radiation monitors required by 12 VAC 5-481-3090., the method of detecting leaking sources required by 12 VAC 5-481-3200., including the sensitivity of the method, and a diagram of the facility that shows the locations of all required interlocks and radiation monitors.

F. If the applicant intends to perform leak testing, the applicant shall establish procedures for performing leak testing of dry-source-storage sealed sources and submit a description of these procedures to the agency. The description must include the:

1. Methods of collecting the leak test samples;

2. Qualifications of the individual who collects the samples;

3. Instruments to be used; and

4. Methods of analyzing the samples.

G. If licensee personnel are to load or unload sources, the applicant shall describe the qualifications and training of the personnel and the procedures to be used. If the applicant intends to contract for source loading or unloading at its facility, the loading or unloading must be done by a person specifically authorized by the agency, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State to load or unload irradiator sources.

H. The applicant shall describe the inspection and maintenance checks, including the frequency of the checks required by 12 VAC 5-481-3210.

12 VAC 5-481-3020. Start of construction.

The applicant may not begin construction of a new irradiator prior to the submission to the agency of

both an application for a license for the irradiator and any fee required by the applicable state requirement or statute. As used in this part, the term "construction" includes the construction of any portion of the permanent irradiator structure on the site but does not include: engineering and design work, purchase of a site, site surveys or soil testing, site preparation, site excavation, construction of warehouse or auxiliary structures, and other similar tasks. Any activities undertaken prior to the issuance of a license are entirely at the risk of the applicant and have no bearing on the issuance of a license with respect to the requirements of the appropriate state statute, rules, regulations, and orders issued under the appropriate state statute.

12 VAC 5-481-3030. Applications for exemptions.

Any application for a license or for amendment of a license authorizing use of a teletherapy-type unit for irradiation of materials or objects may include proposed alternatives for the requirements of this part. The agency will approve the proposed alternatives if the applicant provides adequate rationale for the proposed alternatives and demonstrates that they are likely to provide an adequate level of safety for workers and the public.

12 VAC 5-481-3040. Request for written statements.

Each license is issued with the condition that the licensee will, at any time before expiration of the license, upon the agency's request, submit a written statement to enable the agency to determine whether the license should be modified, suspended, or revoked.

12 VAC 5-481-3050. Performance criteria for sealed sources.

A. Requirements for sealed sources installed after the effective date of these regulations:

1. Must have been evaluated in accordance with 10 CFR 32.210 or the equivalent state regulation;

2. Must be doubly encapsulated;

3. Must use radioactive material that is as nondispersible as practical and that is as insoluble as practical if the source is used in a wet-source-storage or wet-source-change irradiator;

4. Must be encapsulated in a material resistant to general corrosion and to localized corrosion, such as 316L stainless steel or other material with equivalent resistance if the sources are for use in irradiator pools; and

5. In prototype testing of the sealed source, must have been leak tested and found leak-free after each of the tests described in 12 VAC 5-481-3050 B through 12 VAC 5-481-3050 G.

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

C. Pressure. The test source must be twice subjected for at least five minutes to an absolute external pressure of two million newtons per square meter.

D. Impact. A two kilogram steel weight, 2.5 centimeters in diameter, must be dropped from a height of one meter onto the test source.

E. Vibration. The test source must be subjected three times for 10 minutes each to vibrations sweeping from 25 hertz to 500 hertz with a peak amplitude of five times the acceleration of gravity. In addition, each test source must be vibrated for 30 minutes at each resonant frequency found.

F. Puncture. A 50 gram weight and pin, 0.3 centimeter pin diameter, must be dropped from a height of one meter onto the test source.

G. Bend. If the length of the source is more than 15 times larger than the minimum cross-sectional dimension, the test source must be subjected to a force of 2000 newtons at its center equidistant from two support cylinders, the distance between which is 10 times the minimum cross-sectional dimension of the source.

12 VAC 5-481-3060. Access control.

A. Each entrance to a radiation room at a panoramic irradiator must have a door or other physical barrier to prevent inadvertent entry of personnel if the sources are not in the shielded position. Product conveyor systems may serve as barriers as long as they reliably and consistently

function as a barrier. It must not be possible to move the sources out of their shielded position if the door or barrier is open. Opening the door or barrier while the sources are exposed must cause the sources to return promptly to the shielded position. The personnel entrance door or barrier must have a lock that is operated by the same key used to move the sources. The control panel lock must be designed so that the key cannot be removed unless the sources have been returned to the shielded position. The doors and barriers must not prevent any individual in the radiation room from leaving.

B. In addition, each entrance to a radiation room at a panoramic irradiator must have an independent backup access control to detect personnel entry while the sources are exposed. Detection of entry while the sources are exposed must cause the sources to return to their fully shielded position and must also activate a visible and audible alarm to make the individual entering the room aware of the hazard. The alarm must also alert at least one other individual who is on-site of the entry. That individual shall be trained on how to respond to the alarm and prepared to promptly render or summon assistance.

C. A radiation monitor must be provided to detect the presence of high radiation levels in the radiation room of a panoramic irradiator before personnel entry. The monitor must be integrated with personnel access door locks to prevent room access when radiation levels are high. Attempted personnel entry while the monitor measures high radiation levels must activate the alarm described in 12 VAC 5-481-3060 B. The monitor may be located in the entrance, normally referred to as the maze, but not in the direct radiation beam.

D. Before the sources move from their shielded position in a panoramic irradiator, the source

control must automatically activate conspicuous visible and audible alarms to alert people in the radiation room that the sources will be moved from their shielded position. The alarms must give individuals enough time to leave the room before the sources leave the shielded position.

E. Each radiation room at a panoramic irradiator must have a clearly visible and readily accessible control that would allow an individual in the room to make the sources return to their fully shielded position.

F. Each radiation room of a panoramic irradiator must contain a control that prevents the sources from moving from the shielded position unless the control has been activated and the door or barrier to the radiation room has been closed within a preset time after activation of the control.

G. Each entrance to the radiation room of a panoramic irradiator and each entrance to the area within the personnel access barrier of an underwater irradiator must have a sign bearing the radiation symbol and the words, "Caution (or danger) radioactive material." Panoramic irradiators must also have a sign stating "Grave danger, very high radiation area," but the sign may be removed, covered, or otherwise made inoperative when the sources are fully shielded.

H. If the radiation room of a panoramic irradiator has roof plugs or other movable shielding, it must not be possible to operate the irradiator unless the shielding is in its proper location. The requirement may be met by interlocks that prevent operation if shielding is not placed properly or by an operating procedure requiring inspection of shielding before operating.

I. Underwater irradiators must have a personnel access barrier around the pool which must be

locked to prevent access when the irradiator is not attended. Only operators or facility management shall have access to keys that operate the personnel access barrier. There must be an intrusion alarm to detect unauthorized entry when the personnel access barrier is locked. Activation of the intrusion alarm must alert an individual who is not necessarily on-site but who is prepared to respond or summon assistance.

12 VAC 5-481-3070. Shielding.

A. The radiation dose rate in areas that are normally occupied during operation of a panoramic irradiator may not exceed 0.02 millisievert (2 mrem) per hour at any location 30 centimeters or more from the wall of the room when the sources are exposed. The dose rate must be averaged over an area not to exceed 100 square centimeters having no linear dimension greater than 20 centimeters. Any area where the radiation dose rate exceeds 0.02 millisievert (2 mrem) per hour must be locked, roped off, or posted.

B. The radiation dose at 30 centimeters over the edge of the pool of a pool irradiator may not exceed 0.02 millisievert (2 mrem) per hour when the sources are in the fully shielded position.

C. The radiation dose rate at one meter from the shield of a dry-source-storage panoramic irradiator when the source is shielded may not exceed 0.02 millisievert (2 mrem) per hour and at five centimeters from the shield may not exceed 0.2 millisievert (20 mrem) per hour.

12 VAC 5-481-3080. Fire protection.

A. The radiation room at a panoramic irradiator must have heat and smoke detectors. The detectors must activate an audible alarm. The alarm must be capable of alerting a person who is prepared to summon assistance promptly. The sources must automatically become fully shielded if a fire is detected.

B. The radiation room at a panoramic irradiator must be equipped with a fire extinguishing system capable of extinguishing a fire without the entry of personnel into the room. The system for the radiation room must have a shut-off valve to control flooding into unrestricted areas.

12 VAC 5-481-3090. Radiation monitors.

A. Irradiators with automatic product conveyor systems must have a radiation monitor with an audible alarm located to detect loose radioactive sources that are carried toward the product exit. If the monitor detects a source, an alarm must sound and product conveyors must stop automatically. The alarm must be capable of alerting an individual in the facility who is prepared to summon assistance. Underwater irradiators in which the product moves within an enclosed stationary tube are exempt from the requirements of this paragraph.

B. Underwater irradiators that are not in a shielded radiation room must have a radiation monitor over the pool to detect abnormal radiation levels. The monitor must have an audible alarm and a visible indicator at entrances to the personnel access barrier around the pool. The audible alarm may have a manual shut-off. The alarm must be capable of alerting an individual who is prepared to respond promptly.

12 VAC 5-481-3100. Control of source movement.

A. The mechanism that moves the sources of a panoramic irradiator must require a key to actuate. Actuation of the mechanism must cause an audible signal to indicate that the sources are leaving the shielded position. Only one key may be in use at any time, and only operators or facility management may possess it. The key must be attached to a portable radiation survey meter by a chain or cable. The lock for source control must be designed so that the key may not be removed if the sources are in an unshielded position. The door to the radiation room must require the same key.

B. The console of a panoramic irradiator must have a source position indicator that indicates when the sources are in the fully shielded position, when they are in transit, and when the sources are exposed.

C. The control console of a panoramic irradiator must have a control that promptly returns the sources to the shielded position.

D. Each control for a panoramic irradiator must be clearly marked as to its function.

12 VAC 5-481-3110. Irradiator pools.

A. For licenses initially issued after the effective date of these regulations, irradiator pools must either:

1. Have a water-tight stainless steel liner or a liner metallurgically compatible with other components in the pool; or

2. Be constructed so that there is a low likelihood of substantial leakage and have a surface designed to facilitate decontamination. In either case, the licensee shall have a method to safely store the sources during repairs of the pool.

B. For licenses initially issued after the effective date of these regulations, irradiator pools must have no outlets more than 0.5 meter below the normal low water level that could allow water to drain out of the pool. Pipes that have intakes more than 0.5 meter below the normal low water level and that could act as siphons must have siphon breakers to prevent the siphoning of pool water.

C. A means must be provided to replenish water losses from the pool.

D. A visible indicator must be provided in a clearly observable location to indicate if the pool water level is below the normal low water level or above the normal high water level.

E. Irradiator pools must be equipped with a purification system designed to be capable of maintaining the water during normal operation at a conductivity of 20 microsiemens per centimeter or less and with a clarity so that the sources can be seen clearly.

F. A physical barrier, such as a railing or cover, must be used around or over irradiator pools during normal operation to prevent personnel from accidentally falling into the pool. The barrier may

be removed during maintenance, inspection, and service operations.

G. If long-handled tools or poles are used in irradiator pools, the radiation dose rate to the operator at the handling areas of the tools may not exceed 0.02 millisievert (2 mrem) per hour.

12 VAC 5-481-3120. Source rack protection.

If the product to be irradiated moves on a product conveyor system, the source rack and the mechanism that moves the rack must be protected by a carrier or guides to prevent products and product carriers from hitting or touching the rack or mechanism.

12 VAC 5-481-3130. Power failures.

A. If electrical power at a panoramic irradiator is lost for longer than 10 seconds, the sources must automatically return to the shielded position.

B. The lock on the door of the radiation room of a panoramic irradiator must remain locked in the event of a power failure.

C. During a power failure, the area of any irradiator where sources are located may be entered only when using an operable and calibrated radiation survey meter.

12 VAC 5-481-3140. Design requirements.

Irradiators whose construction begins after the effective date of these regulations, must meet the design requirements of this section.

A. Shielding. For panoramic irradiators, the licensee shall design shielding walls to meet generally accepted building code requirements for reinforced concrete and design the walls, wall penetrations, and entranceways to meet the radiation shielding requirements of 12 VAC 5-481-3070. If the irradiator will use more than 2×10^{17} becquerels (5 million Ci) of activity, the licensee shall evaluate the effects of heating of the shielding walls by the irradiator sources.

B. Foundations. For panoramic irradiators, the licensee shall design the foundation, with consideration given to soil characteristics, to ensure it is adequate to support the weight of the facility shield walls.

C. Pool integrity. For pool irradiators, the licensee shall design the pool to assure that it is leak resistant, that it is strong enough to bear the weight of the pool water and shipping casks, that a dropped cask would not fall on sealed sources, that all outlets or pipes meet the requirements of 12 VAC 5-481-3110 B, and that metal components are metallurgically compatible with other components in the pool.

D. Water handling system. For pool irradiators, the licensee shall verify that the design of the water purification system is adequate to meet the requirements of 12 VAC 5-481-3110 E. The system must be designed so that water leaking from the system does not drain to unrestricted areas without being monitored.

E. Radiation monitors. For all irradiators, the licensee shall evaluate the location and sensitivity of the monitor to detect sources carried by the product conveyor system as required by 12 VAC 5-481-3090 A. The licensee shall verify that the product conveyor is designed to stop before a source on the product conveyor would cause a radiation overexposure to any person. For pool irradiators, if the licensee uses radiation monitors to detect contamination under 12 VAC 5-481-3200 B, the licensee shall verify that the design of radiation monitoring systems to detect pool contamination includes sensitive detectors located close to where contamination is likely to concentrate.

F. Source rack. For pool irradiators, the licensee shall verify that there are no crevices on the source or between the source and source holder that would promote corrosion on a critical area of the source. For panoramic irradiators, the licensee shall determine that source rack drops due to loss of power will not damage the source rack and that source rack drops due to failure of cables, or alternate means of support, will not cause loss of integrity of sealed sources. For panoramic irradiators, the licensee shall review the design of the mechanism that moves the sources to assure that the likelihood of a stuck source is low and that, if the rack sticks, a means exists to free it with minimal risk to personnel.

G. Access control. For panoramic irradiators, the licensee shall verify from the design and logic diagram that the access control system will meet the requirements of 12 VAC 5-481-3060.

H. Fire protection. For panoramic irradiators, the licensee shall verify that the number, locations, and spacing of the smoke and heat detectors are appropriate to detect fires and that the detectors are protected from mechanical and radiation damage. The licensee shall verify that the design of

the fire extinguishing system provides the necessary discharge patterns, densities, and flow characteristics for complete coverage of the radiation room and that the system is protected from mechanical and radiation damage.

I. Source return. For panoramic irradiators, the licensee shall verify that the source rack will automatically return to the fully shielded position if power is lost for more than 10 seconds.

J. Seismic. For panoramic irradiators to be built in seismic areas, the licensee shall design the reinforced concrete radiation shields to retain their integrity in the event of an earthquake by designing to the seismic requirements of an appropriate source such as the American Concrete Institute Standard ACI 318-89, "Building Code Requirements for Reinforced Concrete," Chapter 21, "Special Provisions for Seismic Design," or local building codes, if current.

K. Wiring. For panoramic irradiators, the licensee shall verify that electrical wiring and electrical equipment in the radiation room are selected to minimize failures due to prolonged exposure to radiation.

12 VAC 5-481-3150. Construction monitoring and acceptance testing.

The requirements of this section must be met for irradiators whose construction begins after the effective date of these regulations. The requirements must be met prior to loading sources.

A. Shielding. For panoramic irradiators, the licensee shall monitor the construction of the shielding to verify that its construction meets design specifications and generally accepted building code

requirements for reinforced concrete.

B. Foundations. For panoramic irradiators, the licensee shall monitor the construction of the foundations to verify that their construction meets design specifications.

C. Pool integrity. For pool irradiators, the licensee shall verify that the pool meets design specifications and shall test the integrity of the pool. The licensee shall verify that outlets and pipes meet the requirements of 12 VAC 5-481-3110 B.

D. Water handling system. For pool irradiators, the licensee shall verify that the water purification system, the conductivity meter, and the water level indicators operate properly.

E. Radiation monitors. For all irradiators, the licensee shall verify the proper operation of the monitor to detect sources carried on the product conveyor system and the related alarms and interlocks required by 12 VAC 5-481-3090 A. For pool irradiators, the licensee shall verify the proper operation of the radiation monitors and the related alarm if used to meet 12 VAC 5-481-3200 B. For underwater irradiators, the licensee shall verify the proper operation of the over-the-pool monitor, alarms, and interlocks required by 12 VAC 5-481-3090 B.

F. Source rack. For panoramic irradiators, the licensee shall test the movement of the source racks for proper operation prior to source loading; testing must include source rack lowering due to simulated loss of power. For all irradiators with product conveyor systems, the licensee shall observe and test the operation of the conveyor system to assure that the requirements in 12 VAC 5-481-3120 are met for protection of the source rack and the mechanism that moves the rack;

testing must include tests of any limit switches and interlocks used to protect the source rack and mechanism that moves that rack from moving product carriers.

G. Access control. For panoramic irradiators, the licensee shall test the completed access control system to assure that it functions as designed and that all alarms, controls, and interlocks work properly.

H. Fire protection. For panoramic irradiators, the licensee shall test the ability of the heat and smoke detectors to detect a fire, to activate alarms, and to cause the source rack to automatically become fully shielded. The licensee shall test the operability of the fire extinguishing system.

I. Source return. For panoramic irradiators, the licensee shall demonstrate that the source racks can be returned to their fully shielded positions without power.

J. Computer systems. For panoramic irradiators that use a computer system to control the access control system, the licensee shall verify that the access control system will operate properly if power is lost and shall verify that the computer has security features that prevent an irradiator operator from commanding the computer to override the access control system when the system is required to be operable.

K. Wiring. For panoramic irradiators, the licensee shall verify that the electrical wiring and electrical equipment that were installed meet the design specifications.

12 VAC 5-481-3160. Training.

A. Before an individual is permitted to act as an irradiator operator without a supervisor present, the individual must be instructed in:

1. The fundamentals of radiation protection applied to irradiators. This must include the differences between external radiation and radioactive contamination, units of radiation dose, dose limits, why large radiation doses must be avoided, how shielding and access controls prevent large doses, how an irradiator is designed to prevent contamination, the proper use of survey meters and personnel dosimeters, other radiation safety features of an irradiator, and the basic function of the irradiator;

2. The requirements of Parts X (12 VAC 5-481-2580 et seq.) and XII (12 VAC 5-481-2990 et seq.) of these regulations that are relevant to the irradiator;

3. The operation of the irradiator;

4. Those operating and emergency procedures listed in 12 VAC 5-481-3170 that the individual is responsible for performing; and

5. Case histories of accidents or problems involving irradiators.

B. Before an individual is permitted to act as an irradiator operator without a supervisor present, the individual shall pass a written test on the instruction received consisting primarily of questions

based on the licensee's operating and emergency procedures that the individual is responsible for performing and other operations necessary to safely operate the irradiator without supervision.

C. Before an individual is permitted to act as an irradiator operator without a supervisor present, the individual must have received on-the-job training or simulator training in the use of the irradiator as described in the license application. The individual shall also demonstrate the ability to perform those portions of the operating and emergency procedures that he or she is to perform.

D. The licensee shall conduct safety reviews for irradiator operators at least annually. The licensee shall give each operator a brief written test on the information. Each safety review must include, to the extent appropriate, each of the following:

1. Changes in operating and emergency procedures since the last review, if any;

2. Changes in regulations and license conditions since the last review, if any;

3. Reports on recent accidents, mistakes, or problems that have occurred at irradiators, if any;

4. Relevant results of inspections of operator safety performance;

5 Relevant results of the facility's inspection and maintenance checks; and

6. A drill to practice an emergency or abnormal event procedure.

E. The licensee shall evaluate the safety performance of each irradiator operator at least annually to ensure that regulations, license conditions, and operating, safety, and emergency procedures are followed. The licensee shall discuss the results of the evaluation with the operator and shall instruct the operator on how to correct any mistakes or deficiencies observed.

F. Individuals who will be permitted unescorted access to the radiation room of the irradiator or the area around the pool of an underwater irradiator, but who have not received the training required for operators and the radiation safety officer, shall be instructed and tested in any precautions they should take to avoid radiation exposure, any procedures or parts of procedures listed in 12 VAC 5-481-3170 that they are expected to perform or comply with, and their proper response to alarms required in this part. Tests may be oral.

G. Individuals who must be prepared to respond to alarms required by 12 VAC 5-481-3060 B and 12 VAC 5-481-3060 I; 12 VAC 5-481-3080 A; 12 VAC 5-481-3090 A; 12 VAC 5-481-3090 B; and 12 VAC 5-481-3200 B shall be trained and tested on how to respond. Each individual shall be retested at least annually. Tests may be oral.

12 VAC 5-481-3170. Operating and emergency procedures.

A. The licensee shall have and follow written operating procedures for:

1. Operation of the irradiator, including entering and leaving the radiation room;

2. Use of personnel dosimeters;

3. Surveying the shielding of panoramic irradiators;

4. Monitoring pool water for contamination while the water is in the pool and before release of pool water to unrestricted areas;

5. Leak testing of sources;

6. Inspection and maintenance checks required by 12 VAC 5-481-3210.;

7. Loading, unloading, and repositioning sources, if the operations will be performed by the licensee; and

8. Inspection of movable shielding required by 12 VAC 5-481-3060 H, if applicable.

B. The licensee shall have and follow emergency or abnormal event procedures, appropriate for the irradiator type, for:

1. Sources stuck in the unshielded position;

2. Personnel overexposures;

3. A radiation alarm from the product exit portal monitor or pool monitor;

4. Detection of leaking sources, pool contamination, or alarm caused by contamination of pool water;

5. A low or high water level indicator, an abnormal water loss, or leakage from the source storage pool;

6. A prolonged loss of electrical power;

7. A fire alarm or explosion in the radiation room;

8. An alarm indicating unauthorized entry into the radiation room, area around pool, or another alarmed area;

9. Natural phenomena, including an earthquake, a tornado, flooding, or other phenomena as appropriate for the geographical location of the facility; and

10. The jamming of automatic conveyor systems.

C. The licensee may revise operating and emergency procedures without agency approval only if all of the following conditions are met:

1. The revisions do not reduce the safety of the facility;

2. The revisions are consistent with the outline or summary of procedures submitted with the license application;

3. The revisions have been reviewed and approved by the radiation safety officer; and

4. The users or operators are instructed and tested on the revised procedures before they are put into use.

12 VAC 5-481-3180. Personnel monitoring.

A. Irradiator operators shall wear either a film badge or a thermoluminescent dosimeter (TLD) while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator. The film badge or TLD processor must be accredited by the National Voluntary Laboratory Accreditation Program for high energy photons in the normal and accident dose ranges (see Part 12 VAC 5-481-730 C). Each film badge or TLD must be assigned to and worn by only one individual. Film badges must be processed at least monthly, and TLDs must be processed at least quarterly.

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 paragraph, a check of their response to radiation must be done at least annually. Acceptable dosimeters must read within ±20% of the true radiation dose.

12 VAC 5-481-3190. Radiation surveys.

A. A radiation survey of the area outside the shielding of the radiation room of a panoramic irradiator must be conducted with the sources in the exposed position before the facility starts to operate. A radiation survey of the area above the pool of pool irradiators must be conducted after the sources are loaded but before the facility starts to operate. Additional radiation surveys of the shielding must be performed at intervals not to exceed three years and before resuming operation after addition of new sources or any modification to the radiation room shielding or structure that might increase dose rates.

B. If the radiation levels specified in 12 VAC 5-481-3080 are exceeded, the facility must be modified to comply with the requirements in 12 VAC 5-481-3070.

C. Portable radiation survey meters must be calibrated at least annually to an accuracy of ±20% for the gamma energy of the sources in use. The calibration must be done at two points on each scale or, for digital instruments, at one point per decade over the range that will be used. Portable radiation survey meters must be of a type that does not saturate and read zero at high radiation dose rates.

D. Water from the irradiator pool, other potentially contaminated liquids, and sediments from pool vacuuming must be monitored for radioactive contamination before release to unrestricted areas. Radioactive concentrations must not exceed those specified in Part IV (12 VAC 5-481-600 et seq.), Table II, Column 2 or Table III of Appendix F, "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure; Effluent

Concentrations; Concentrations for Release to Sanitary Sewerage."

E. Before releasing resins for unrestricted use, they must be monitored in an area with a background level less than 0.5 microsievert (0.05 mrem) per hour. The resins may be released only if the survey does not detect radiation levels above background radiation levels. The survey meter used must be capable of detecting radiation levels of 0.5 microsievert (0.05 mrem) per hour.

12 VAC 5-481-3200. Detection of leaking sources.

A. Each dry-source-storage sealed source must be tested for leakage at intervals not to exceed six months using a leak test kit or method approved by the agency, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State. In the absence of a certificate from a transferor that a test has been made within the six months before the transfer, the sealed source may not be used until tested. The test must be capable of detecting the presence of 200 becquerels (0.005 μCi) of radioactive material and must be performed by a person approved by the agency, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State to perform the test.

B. For pool irradiators, sources may not be put into the pool unless the licensee tests the sources for leaks or has a certificate from a transferor that a leak test has been done within the six months before the transfer. Water from the pool must be checked for contamination each day the irradiator operates. The check may be done either by using a radiation monitor on a pool water circulating system or by analysis of a sample of pool water. If a check for contamination is done by analysis of a sample of pool water, the results of the analysis must be available within 24

hours. If the licensee uses a radiation monitor on a pool water circulating system, the detection of above normal radiation levels must activate an alarm. The alarm set-point must be set as low as practical, but high enough to avoid false alarms. The licensee may reset the alarm set-point to a higher level if necessary to operate the pool water purification system to clear up contamination in the pool if specifically provided for in written emergency procedures.

C. If a leaking source is detected, the licensee shall arrange to remove the leaking source from service and have it decontaminated, repaired, or disposed of by an agency, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State licensee that is authorized to perform these functions. The licensee shall promptly check its personnel, equipment, facilities, and irradiated product for radioactive contamination. No product may be shipped until the product has been checked and found free of contamination. If a product has been shipped that may have been inadvertently contaminated, the licensee shall arrange to locate and survey that product for contamination. If any personnel are found to be contaminated, decontamination must be performed promptly. If contaminated equipment, facilities, or products are found, the licensee shall arrange to have them decontaminated or disposed of by an agency, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State licensee that is authorized to perform these functions. If a pool is contaminated, the licensee shall arrange to clean the pool until the contamination levels do not exceed the appropriate concentration in Table 2, Column 2, Appendix F of Part IV. See 10 CFR 30.50, or the equivalent state regulations, for reporting requirements.

12 VAC 5-481-3210. Inspection and maintenance.

A. The licensee shall perform inspection and maintenance checks that include, as a minimum, each of the following at the frequency specified in the license or license application:

1. Operability of each aspect of the access control system required by 12 VAC 5-481-3060.

2. Functioning of the source position indicator required by 12 VAC 5-481-3100 B.

3. Operability of the radiation monitor for radioactive contamination in pool water required by 12 VAC 5-481-3200 B using a radiation check source, if applicable.

4. Operability of the over-pool radiation monitor at underwater irradiators as required by 12 VAC 5-481-3090 B.

5. Operability of the product exit monitor required by 12 VAC 5-481-3090 A.

6. Operability of the emergency source return control required by 12 VAC 5-481-3100 C.

7. Visual inspection of leak-tightness of systems through which pool water circulates.

8. Operability of the heat and smoke detectors and extinguisher system required by 12 VAC 5-481-3080, without turning extinguishers on.

9. Operability of the means of pool water replenishment required by 12 VAC 5-481-3110 C.

10. Operability of the indicators of high and low pool water levels required by 12 VAC 5-481-3110 D.

11. Operability of the intrusion alarm required by 12 VAC 5-481-3060 I, if applicable.

12. Functioning and wear of the system, mechanisms, and cables used to raise and lower sources.

13. Condition of the barrier to prevent products from hitting the sources or source mechanism as required by 12 VAC 5-481-3120.

14. Amount of water added to the pool to determine if the pool is leaking.

15. Electrical wiring on required safety systems for radiation damage.

16. Pool water conductivity measurements and analysis as required by 12 VAC 5-481-3220 B.

B. Malfunctions and defects found during inspection and maintenance checks must be repaired within time frames specified in the license or license application.

12 VAC 5-481-3220. Pool water purity.

A. Pool water purification system must be run sufficiently to maintain the conductivity of the pool water below 20 microsiemens per centimeter under normal circumstances. If pool water conductivity rises above 20 microsiemens per centimeter, the licensee shall take prompt actions to lower the pool water conductivity and shall take corrective actions to prevent future recurrences.

B. The licensee shall measure the pool water conductivity frequently enough, but no less than weekly, to assure that the conductivity remains below 20 microsiemens per centimeter. Conductivity meters must be calibrated at least annually.

12 VAC 5-481-3230. Attendance during operation.

A. Both an irradiator operator and at least one other individual, who are trained on how to respond and how to be prepared to promptly render or summon assistance if the access control alarm sounds, shall be present on site:

1. Whenever the irradiator is operated using an automatic product conveyor system; and

2. Whenever the product is moved into or out of the radiation room when the irradiator is operated in a batch mode.

B. At a panoramic irradiator at which static irradiations with no movement of the product are occurring, a person who has received the training on how to respond to alarms described in 12

VAC 5-481-3160 G must be on site.

C. At an underwater irradiator, an irradiator operator must be present at the facility whenever the product is moved into or out of the pool. Individuals who move the product into or out of the pool of an underwater irradiator need not be qualified as irradiator operators; however, they must have received the training described in 12 VAC 5-481-3160 F and 12 VAC 5-481-3160 G. Static irradiations may be performed without a person present at the facility.

12 VAC 5-481-3240. Entering and leaving the radiation room.

A. Upon first entering the radiation room of a panoramic irradiator after an irradiation, the irradiator operator shall use a survey meter to determine that the source has returned to its fully shielded position. The operator shall check the functioning of the survey meter with a radiation check source prior to entry.

B. Before exiting from and locking the door to the radiation room of a panoramic irradiator prior to a planned irradiation, the irradiator operator shall:

1. Visually inspect the entire radiation room to verify that no one else is in it; and

2. Activate a control in the radiation room that permits the sources to be moved from the shielded position only if the door to the radiation room is locked within a preset time after setting the control.

C. During a power failure, the area around the pool of an underwater irradiator may not be entered without using an operable and calibrated radiation survey meter unless the over-the-pool monitor required by 12 VAC 5-481-3090 B is operating with backup power.

12 VAC 5-481-3250. Irradiation of explosive or flammable materials.

A. Irradiation of explosive material is prohibited unless the licensee has received prior written authorization from the agency. Authorization will not be granted unless the licensee can demonstrate that detonation of the explosive would not rupture the sealed sources, injure personnel, damage safety systems, or cause radiation overexposures of personnel.

B. Irradiation of more than small quantities of flammable material with a flash point below 140°F is prohibited in panoramic irradiators unless the licensee has received prior written authorization from the agency. Authorization will not be granted unless the licensee can demonstrate that a fire in the radiation room could be controlled without damage to sealed sources or safety systems and without radiation overexposures of personnel.

12 VAC 5-481-3260. Records and retention periods.

The licensee shall maintain the following records at the irradiator for the periods specified.

A. A copy of the license, the license conditions, documents incorporated into the license by reference, and amendments thereto until superseded by new documents or until the agency terminates the license for documents not superseded.

B. Records of each individual's training, tests, and safety reviews provided to meet the requirements of 12 VAC 5-481-3160 A, B, C, D, F and G until three years after the individual terminates work.

C. Records of the annual evaluations of the safety performance of irradiator operators required by 12 VAC 5-481-3160 E for three years after the evaluation.

D. A copy of the current operating and emergency procedures required by 12 VAC 5-481-3170 until superseded or the agency terminates the license. Records of the radiation safety officer's review and approval of changes in procedures as required by 12 VAC 5-481-3170 C 3 retained for three years from the date of the change.

E. Film badge and TLD results required by 12 VAC 5-481-3180 until the agency terminates the license.

F. Records of radiation surveys required by 12 VAC 5-481-3190 for three years from the date of the survey.

G. Records of radiation survey meter calibrations required by 12 VAC 5-481-3190 and pool water conductivity meter calibrations required by 12 VAC 5-481-3220 B until three years from the date of calibration.

H. Records of the results of leak tests required by 12 VAC 5-481-3200 A and the results of

contamination checks required by 12 VAC 5-481-3200 B for three years from the date of each test.

I. Records of inspection and maintenance checks required by 12 VAC 5-481-3210 for three years.

J. Records of major malfunctions, significant defects, operating difficulties or irregularities, and major operating problems that involve required radiation safety equipment for three years after repairs are completed.

K. Records of the receipt, transfer and disposal, of all licensed sealed sources as required by 12 VAC 5-481-570 of these regulations and 10 CFR 30.51 or the equivalent state regulations.

L. Records on the design checks required by 12 VAC 5-481-3140 and the construction control checks as required by 12 VAC 5-481-3150 until the license is terminated. The records must be signed and dated. The title or qualification of the person signing must be included.

M. Records related to decommissioning of the irradiator as required by 10 CFR 30.35(g) or the equivalent state regulation.

12 VAC 5-481-3270. Reports.

A. In addition to the reporting requirements in other parts of these regulations, the licensee shall report the following events if not reported under other parts of these regulations:

1. Source stuck in an unshielded position.

2. Any fire or explosion in a radiation room.

3. Damage to the source racks.

4. Failure of the cable or drive mechanism used to move the source racks.

5. Inoperability of the access control system.

6. Detection of radiation source by the product exit monitor.

7. Detection of radioactive contamination attributable to licensed radioactive material.

8. Structural damage to the pool liner or walls.

9. Water loss or leakage from the source storage pool, greater than the irradiator pool design parameters submitted by the licensee or applicant.

10. Pool water conductivity exceeding 100 microsiemens per centimeter.

B. The report must include a telephone report within 24 hours as described in 10 CFR 30.50(c)(1), or the equivalent state regulation, and a written report within 30 days as described in 10 CFR 30.50(c)(2) or the equivalent state regulation.

PART XIII.

TRANSPORTATION OF RADIOACTIVE MATERIAL.

ARTICLE 1.

PURPOSE AND SCOPE.

12 VAC 5-481-3280. Purpose and scope.

12 VAC 5-481-3280. Purpose and scope.

The regulations in this Part establish requirements for packaging, preparation for shipment, and transportation of radioactive material and apply to any person who transports radioactive material or delivers radioactive material to a carrier for transport.

ARTICLE 2.

GENERAL REGULATORY PROVISIONS.

12 VAC 5-481-3290. Requirement for license.

12 VAC 5-481-3300. Exemptions.

12 VAC 5-481-3310. Transportation of licensed material.

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12 VAC 5-481-3290. Requirement for license.

No person shall transport radioactive material or deliver radioactive material to a carrier for transport except as authorized in a general or specific license issued by the agency or as exempted in 12 VAC 5-481-3300.

12 VAC 5-481-3300. Exemptions.

A. Common and contract carriers, freight forwarders, and warehouse workers which are subject to the requirements of the U. S. Department of Transportation in 49 CFR 170 through 189 or the U. S. Postal Service in the Postal Service Domestic Mail Manual (DMM), Section C-023.9.0, and the U. S. Postal Service, are exempt from the requirements of this Part to the extent that they transport or store radioactive material in the regular course of their carriage for others or storage incident thereto. Common and contract carriers who are not subject to the requirements of the U. S.

Department of Transportation or U. S. Postal Service are subject to 12 VAC 5-481-3290 and other applicable requirements of these regulations.

B. Any licensee is exempt from the requirements of this Part to the extent that the licensee delivers to a carrier for transport a package containing radioactive material having a specific activity not greater than 70 becquerel per gram (0.002 µCi/g).

12 VAC 5-481-3310. Transportation of licensed material.

A. Each licensee who transports licensed material outside the site of usage, as specified in the agency license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, shall:

1. Comply with the applicable requirements, appropriate to the mode of transport, of the regulations of the U. S. Department of Transportation; particularly the regulations of the U. S. Department of Transportation in the following areas:

a. Packaging - 49 CFR Part 173: Subparts A and B and I.

b. Marking and labeling - 49 CFR Part 172: Subpart D, 172.400 through 172.407, 172.436 through 172.440, and Subpart E.

c. Placarding - 49 CFR Part 172: Subpart F, especially sections 172.500 through 172.519, 172.556, and Appendices B and C.

d. Accident reporting - 49 CFR Part 171: Sections 171.15 and 171.16.

e. Shipping papers and emergency information - 49 CFR Part 172: Subpart C and Subpart G.

f. Hazardous material employee training - 49 CFR Part 172: Subpart H.

g. Hazardous material shipper/carrier registration - 49 CFR Part 107: Subpart G.

2. The licensee shall also comply with applicable U. S. Department of Transportation regulations pertaining to the following modes of transportation:

a. Rail - 49 CFR Part 174: Subparts A through D and K.

b. Air - 49 CFR Part 175.

c. Vessel - 49 CFR Part 176: Subparts A through F and M.

d. Public Highway - 49 CFR Part 177 and Parts 390 through 397.

3. Assure that any special instructions needed to safely open the package are sent to or have been made available to the consignee in accordance with 12 VAC 5-481-900 E.

B. If, for any reason, the regulations of the U. S. Department of Transportation are not applicable to a shipment of licensed material, the licensee shall conform to the standards and requirements of 49 CFR Parts 170 through 189 appropriate to the mode of transport to the same extent as if the shipment was subject to the regulations.

ARTICLE 3.

GENERAL LICENSES.

12 VAC 5-481-3320. General licenses for carriers.

A. A general license is hereby issued to any common or contract carrier not exempt under 12 VAC 5-481-3300 to receive, possess, transport, and store radioactive material in the regular course of their carriage for others or storage incident thereto, provided the transportation and storage is in accordance with the applicable requirements, appropriate to the mode of transport, of the U. S.

Department of Transportation insofar as such requirements relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting. Notification of an incident shall be filed with, or made to, the agency as prescribed in 49 CFR, regardless of or in addition to notification made to the U. S. Department of Transportation or other agencies.

B. A general license is hereby issued to any private carrier to transport radioactive material, provided the transportation is in accordance with the applicable requirements, appropriate to the mode of transport, of the U. S. Department of Transportation insofar as such requirements relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting. Notification of an incident shall be filed with, or made to, the agency as prescribed in 49 CFR, regardless of or in addition to notification made to the U. S. Department of Transportation or other agencies.

C. Persons who transport radioactive material pursuant to the general licenses in 12 VAC 5-481-3320 A or 12 VAC 5-481-3320 B are exempt from the requirements of Parts IV (12 VAC 5-481-600 et seq.) and X (12 VAC 5-481-2580 et seq.) of these regulations to the extent that they transport radioactive material.

12 VAC 5-481-3330. General license: Nuclear Regulatory Commission - 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, or other approval has been issued by the Nuclear Regulatory Commission.

B. This general license applies only to a licensee who:

1. Has a copy of the specific license, certificate of compliance, or other approval by the Nuclear Regulatory Commission 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 Nuclear Regulatory Commission, as applicable, and the applicable requirements of this Part XIII (12 VAC 5-481-3280 et seq.);

3. Prior to the licensee's first use of the package, has registered with the Nuclear Regulatory Commission; and

4. Has a quality assurance program required by 12 VAC 5-481-3460.

C. The general license in 12 VAC 5-481-3330 7 A 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 Nuclear Regulatory Commission before April 1, 1996, the general license is subject to the additional restrictions of 12 VAC 5-481-3340.

12 VAC 5-481-3340. General license: previously approved packages.

A. A Type B package previously approved by the Nuclear Regulatory Commission, but not designated as B(U) or B(M) in the identification number of the Nuclear Regulatory Commission certificate of compliance, may be used under the general license of 12 VAC 5-481-3330 with the following additional conditions:

1. Fabrication of the packaging was satisfactorily completed before August 31, 1986, as demonstrated by application of its model number in accordance with Nuclear Regulatory Commission regulations at 10 CFR 71.85(c);

2. A package used for a shipment to a location outside the United States is subject to multilateral approval, as defined in U. S. Department of Transportation regulations at 49 CFR 173.403; and

3. A serial number that uniquely identifies each packaging which conforms to the approved design is assigned to, and legibly and durably marked on, the outside of each packaging.

B. A Type B(U) package, a Type B(M) package, a low specific activity (LSA) material package or a fissile material package, previously approved by the Nuclear Regulatory Commission but without the designation "-85" in the identification number of the Nuclear Regulatory Commission certificate of compliance, may be used under the general license of 12 VAC 5-481-3330 with the following additional conditions:

1. Fabrication of the package is satisfactorily completed by April 1, 1999, as demonstrated by application of its model number in accordance with Nuclear Regulatory Commission regulations at 10 CFR 71.85(c);

2. A package used for a shipment to a location outside the United States is subject to multilateral approval except approved under special arrangement in accordance with U. S. Department of Transportation regulations at 49 CFR 173.403; and

3. A serial number which uniquely identifies each packaging which conforms to the approved design is assigned to and legibly and durably marked on the outside of each packaging.

12 VAC 5-481-3350. General License: U. S. Department of Transportation specification container.

A. A general license is issued to any licensee to transport, or to deliver to a carrier for transport, licensed material in a specification container for fissile material or for a Type B quantity of radioactive material as specified in 49 CFR Parts 173 and 178.

B. This general license applies only to a licensee who:

1. Has a copy of the specification;

2. Complies with the terms and conditions of the specification and the applicable requirements of this Part; and

3. Has a quality assurance program required by 12 VAC 5-481-3460.

C. The general license in 12 VAC 5-481-3350 A is subject to the limitation that the specification container may not be used for a shipment to a location outside the United States except by multilateral approval as defined in 49 CFR 173.403.

12 VAC 5-481-3360. General License: use of foreign approved package.

A. A general license is issued to any licensee to transport, or to deliver to a carrier for transport, licensed material in a package the design of which has been approved in a foreign national competent authority certificate which has been revalidated by the U. S. Department of Transportation as meeting the applicable requirements of 49 CFR 171.12.

B. This general license applies only to international shipments.

C. This general license applies only to a licensee who:

1. Has a copy of the applicable certificate, the revalidation, and the drawings and other documents referenced in the certificate 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 certificate and revalidation, and with the applicable requirements of this Part; and

3. The licensee has a quality assurance program approved by the Nuclear Regulatory Commission.

12 VAC 5-481-3370. General License: fissile material, limited quantity per package.

A. A general license is hereby issued to any licensee to transport fissile material, or to deliver fissile material to a carrier for transport, if the material is shipped in accordance with this Section.

B. This general license applies only when a package contains no more than a Type A quantity of radioactive material, including only one of the following:

1. Up to 40 grams of uranium-235;

2. Up to 30 grams of uranium-233;

3. Up to 25 grams of the fissile radionuclides of plutonium, except that for encapsulated plutonium-beryllium neutron sources in special form, an A_1 quantity of plutonium may be present; or

4. A combination of fissile radionuclides in which the sum of the ratios of the amount of each radionuclide to the corresponding maximum amounts in 12 VAC 5-481-3370 B 1; 12 VAC 5-481-3370 B 2; and 12 VAC 5-481-3370 B 3 do not exceed unity.

C. Except as specified in 12 VAC 5-481-3370 C 2, this general license applies only when all of the

following requirements are met:

1. A package containing more than 15 grams of fissile radionuclides is labeled with a transport index not less than the number given by the following equation:

Minimum Transport Index = (0.40x + 0.67y + z) (1 - 15/(x+y+z))

where the package contains x grams of uranium-235, y grams of uranium-233, and z grams of the fissile radionuclides of plutonium;

2. For a package in which the only fissile material is in the form of encapsulated plutonium-beryllium neutron sources in special form, the transport index based on criticality considerations may be taken as 0.026 times the number of grams of the fissile radionuclides of plutonium in excess of 15 grams.

3. In all cases, the transport index must be rounded up to one decimal place and shall not exceed 10.0.

4. The licensee has a quality assurance program as required by 12 VAC 5-481-3460.

12 VAC 5-481-3380. General License: fissile material, limited moderator per package.

A. A general license is hereby issued to any licensee to transport fissile material, or to deliver fissile material to a carrier for transport, if the material is shipped in accordance with this Section.

B. This general license applies only when all of the following requirements are met:

1. The package contains no more than a Type A quantity of radioactive material;

2. Neither beryllium nor hydrogenous material enriched in deuterium are present;

3. The total mass of graphite present does not exceed 7.7 times the total mass of uranium-235 plus plutonium;

4. Substances having a higher hydrogen density than water, for example certain hydrocarbon oils, are not present, except that polyethylene may be used for packing or wrapping;

5. Uranium-233 is not present, and the amount of plutonium does not exceed 1% of the amount of uranium-235;

6. The amount of uranium-235 is limited as follows:

a. If the fissile radionuclides are not uniformly distributed, the maximum amount of uranium-235 per package may not exceed the value given in TABLE I; or

b. If the fissile radionuclides are distributed uniformly, for example, cannot form a lattice arrangement within the packaging, the maximum amount of uranium-235 per package may not exceed the value given in TABLE II; and

7. The transport index of each package based on criticality considerations is taken as 10 times the number of grams of uranium-235 in the package divided by the maximum allowable number of grams per package in accordance with TABLE I or TABLE II as applicable.

TABLE I

PERMISSIBLE MASS OF URANIUM-235 PER FISSILE MATERIAL PACKAGE

(NONUNIFORM DISTRIBUTION)

Uranium Enrichment in Weight Percent of Uranium-235 Not Exceeding	Permissible Maximum Grams of Uranium-235 Per Package
24	40
20	42
15	45
11	48
10	51
9.5	52
9	54
8.5	55
8	57
7.5	59
7	60
6.5	62
6	65
5.5	68
5	72
4.5	76
4	80
3.5	88
3	100
2.5	120
2	164
1.5	272
1.35	320

1	680*
0.92	1,200*

**Pursuant to the agency's agreement with the Nuclear Regulatory Commission, jurisdiction extends only to 350 grams of uranium-235.*

TABLE II

PERMISSIBLE MASS OF URANIUM-235 PER FISSILE MATERIAL PACKAGE

(UNIFORM DISTRIBUTION)

Uranium Enrichment in Weight Percent of Uranium-235 Not Exceeding	Permissible Maximum Grams of Uranium-235 Per Package
4	84
3.5	92
3	112
2.5	148
2	240
1.5	560*
1.35	800*

**Pursuant to the agency's agreement with the Nuclear Regulatory Commission, jurisdiction extends only to 350 grams of uranium-235.*

C. The licensee has a quality assurance program as required by 12 VAC 5-481-3460.

ARTICLE 4.

OPERATING CONTROLS AND PROCEDURES.

12 VAC 5-481-3390. Assumptions as to unknown properties of fissile material.

When the isotopic abundance, mass, concentration, degree of irradiation, degree of moderation, or other pertinent property of fissile material in any package is not known, the licensee shall package the fissile material as if the unknown properties have credible values that will cause the maximum neutron multiplication.

12 VAC 5-481-3400. Preliminary determinations.

Prior to the first use of any packaging for the shipment of radioactive material:

A. The licensee shall ascertain that there are no defects which could significantly reduce the effectiveness of the packaging;

B. Where the maximum normal operating pressure will exceed 35 kilopascal (5 lb/in^2) gauge, the licensee shall test the containment system at an internal pressure at least 50% higher than the maximum normal operating pressure to verify the capability of that system to maintain its structural integrity at that pressure;

C. The licensee shall determine that the packaging has been fabricated in accordance with the design approved by the Nuclear Regulatory Commission; and

D. The licensee shall conspicuously and durably mark the packaging with its model number, serial number, gross weight, and a package identification number as assigned by the Nuclear Regulatory Commission.

12 VAC 5-481-3410. Routine determinations.

Prior to each shipment of licensed material, the licensee shall determine that:

A. The package is proper for the contents to be shipped;

B. The package is in unimpaired physical condition except for superficial defects such as marks or dents;

C. Each closure device of the packaging, including any required gasket, is properly installed and secured and free of defects;

D. Any system for containing liquid is adequately sealed and has adequate space or other specified provision for expansion of the liquid;

E. Any pressure relief device is operable and set in accordance with written procedures;

F. The package has been loaded and closed in accordance with written procedures;

G. Any structural part of the package which could be used to lift or tie down the package during transport is rendered inoperable for that purpose unless it satisfies design requirements specified in 10 CFR 71.45;

H. The level of non-fixed radioactive contamination on the external surfaces of each package offered for shipment is as low as reasonably achievable.

1. The level of non-fixed radioactive contamination may be determined by wiping an area of 300 square centimeters of the surface concerned with an absorbent material, using moderate

pressure, and measuring the activity on the wiping material. Sufficient measurements must be taken in the most appropriate locations to yield a representative assessment of the removable contamination levels. Except as provided in 12 VAC 5-481-3410 H 2, the amount of radioactivity measured on any single wiping material, when averaged over the surface wiped, must not exceed the limits given in TABLE III at any time during transport. Other methods of assessment of equal or greater efficiency may be used. When other methods are used, the detection efficiency of the method used must be taken into account and in no case may the removable contamination on the external surfaces of the package exceed 10 times the limits listed in TABLE III.

2. In the case of packages transported as exclusive use shipments by rail or highway only, the non-fixed radioactive contamination at any time during transport must not exceed 10 times the levels prescribed in 12 VAC 5-481-3410 H 1. The levels at the beginning of transport must not exceed the levels in 12 VAC 5-481-3410 H 1;

TABLE III

NON-FIXED (REMOVABLE) EXTERNAL RADIOACTIVE CONTAMINATION - WIPE LIMITS

Beta and gamma emitters and low toxicity alpha emitters	0.4	10-5	22
All other alpha emitting radionuclides	0.04	10-6	2.2

I. External radiation levels around the package and around the vehicle, if applicable, will not exceed two millisievert per hour (200 mrem/hr) at any point on the external surface of the package at any time during transportation. The transport index shall not exceed 10.0;

J. For a package transported in exclusive use by rail, highway or water, radiation levels external to the package may exceed the limits specified in 12 VAC 5-481-3410 1, but shall not exceed any of the following:

1. 2 millisievert per hour (200 mrem/hr) on the accessible external surface of the package unless the following conditions are met, in which case the limit is 10 millisievert per hour (1000 mrem/hr);

a. The shipment is made in a closed transport vehicle;

b. Provisions are made to secure the package so that its position within the vehicle remains fixed during transportation; and

c. There are no loading or unloading operations between the beginning and end of the transportation.

2. 2 millisievert per hour (200 mrem/hr) at any point on the outer surface of the vehicle, including the top and underside of the vehicle, or, in the case of a flat-bed style vehicle, with a personnel barrier, at any point on the vertical planes projected from the outer edges of the vehicle, on the upper surface of the load (or enclosure, if used), and on the lower external surface of the vehicle;

3. 0.1 millisievert per hour (10 mrem/hr) at any point two meters from the vertical planes represented by the outer lateral surfaces of the vehicle, or, in the case of a flat-bed style vehicle, at any point two meters from the vertical planes projected from the outer edges of the vehicle; and

4. 0.02 millisievert per hour (2 mrem/hr) in any normally occupied positions of the vehicle, except that this provision does not apply to private motor carriers when persons occupying these positions are provided with special health supervision, personnel radiation exposure monitoring devices, and training in accordance with 12 VAC 5-481-2600 of these regulations; and

K. A package must be prepared for transport so that in still air at 38 degrees Celsius (100 degrees Fahrenheit) and in the shade, no accessible surface of a package would have a temperature exceeding 50 degrees Celsius (122 Fahrenheit) in a nonexclusive use shipment or 85 degrees Celsius (185 degrees Fahrenheit) in an exclusive use shipment. Accessible package surface temperatures shall not exceed these limits at any time during transportation.

L. A package may not incorporate a feature intended to allow continuous venting during transport.

12 VAC 5-481-3420. Air transport of plutonium.

Notwithstanding the provisions of any general licenses and notwithstanding any exemptions stated directly in this Part or included indirectly by citation of the U. S. Department of Transportation regulations, as may be applicable, the licensee shall assure that plutonium in any form is not transported by air, or delivered to a carrier for air transport, unless:

A. The plutonium is contained in a medical device designed for individual human application;

B. The plutonium is contained in a material in which the specific activity is not greater than 70 becquerel per gram (0.002 μCi/g/gm) of material and in which the radioactivity is essentially uniformly distributed;

C. The plutonium is shipped in a single package containing no more than an A_2 quantity of plutonium in any isotope or form and is shipped in accordance with 12 VAC 5-481-3310;

D. The plutonium is shipped in a package specifically authorized, in the certificate of compliance, issued by the Nuclear Regulatory Commission, for the shipment of plutonium by air and the licensee requires, through special arrangement with the carrier, compliance with 49 CFR 175.704, the U. S. Department of Transportation regulations applicable to the air transport of plutonium.

12 VAC 5-481-3430. Shipment records.

Each licensee shall maintain for a period of three years after shipment a record of each shipment of licensed material not exempt under 12 VAC 5-481-3300, showing, where applicable:

A. Identification of the packaging by model number and serial number;

B. Verification that the packaging, as shipped, had no significant defect;

C. Volume and identification of coolant;

D. Type and quantity of licensed material in each package, and the total quantity of each shipment;

E. Date of the shipment;

F. Name and address of the transferee;

G. Address to which the shipment was made; and

H. Results of the determinations required by 12 VAC 5-481-3410 and by the conditions of the package approval.

12 VAC 5-481-3440. Reports.

The licensee shall report to the agency within 30 days:

A. Any instance in which there is significant reduction in the effectiveness of any packaging during use;

B. Details of any defects with safety significance in the packaging after first use, with the means employed to repair the defects and prevent their recurrence; or

C. Instances in which the conditions of approval in the certificate of compliance were not observed in making a shipment.

12 VAC 5-481-3450. 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 to the governor, or governor's designee, of each state within or through which the waste will be transported.

B. Advance notification is required only when:

1. The nuclear waste is required to be in Type B packaging for transportation;

2. The nuclear waste is being transported into, within, or through a state enroute 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 Appendix L, Table I for special form radioactive material;

b. 3000 times the A_2 value of the radionuclides as specified in Appendix L, Table I for normal form radioactive material; or

c. 1000 terabecquerel (27,000 Ci).

C. Each advance notification required by 12 VAC 5-481-3450 A 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 7-day period during which departure of the shipment is estimated to occur;

4. The 7-day period during which arrival of the shipment at state boundaries is estimated to occur;

5. The destination of the shipment, and the 7-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 12 VAC 5-481-3450 A shall be made in writing to the office of each appropriate governor, or governor's designee, and to the agency. A notification delivered by mail must be postmarked at least seven days before the beginning of the 7-day period during which departure of the shipment is estimated to occur. A notification delivered by messenger must reach the office of the governor, or governor's designee, at least four days before the beginning of the 7-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.

E. The licensee shall notify each appropriate governor, or governor's designee, and the agency of any changes to schedule information provided pursuant to 12 VAC 5-481-3450 A. Such notification shall be by telephone to a responsible individual in the office of the governor, or governor's designee, of the appropriate state or states. 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, of each appropriate state and to the agency. A copy of the notice shall be retained by the licensee for three years.

ARTICLE 5.

QUALITY ASSURANCE.

12 VAC 5-481-3460. Quality assurance requirements.

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12 VAC 5-481-3460. Quality assurance requirements.

A. Unless otherwise authorized by the agency, each licensee shall establish, maintain, and execute a quality assurance program to verify by procedures such as checking, auditing, and inspection that deficiencies, deviations, and defective material and equipment relating to the shipment of packages containing radioactive material are promptly identified and corrected.

B. The licensee shall identify the material and components to be covered by the quality assurance program.

C. Each licensee shall document the quality assurance program by written procedures or instructions and shall carry out the program in accordance with those procedures throughout the period during which packaging is used.

D. Prior to the use of any package for the shipment of radioactive material, each licensee shall obtain approval by the agency of its quality assurance program.

E. The licensee shall maintain sufficient written records to demonstrate compliance with the quality assurance program. Records of quality assurance pertaining to the use of a package for shipment of radioactive material shall be maintained for a period of three years after shipment.

PART XIV.

RADIATION SAFETY REQUIREMENTS FOR WIRELINE SERVICE OPERATIONS AND SUBSURFACE TRACER STUDIES.

ARTICLE 1.

PURPOSE AND SCOPE.

12 VAC 5-481-3470. Purpose.

12 VAC 5-481-3480. Scope.

12 VAC 5-481-3470. Purpose.

The regulations in this Part establish radiation safety requirements for using sources of radiation for wireline service operations including mineral-logging, radioactive markers, and subsurface tracer studies. The requirements of this Part are in addition to, and not in substitution for, the requirements of Parts I (12 VAC 5-481-10 et seq.); II (12 VAC 5-481-260 et seq.); III (12 VAC 5-481-380 et seq.); IX (12 VAC 5-481-2470 et seq.); and X (12 VAC 5-481-2580 et seq.) of these regulations.

12 VAC 5-481-3480. Scope.

The regulations in this Part apply to all licensees or registrants who use sources of radiation for wireline service operations including mineral-logging, radioactive markers, or subsurface tracer studies.

ARTICLE 2.

PROHIBITION.

12 VAC 5-481-3490. Prohibition.

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12 VAC 5-481-3490. Prohibition.

No licensee shall perform wireline service operations with a sealed source(s) unless, prior to

commencement of the operation, the licensee has a written agreement with the well-operator, well-owner, drilling contractor, or land owner that:

A. In the event a sealed source is lodged downhole, a reasonable effort at recovery will be made; and

B. In the event a decision is made to abandon the sealed source downhole, the requirements of 12 VAC 5-481-3700 C shall be met.

ARTICLE 3.

EQUIPMENT CONTROL.

12 VAC 5-481-3500. Limits on levels of radiation.

12 VAC 5-481-3510. Storage precautions.

12 VAC 5-481-3520. Transport precautions.

12 VAC 5-481-3530. Radiation survey instruments.

12 VAC 5-481-3540. Leak testing of sealed sources.

12 VAC 5-481-3550. Quarterly inventory.

12 VAC 5-481-3560. Utilization records.

12 VAC 5-481-3570. Design, performance, and certification criteria for sealed sources used in downhole operations.

12 VAC 5-481-3580. Labeling.

12 VAC 5-481-3590. Inspection and maintenance.

12 VAC 5-481-3500. Limits on levels of radiation.

Sources of radiation shall be used, stored, and transported in such a manner that the transportation requirements of Part XIII (12 VAC 5-481-3280 et seq.) and the dose limitation requirements of Part IV (12 VAC 5-481-600 et seq.) of these regulations are met.

12 VAC 5-481-3510. Storage precautions.

A. Each source of radiation, except accelerators, shall be provided with a storage or transport container. The container shall be provided with a lock, or tamper seal for calibration sources, to prevent unauthorized removal of, or exposure to, the source of radiation.

B. Sources of radiation shall be stored in a manner which will minimize danger from explosion or fire.

12 VAC 5-481-3520. Transport precautions.

Transport containers shall be physically secured to the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal.

12 VAC 5-481-3530. Radiation survey instruments.

A. The licensee or registrant shall maintain sufficient calibrated and operable radiation survey instruments at each field station to make physical radiation surveys as required by this Part and by Section 12 VAC 5-481-640 of these regulations. Instrumentation shall be capable of measuring 0.1 milliroentgen (25.8 nanocoulombs/kg) per hour through at least 50 milliroentgens (12.9 microcoulombs/kg) per hour. Survey instruments acquired before the effective date of these regulations and capable of measuring 0.1 milliroentgen (25.8 nanocoulombs/kg) per hour through at least 20 milliroentgens (5.16 microcoulombs/kg) per hour also satisfies this requirement five years after the effective date of these regulations.

B. Each radiation survey instrument shall be calibrated:

1. At intervals not to exceed six months and after each instrument servicing;

2. For linear scale instruments, at two points located approximately 25% and 75% of full-scale on each scale; for logarithmic scale instruments, at midrange of each decade, and at two points of at least one decade; and for digital instruments, at appropriate points; and

3. So that accuracy within 20% of the true radiation level can be demonstrated on each scale.

C. Calibration records shall be maintained for a period of two years for inspection by the agency.

12 VAC 5-481-3540. Leak testing of sealed sources.

A. Requirements. Each licensee using sealed sources of radioactive material shall have the sources tested for leakage. Records of leak test results shall be kept in units of microcuries (Bq) and maintained for inspection by the agency for six months after the next required leak test is performed or until transfer or disposal of the sealed source.

B. Method of Testing. Tests for leakage shall be performed only by persons specifically authorized to perform such tests by the agency, the U.S. Nuclear Regulatory Commission (NRC), an Agreement State, or a Licensing State. The test sample shall be taken from the surface of the source, source holder, or from the surface of the device in which the source is stored or mounted and on which one might expect contamination to accumulate. The test sample shall be analyzed for radioactive contamination, and the analysis shall be capable of detecting the presence of 0.005 microcurie (185 Bq) of radioactive material on the test sample.

C. Interval of Testing. Each sealed source of radioactive material shall be tested at intervals not to exceed six months. In the absence of a certificate from a transferor indicating that a test has been made prior to the transfer, the sealed source shall not be put into use until tested. If, for any reason, it is suspected that a sealed source may be leaking, it shall be removed from service immediately and tested for leakage as soon as practical.

D. Leaking or Contaminated Sources. If the test reveals the presence of 0.005 microcurie (185 Bq) or more of leakage or contamination, the licensee shall immediately withdraw the source from use and shall cause it to be decontaminated, repaired, or disposed of in accordance with these regulations. A report describing the equipment involved, the test results, and the corrective action taken shall be filed with the agency within five days of receiving the test results.

E. Exemptions. The following sources are exempted from the periodic leak test requirements of 12 VAC 5-481-3540 A through 12 VAC 5-481-3540 D:

1. Hydrogen-3 sources;

2. Sources of radioactive material with a half-life of 30 days or less;

3. Sealed sources of radioactive material in gaseous form;

4. Sources of beta- or gamma-emitting radioactive material with an activity of 100 microcuries (3.7 MBq) or less; and

5 Sources of alpha-emitting radioactive material with an activity of 10 microcuries (0.370 MBq) or less.

12 VAC 5-481-3550. Quarterly inventory.

Each licensee or registrant shall conduct a quarterly physical inventory to account for all sources of radiation. Records of inventories shall be maintained for two years from the date of the inventory for inspection by the agency and shall include the quantities and kinds of sources of radiation, the location where sources of radiation are assigned, the date of the inventory, and the name of the individual conducting the inventory.

12 VAC 5-481-3560. Utilization records.

Each licensee or registrant shall maintain current records, which shall be kept available for inspection by the agency for two years from the date of the recorded event, showing the following information for each source of radiation:

A. Make, model number, and a serial number or a description of each source of radiation used;

B. The identity of the well-logging supervisor or field unit to whom assigned;

C. Locations where used and dates of use; and

D. In the case of tracer materials and radioactive markers, the utilization record shall indicate the radionuclide and activity used in a particular well.

12 VAC 5-481-3570. Design, performance, and certification criteria for sealed sources used in downhole operations.

A. Each sealed source, except those containing radioactive material in gaseous form, used in downhole operations and manufactured after one year after the effective date of these regulations shall be certified by the manufacturer, or other testing organization acceptable to the agency, to meet the following minimum criteria:

1. Be of doubly encapsulated construction;

2. Contain radioactive material whose chemical and physical forms are as insoluble and non-dispersible as practical; and

3. Has been individually pressure tested to at least 24,656 pounds per square inch absolute (170 MN/m^2) without failure.

B. For sealed sources, except those containing radioactive material in gaseous form, acquired after one year after the effective date of these regulations, in the absence of a certificate from a transferor certifying that an individual sealed source meets the requirements of 12 VAC 5-481-3570, the sealed source shall not be put into use until such determinations and testing have been performed.

C. Each sealed source, except those containing radioactive material in gaseous form, used in downhole operations after two years after the effective date of these regulations shall be certified by the manufacturer, or other testing organization acceptable to the agency, as meeting the sealed

source performance requirements for oil well-logging as contained in the American National Standard N43.6, "Classification of Sealed Radioactive Sources," (formerly N542, ANSI/NBS 126) in effect on the effective date of these regulations.

D. Certification documents shall be maintained for inspection by the agency for a period of two years after source disposal. If the source is abandoned downhole, the certification documents shall be maintained until the agency authorizes disposition.

12 VAC 5-481-3580. Labeling.

A. Each source, source holder, or logging tool containing radioactive material shall bear a durable, legible, and clearly visible marking or label, which has, as a minimum, the standard radiation caution symbol, without the conventional color requirement, and the following wording:

DANGER

RADIOACTIVE

This labeling shall be on the smallest component transported as a separate piece of equipment.

B. Each transport container shall have permanently attached to it a durable, legible, and clearly visible label which has, as a minimum, the standard radiation caution symbol and the following wording:

DANGER

RADIOACTIVE

NOTIFY CIVIL AUTHORITIES (OR NAME OF COMPANY)

12 VAC 5-481-3590. Inspection and maintenance.

A. Each licensee or registrant shall conduct, at intervals not to exceed six months, a program of inspection and maintenance of source holders, logging tools, source handling tools, storage containers, transport containers, and injection tools to assure proper labeling and physical condition. Records of inspection and maintenance shall be maintained for a period of two years for inspection by the agency.

B. If any inspection conducted pursuant to 12 VAC 5-481-3590 A reveals damage to labeling or components critical to radiation safety, the device shall be removed from service until repairs have been made.

C. If a sealed source is stuck in the source holder, the licensee shall not perform any operation, such as drilling, cutting, or chiseling, on the source holder unless the licensee is specifically approved by the Nuclear Regulatory Commission, an Agreement State, or a Licensing State to perform this operation.

D. The repair, opening, or modification of any sealed source shall be performed only by persons specifically authorized to do so by the agency, the NUCLEAR REGULATORY COMMISSION,

an Agreement State, or a Licensing State.

ARTICLE 4.

REQUIREMENTS FOR PERSONAL SAFETY.

12 VAC 5-481-3600. Training requirements.

12 VAC 5-481-3610. Operating and emergency procedures.

12 VAC 5-481-3620. Personnel monitoring.

12 VAC 5-481-3600. Training requirements.

A. No licensee or registrant shall permit any individual to act as a logging supervisor as defined in this Part until such individual has:

1. Received, in a course recognized by the agency, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State, instruction in the subjects outlined in Appendix M and demonstrated an understanding thereof;

2. Read and received instruction in the regulations contained in this Part and the applicable Sections of Parts I (12 VAC 5-481-10 et seq.); IV (12 VAC 5-481-600 et seq.); and X (12 VAC 5-481-2580 et seq.) of these regulations or their equivalent, conditions of

appropriate license or certificate of registration, and the licensee's or registrant's operating and emergency procedures, and demonstrated an understanding thereof; and

3. Demonstrated competence to use sources of radiation, related handling tools, and radiation survey instruments which will be used on the job.

B. No licensee or registrant shall permit any individual to assist in the handling of sources of radiation until such individual has:

1. Read or received instruction in the licensee's or registrant's operating and emergency procedures and demonstrated an understanding thereof; and

2. Demonstrated competence to use, under the personal supervision of the logging supervisor, the sources of radiation, related handling tools, and radiation survey instruments which will be used on the job.

C. The licensee or registrant shall maintain employee training records for inspection by the agency for two years following termination of the individual's employment.

12 VAC 5-481-3610. Operating and emergency procedures.

The licensee's or registrant's operating and emergency procedures shall include instructions in at least the following:

A. Handling and use of sources of radiation to be employed so that no individual is likely to be exposed to radiation doses in excess of the standards established in Part IV (12 VAC 5-481-600 et seq.) of these regulations;

B. Methods and occasions for conducting radiation surveys;

C. Methods and occasions for locking and securing sources of radiation;

D. Personnel monitoring and the use of personnel monitoring equipment;

E. Transportation to temporary jobsites and field stations, including the packaging and placing of sources of radiation in vehicles, placarding of vehicles, and securing sources of radiation during transportation;

F. Minimizing exposure of individuals in the event of an accident;

G. Procedure for notifying proper personnel in the event of an accident;

H. Maintenance of records;

I. Use, inspection and maintenance of source holders, logging tools, source handling tools, storage containers, transport containers, and injection tools;

J. Procedure to be followed in the event a sealed source is lodged downhole;

K. Procedures to be used for picking up, receiving, and opening packages containing radioactive material;

L. For the use of tracers, decontamination of the environment, equipment, and personnel;

M. Maintenance of records generated by logging personnel at temporary jobsites;

N. Notifying proper persons in the event of an accident; and

O. Actions to be taken if a sealed source is ruptured, including actions to prevent the spread of contamination and minimize inhalation and ingestion of radioactive material and actions to obtain suitable radiation survey instruments as required by 12 VAC 5-481-3530.

12 VAC 5-481-3620. Personnel monitoring.

A. No licensee or registrant shall permit any individual to act as a logging supervisor or to assist in the handling of sources of radiation unless each such individual wears either a film badge or a thermoluminescent dosimeter (TLD). Each film badge or TLD shall be assigned to and worn by only one individual. Film badges must be replaced at least monthly and TLDs replaced at least quarterly. After replacement, each film badge or TLD must be promptly processed.

B. Personnel monitoring records shall be maintained for inspection until the agency authorizes disposition.

ARTICLE 5.

PRECAUTIONARY PROCEDURES IN LOGGING AND SUBSURFACE TRACER STUDIES.

12 VAC 5-481-3630. Security.

12 VAC 5-481-3640. Handling tools.

12 VAC 5-481-3650. Subsurface tracer studies.

12 VAC 5-481-3660. Particle accelerators.

12 VAC 5-481-3630. Security.

During each logging or tracer application, the logging supervisor or other designated employee shall maintain direct surveillance of the operation to protect against unauthorized or unnecessary entry into a restricted area, as defined in Part I (12 VAC 5-481-10 et seq.) of these regulations.

12 VAC 5-481-3640. Handling tools.

The licensee shall provide and require the use of tools that will assure remote handling of sealed sources

other than low-activity calibration sources.

12 VAC 5-481-3650. Subsurface tracer studies.

A. Protective gloves and other appropriate protective clothing and equipment shall be used by all personnel handling radioactive tracer material. Precautions shall be taken to avoid ingestion or inhalation of radioactive material.

B. No licensee shall cause the injection of radioactive material into potable aquifers without prior written authorization from the agency.

12 VAC 5-481-3660. Particle accelerators.

No licensee or registrant shall permit above-ground testing of particle accelerators, designed for use in well-logging, which results in the production of radiation, except in areas or facilities so controlled or shielded that the requirements of Sections 12 VAC 5-481-630 and 12 VAC 5-481-640 of these regulations, as applicable, are met.

ARTICLE 6.

RADIATION SURVEYS AND RECORDS.

12 VAC 5-481-3670. Radiation surveys.

12 VAC 5-481-3680. Documents and records required at field stations.

12 VAC 5-481-3690. Documents and records required at temporary jobsites

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12 VAC 5-481-3670. Radiation surveys.

A. Radiation surveys or calculations shall be made and recorded for each area where radioactive materials are used and stored.

B. Radiation surveys shall be made and recorded for the radiation levels in occupied positions and on the exterior of each vehicle used to transport radioactive material. Such surveys shall include each source of radiation or combination of sources to be transported in the vehicle.

C. If the sealed source assembly is removed from the logging tool before departing the jobsite, the logging tool detector shall be energized, or a survey meter used, to assure that the logging tool is free of contamination.

D. Radiation surveys shall be made and recorded at the jobsite or well-head for each tracer operation, except those using hydrogen-3, carbon-14, and sulfur-35. These surveys shall include measurements of radiation levels before and after the operation.

E. Records required pursuant to 12 VAC 5-481-3670 A through 12 VAC 5-481-3670 D shall include the dates, the identification of individual(s) making the survey, the identification of

survey instrument(s) used, and an exact description of the location of the survey. Records of these surveys shall be maintained for inspection by the agency for two years after completion of the survey.

12 VAC 5-481-3680. Documents and records required at field stations.

Each licensee or registrant shall maintain, for inspection by the agency, the following documents and records for the specific devices and sources used at the field station:

A. Appropriate license, certificate of registration, or equivalent document(s);

B. Operating and emergency procedures;

C. Applicable regulations;

D. Records of the latest survey instrument calibrations pursuant to 12 VAC 5-481-3530;

E. Records of the latest leak test results pursuant to 12 VAC 5-481-3540;

F. Records of quarterly inventories required pursuant to 12 VAC 5-481-3550;

G. Utilization records required pursuant to 12 VAC 5-481-3560;

H. Records of inspection and maintenance required pursuant to 12 VAC 5-481-3590;

I. Survey records required pursuant to 12 VAC 5-481-3670; and

J. Training records required pursuant to 12 VAC 5-481-3600.

12 VAC 5-481-3690. Documents and records required at temporary jobsites.

Each licensee or registrant conducting operations at a temporary jobsite shall have the following documents and records available at that site for inspection by the agency:

A. Operating and emergency procedures;

B. Survey records required pursuant to 12 VAC 5-481-3670 for the period of operation at the site;

C. Evidence of current calibration for the radiation survey instruments in use at the site;

D. When operating in the state under reciprocity, a copy of the appropriate license, certificate of registration, or equivalent document(s); and

E. Shipping papers for the transportation of radioactive material.

ARTICLE 7.

NOTIFICATION.

12 VAC 5-481-3700. Notification of incidents, abandonment, and lost sources.

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12 VAC 5-481-3700. Notification of incidents, abandonment, and lost sources.

A. Notification of incidents and sources lost in other than downhole logging operations shall be made in accordance with appropriate provisions of Part IV (12 VAC 5-481-600 et seq.) of these regulations.

B. Whenever a sealed source or device containing radioactive material is lodged downhole, the licensee shall:

1. Monitor at the surface for the presence of radioactive contamination with a radiation survey instrument or logging tool during logging tool recovery operations; and

2. Notify the agency immediately by telephone and subsequently, within 30 days, by confirmatory letter if the licensee knows or has reason to believe that a sealed source has been ruptured. This letter shall identify the well or other location, describe the magnitude and extent of the escape of radioactive material, assess the consequences of the rupture,

and explain efforts planned or being taken to mitigate these consequences.

C. When it becomes apparent that efforts to recover the radioactive source will not be successful, the licensee shall:

1. Advise the well-operator of the regulations of the Virginia Department of Mines, Minerals, and Energy; Division of Gas and Oil regarding abandonment and an appropriate method of abandonment, which shall include:

a. The immobilization and sealing in place of the radioactive source with a cement plug,

b. The setting of a whipstock or other deflection device, and

c. The mounting of a permanent identification plaque at the surface of the well, containing the appropriate information required by 12 VAC 5-481-3700 D;

2. Notify the agency by telephone, giving the circumstances of the loss, and request approval of the proposed abandonment procedures; and

3. File a written report with the agency within 30 days of the abandonment. The licensee shall send a copy of the report to the Virginia Department of Mines, Minerals, and Energy; Division of Gas and Oil. The report shall contain the following information:

a. Date of occurrence;

b. A description of the well logging source involved, including the radionuclide and its quantity, chemical, and physical form;

c. Surface location and identification of the well;

d. Results of efforts to immobilize and seal the source in place;

e. A brief description of the attempted recovery effort;

f. Depth of the source;

g. Depth of the top of the cement plug;

h. Depth of the well;

i. Any other information, such as a warning statement, contained on the permanent identification plaque; and

j. The names of state agencies receiving a copy of this report.

D. Whenever a sealed source containing radioactive material is abandoned downhole, the licensee shall provide a permanent plaque for posting the well or well-bore. This plaque shall:

1. Be constructed of long-lasting material, such as stainless steel or monel; and

2. Contain the following information engraved on its face:

a. The word "CAUTION";

b. The radiation symbol without the conventional color requirement;

c. The date of abandonment;

d. The name of the well-operator or well-owner;

e. The well name and well identification number(s) or other designation;

f. The sealed source(s) by radionuclide and activity;

g. The source depth and the depth to the top of the plug; and

h. An appropriate warning, depending on the specific circumstances of each abandonment.

E. The licensee shall immediately notify the agency by telephone and subsequently by confirming letter if the licensee knows or has reason to believe that radioactive material has been lost in or to an underground potable aquifer. Such notice shall designate the well location and shall describe the magnitude and extent of loss of radioactive material, assess the consequences of such loss, and explain efforts planned or being taken to mitigate these consequences.

PART XV

THERAPEUTIC RADIATION MACHINES

12 VAC 5-481-3710. Purpose and scope.

A. This Part establishes requirements, for which the registrant is responsible, for use of therapeutic radiation machines. The provisions of this Part are in addition to, and not in substitution for, other applicable provisions of these regulations.

B. The use of therapeutic radiation machines shall be by, or under the supervision of, a licensed practitioner of the healing arts who meets the training/experience criteria established by 12 VAC 5-481-3720 C.

12 VAC 5-481-3720. General administrative requirements for facilities using therapeutic radiation machines.

A. Administrative controls. The registrant shall be responsible for directing the operation of the therapeutic radiation machines that have been registered with the agency. The registrant or the registrant's agent shall ensure that the requirements of Part XV (12 VAC 5-481-3710 et seq.) are met in the operation of the therapeutic radiation machine(s).

B. A therapeutic radiation machine that does not meet the provisions of these regulations shall not be used for irradiation of patients.

C. Training for external beam radiation therapy authorized users. The registrant for any therapeutic radiation machine subject to 12 VAC 5-481-3750 or 12 VAC 5-481-3760 shall require the authorized user to be a physician who:

1. Is certified in:

a. Radiology or therapeutic radiology by the American Board of Radiology; or

b. Radiation oncology by the American Osteopathic Board of Radiology; or

c. Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

d. Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons;

Or

2. Is in the active practice of therapeutic radiology, and has completed 200 hours of instruction in basic radiation techniques applicable to the use of an external beam radiation therapy unit, 500 hours of supervised work experience, and a minimum of three years of supervised clinical experience.

a. To satisfy the requirement for instruction, the classroom and laboratory training shall include:

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of ionization radiation;

and

(4) Radiation biology.

b. To satisfy the requirement for supervised work experience, training shall be under the supervision of an authorized user and shall include:

(1) Review of the full calibration measurements and periodic quality assurance checks;

(2) Evaluation of prepared treatment plans and calculation of treatment times/patient treatment settings;

(3) Using administrative controls to prevent misadministrations;

(4) Implementing emergency procedures to be followed in the event of the abnormal operation of an external beam radiation therapy unit or console; and

(5) Checking and using radiation survey meters.

c. To satisfy the requirement for a period of supervised clinical experience, training shall include one year in a formal training program approved by the Residency

Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user. The supervised clinical experience shall include:

(1) Examining individuals and reviewing their case histories to determine their suitability for external beam radiation therapy treatment, and any limitations/contraindications;

(2) Selecting proper dose and how it is to be administered;

(3) Calculating the external beam radiation therapy doses and collaborating with the authorized user in the review of patients' progress and consideration of the need to modify originally prescribed doses and/or treatment plans as warranted by patients' reaction to radiation; and

(4) Post-administration follow-up and review of case histories.

3. Notwithstanding the requirements of 12 VAC 5-481-3720 C 1 and 12 VAC 5-481-3720 C 2, the registrant for any therapeutic radiation machine subject to 12 VAC 5-481-3750 may also submit the training of the prospective authorized user physician for agency review on a case-by-case basis.

4. A physician shall not act as an authorized user for any therapeutic radiation machine until such time as said physician's training has been reviewed and approved by the agency.

D. Training for radiation therapy physicist. The registrant for any therapeutic radiation machine subject to 12 VAC 5-481-3750 and 12 VAC 5-481-3760 shall require the radiation therapy physicist to:

1. Be registered with the agency, under the provisions of Part II (12 VAC 5-481-260 et seq.) of these regulations, as a provider of radiation services in the area of calibration and compliance surveys of external beam radiation therapy units; and

2. Shall meet the requirements of Appendix M.

E. Qualifications of operators.

1. Individuals who will be operating a therapeutic radiation machine for medical use shall be American Registry of Radiologic Technologists (ARRT) Registered Radiation Therapy Technologists. Individuals who are not ARRT Registered Radiation Therapy Technologists shall submit evidence that they have satisfactorily completed a radiation therapy technologist training program that complies with the requirements of the Joint Review Committee on Education in Radiologic Technology.

2. The names and training of all personnel currently operating a therapeutic radiation machine

shall be kept on file at the facility. Information on former operators shall be retained for a period of at least two years beyond the last date they were authorized to operate a therapeutic radiation machine at that facility.

F. Written safety procedures and rules shall be developed by a radiation therapy physicist and shall be available in the control area of a therapeutic radiation machine, including any restrictions required for the safe operation of the particular therapeutic radiation machine. The operator shall be able to demonstrate familiarity with these rules.

G. Individuals shall not be exposed to the useful beam except for medical therapy purposes and unless such exposure has been ordered in writing by a licensed practitioner of the healing arts who is specifically identified on the Certificate of Registration. This provision specifically prohibits deliberate exposure of an individual for training, demonstration or other non-healing-arts purposes.

H. Visiting authorized user. Notwithstanding the provisions of 12 VAC 5-481-3720 G, a registrant may permit any physician to act as a visiting authorized user under the term of the registrant's Certificate of Registration for up to 60 days per calendar year under the following conditions:

1. The visiting authorized user has the prior written permission of the registrant's management and, if the use occurs on behalf of an institution, the institution's radiation safety committee; and

2. The visiting authorized user meets the requirements established for authorized user(s) in 12

VAC 5-481-3720 C 1 and 12 VAC 5-481-3720 2; and

3. The registrant maintains copies of all records specified by 12 VAC 5-481-3720 H for five years from the date of the last visit.

I. All individuals associated with the operation of a therapeutic radiation machine shall be instructed in and shall comply with the provisions of the registrant's quality management program. In addition to the requirements of Part XV (12 VAC 5-481-3710 et seq.), these individuals are also subject to the requirements of 12 VAC 5-481-640; 12 VAC 5-481-680; and 12 VAC 5-481-760 of these regulations.

J. Information and maintenance record and associated information. The registrant shall maintain the following information in a separate file or package for each therapeutic radiation machine, for inspection by the agency:

1. Report of acceptance testing;

2. Records of all surveys, calibrations, and periodic quality assurance checks of the therapeutic radiation machine required by Part XV (12 VAC 5-481-3710 et seq.), as well as the name(s) of person(s) who performed such activities;

3. Records of maintenance and/or modifications performed on the therapeutic radiation machine after the effective date of these regulations, as well as the name(s) of person(s) who

performed such services;

4. Signature of person authorizing the return of therapeutic radiation machine to clinical use after service, repair, or upgrade.

K. Records retention. All records required by Part XV (12 VAC 5-481-3710 et seq.) shall be retained until disposal is authorized by the agency unless another retention period is specifically authorized in Part XV (12 VAC 5-481-3710 et seq.). All required records shall be retained in an active file from at least the time of generation until the next agency inspection. Any required record generated prior to the last agency inspection may be microfilmed or otherwise archived as long as a complete copy of said record can be retrieved until such time as the agency authorizes final disposal.

12 VAC 5-481-3730. General technical requirements for facilities using therapeutic radiation machines.

A. Protection surveys.

1. The registrant shall ensure that radiation protection surveys of all new facilities, and existing facilities not previously surveyed are performed with an operable radiation measurement survey instrument calibrated in accordance with 12 VAC 5-481-3770. The radiation protection survey shall be performed by, or under the direction of, a radiation therapy physicist or a private inspector and shall verify that, with the therapeutic radiation machine in a "BEAM-ON" condition, with the largest clinically available treatment field and with a

scattering phantom in the useful beam of radiation:

a. Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in 12 VAC 5-481-640 A of these regulations.; and

b. Radiation levels in unrestricted areas do not exceed the limits specified in 12 VAC 5-481-720 A and 12 VAC 5-481-720 B of these regulations.

2. In addition to the requirements of 12 VAC 5-481-3730 A 1, a radiation protection survey shall also be performed prior to any subsequent medical use and:

a. After making any change in the treatment room shielding;

b. After making any change in the location of the therapeutic radiation machine within the treatment room;

c. After relocating the therapeutic radiation machine; or

d. Before using the therapeutic radiation machine in a manner that could result in increased radiation levels in areas outside the external beam radiation therapy treatment room.

3. The survey record shall indicate all instances where the facility, in the opinion of the

radiation therapy physicist or a private inspector, is in violation of applicable regulations. The survey record shall also include: the date of the measurements; the reason the survey is required; the manufacturer's name; model number and serial number of the therapeutic radiation machine; the instrument(s) used to measure radiation levels; a plan of the areas surrounding the treatment room that were surveyed; the measured dose rate at several points in each area expressed in microsieverts or millirems per hour; the calculated maximum level of radiation over a period of one week for each restricted and unrestricted area; and the signature of the individual responsible for conducting the survey;

4. If the results of the surveys required by 12 VAC 5-481-3730 A 1 or 12 VAC 5-481-3730 A 2 indicate any radiation levels in excess of the respective limit specified in 12 VAC 5-481-3730 A 1, the registrant shall lock the control in the "OFF" position and not use the unit:

a. Except as may be necessary to repair, replace, or test the therapeutic radiation machine, the therapeutic radiation machine shielding, or the treatment room shielding; or

b. Until the registrant has received a specific exemption from the agency.

B. Modification of radiation therapy unit or room before beginning a treatment program. If the survey required by 12 VAC 5-481-3730 A indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by 12 VAC 5-481-720 A and 12 VAC 5-481-720 B of these regulations, before beginning the treatment program the registrant shall:

1. Either equip the unit with beam direction interlocks or add additional radiation shielding to ensure compliance with 12 VAC 5-481-720 A and 12 VAC 5-481-720 B of these regulations;

2. Perform the survey required by 12 VAC 5-481-3730 A again; and

3. Include in the report required by 12 VAC 5-481-3730 D the results of the initial survey, a description of the modification made to comply with 12 VAC 5-481-3730 B 1, and the results of the second survey; or

4. Request and receive a registration amendment under 12 VAC 5-481-720 C of these regulations that authorizes radiation levels in unrestricted areas greater than those permitted by 12 VAC 5-481-720 A and 12 VAC 5-481-720 B of these regulations.

C. Dosimetry equipment.

1. The registrant shall have a calibrated dosimetry system available for use. The system shall have been calibrated by the National Institute for Standards and Technology (NIST) or by an American Association of Physicists in Medicine (AAPM) Accredited Dosimetry Calibration Laboratory (ADCL). The calibration shall have been performed within the previous 24 months and after any servicing that may have affected system calibration. An independent survey shall be conducted by a private inspector or radiation therapy physicist other than the

person performing the original survey prior to the equipment being used except as described in 12 VAC 5-481-3730 A 4.

a. For beams with energies greater than one MV (1 MeV), the dosimetry system shall have been calibrated for Cobalt-60;

b. For beams with energies equal to or less than one MV (1 MeV), the dosimetry system shall have been calibrated at an energy (energy range) appropriate for the radiation being measured;

2. The registrant shall have available for use a dosimetry system for quality assurance check measurements. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with 12 VAC 5-481-3730 C 1. This comparison shall have been performed within the previous 12 months and after each servicing that may have affected system calibration. The quality assurance check system may be the same system used to meet the requirement in 12 VAC 5-481-3730 C 1;

3. The registrant shall maintain a record of each dosimetry system calibration, intercomparison, and comparison for the duration of the license and/or registration. For each calibration, intercomparison, or comparison, the record shall include: the date; the model numbers and serial numbers of the instruments that were calibrated, inter-compared, or compared as required by 12 VAC 5-481-3730 C 1 and 12 VAC 5-481-3730 C 2; the correction factors that were determined; the names of the individuals who performed the calibration,

intercomparison, or comparison; and evidence that the intercomparison was performed by, or under the direct supervision and in the physical presence of, a radiation therapy physicist.

D. Reports of external beam radiation therapy surveys and measurements. The registrant for any therapeutic radiation machine subject to 12 VAC 5-481-3750 or 12 VAC 5-481-3760 shall furnish a copy of the records required in 12 VAC 5-481-3730 A and 12 VAC 5-481-3730 B to the agency within 30 days following completion of the action that initiated the record requirement.

12 VAC 5-481-3740. Quality management program.

The facility shall implement a quality management program. The facility may use the quality management programs found in either Appendix P or Q.

12 VAC 5-481-3750. Therapeutic radiation machines of less than 500 kV.

A. Leakage radiation. When the X-ray tube is operated at its maximum rated tube current for the maximum kV, the leakage air kerma rate shall not exceed the value specified at the distance specified for that classification of therapeutic radiation machine:

1. 5-50 kV Systems. The leakage air kerma rate measured at any position five centimeters from the tube housing assembly shall not exceed one mGy (100 mrad) in any one hour.

2. >50 and <500 kV Systems. The leakage air kerma rate measured at a distance of one meter

from the target in any direction shall not exceed one cGy (1 rad) in any one hour. This air kerma rate measurement may be averaged over areas no larger than 100 square centimeters. In addition, the air kerma rate at a distance of five centimeters from the surface of the tube housing assembly shall not exceed 30 cGy (30 rad) per hour.

3. For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in 12 VAC 5-481-3750 A 1 and 12 VAC 5-481-3750 A 2 for the specified operating conditions. Records on leakage radiation measurements shall be maintained at the installation for inspection by the agency.

B. Permanent beam limiting devices. Permanent diaphragms or cones used for limiting the useful beam shall provide at least the same degree of attenuation as required for the tube housing assembly.

C. Adjustable or removable beam limiting devices.

1. All adjustable or removable beam limiting devices, diaphragms, cones or blocks shall not transmit more than 5% of the useful beam for the most penetrating beam used;

2. When adjustable beam limiting devices are used, the position and shape of the radiation field shall be indicated by a light beam.

D. Filter system. The filter system shall be so designed that:

1. Filters cannot be accidentally displaced at any possible tube orientation;

2. For equipment installed after the effective date of these regulations, an interlock system prevents irradiation if the proper filter is not in place;

3. The air kerma rate escaping from the filter slot shall not exceed one cGy (1 rad) per hour at one meter under any operating conditions; and

4. Each filter shall be marked as to its material of construction and its thickness.

E. Tube immobilization.

1. The X-ray tube shall be so mounted that it cannot accidentally turn or slide with respect to the housing aperture; and

2. The tube housing assembly shall be capable of being immobilized for stationary portal treatments.

F. Source marking. The tube housing assembly shall be so marked that it is possible to determine the location of the source to within five millimeters, and such marking shall be readily accessible for use during calibration procedures.

G. Beam block. Contact therapy tube housing assemblies shall have a removable shield of material,

equivalent in attenuation to 0.5 millimeters of lead at 100 kV, which can be positioned over the entire useful beam exit port during periods when the beam is not in use.

H. Timer. A suitable irradiation control device shall be provided to terminate the irradiation after a pre-set time interval.

1. A timer with a display shall be provided at the treatment control panel. The timer shall have a pre-set time selector and an elapsed time or time remaining indicator;

2. The timer shall be a cumulative timer that activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator;

3. The timer shall terminate irradiation when a pre-selected time has elapsed, if any dose monitoring system present has not previously terminated irradiation;

4. The timer shall permit accurate pre-setting and determination of exposure times as short as one second;

5. The timer shall not permit an exposure if set at zero;

6. The timer shall not activate until the shutter is opened when irradiation is controlled by a

shutter mechanism unless calibration includes a timer error correction to compensate for mechanical lag; and

7. Timer shall be accurate to within 1% of the selected value or one second, whichever is greater.

I. Control panel functions. The control panel, in addition to the displays required by other provisions in 12 VAC 5-481-3750, shall have:

1. An indication of whether electrical power is available at the control panel and if activation of the X-ray tube is possible;

2. An indication of whether X-rays are being produced;

3. A means for indicating X-ray tube potential and current;

4. The means for terminating an exposure at any time;

5. A locking device which will prevent unauthorized use of the therapeutic radiation machine; and

6. For therapeutic radiation machines manufactured after the effective date of these regulations, a positive display of specific filter(s) in the beam.

J. Multiple tubes. When a control panel may energize more than one X-ray tube:

1. It shall be possible to activate only one X-ray tube at any time;

2. There shall be an indication at the control panel identifying which X-ray tube is activated; and

3. There shall be an indication at the tube housing assembly when that tube is energized.

K. Target-to-skin distance (TSD). There shall be a means of determining the central axis TSD to within one centimeter and of reproducing this measurement to within two millimeters thereafter.

L. Shutters. Unless it is possible to bring the X-ray output to the prescribed exposure parameters within five seconds after the X-ray "ON" switch is energized, the beam shall be attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly. In addition, after the unit is at operating parameters, the shutter shall be controlled by the operator from the control panel. An indication of shutter position shall appear at the control panel.

M. Low filtration X-ray tubes. Each therapeutic radiation machine equipped with a beryllium or other low-filtration window shall be clearly labeled as such upon the tube housing assembly and shall be provided with a permanent warning device on the control panel that is activated when no additional filtration is present, to indicate that the dose rate is very high.

N. Facility design requirements for therapeutic radiation machines capable of operating in the range 50 kV to 500 kV. In addition to adequate shielding to meet requirements of 12 VAC 5-481-3780, the treatment room shall meet the following design requirements:

1. Aural communication. Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel;

2. Viewing systems. Provision shall be made to permit continuous observation of the patient during irradiation and the viewing system shall be so located that the operator can observe the patient from the control panel. The therapeutic radiation machine shall not be used for patient irradiation unless at least one viewing system is operational.

O. Additional requirements. Treatment rooms that contain a therapeutic radiation machine capable of operating above 150 kV shall meet the following additional requirements:

1. All protective barriers shall be fixed except for entrance doors or beam interceptors;

2. The control panel shall be located outside the treatment room or in a totally enclosed booth, which has a ceiling, inside the room;

3. Interlocks shall be provided such that all entrance doors, including doors to any interior booths, shall be closed before treatment can be initiated or continued. If the radiation beam

is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel; and

4. When any door referred to in 12 VAC 5-481-3750 O 3 is opened while the X-ray tube is activated, the air kerma rate at a distance of one meter from the source shall be reduced to less than one mGy (100 mrad) per hour.

P. Full calibration measurements.

1. Full calibration of a therapeutic radiation machine subject to 12 VAC 5-481-3750 shall be performed by, or under the direct supervision of, a radiation therapy physicist:

a. Before the first medical use following installation or reinstallation of the therapeutic radiation machine;

b. At intervals not exceeding one year; and

c. Before medical use under the following conditions:

(1) Whenever quality assurance check measurements indicate that the radiation output differs by more than 5% from the value obtained at the last full calibration and the difference cannot be reconciled; and

(2) Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam.

d. Notwithstanding the requirements of 12 VAC 5-481-3750 P 1 c:

(1) Full calibration of therapeutic radiation machines with multi-energy capabilities is required only for those modes and/or energies that are not within their acceptable range; and

(2) If the repair, replacement or modification does not affect all energies, full calibration shall be performed on the affected energy that is in most frequent clinical use at the facility. The remaining energies may be validated with quality assurance check procedures against the criteria in 12 VAC 5-481-3750 P 1 c (1).

2. To satisfy the requirement of 12 VAC 5-481-3750 P 1, full calibration shall include all measurements recommended for annual calibration by NCRP Report 69, "Dosimetry of X-ray and Gamma Ray Beams for Radiation Therapy in the Energy Range 10 keV to 50 MeV" (1981).

3. The registrant shall maintain a record of each calibration for the duration of the registration.

The record shall include: the date of the calibration; the manufacturer's name, model number, and serial number for both the therapeutic radiation machine and the X-ray tube; the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine; and the signature of the radiation therapy physicist responsible for performing the calibration.

Q. Periodic quality assurance checks.

1. Periodic quality assurance checks shall be performed on therapeutic radiation machines subject to 12 VAC 5-481-3750, which are capable of operation at greater than or equal to 50 kV.

2. To satisfy the requirement of 12 VAC 5-481-3750 Q 1, quality assurance checks shall meet the following requirements:

a. The registrant shall perform quality assurance checks in accordance with written procedures established by the radiation therapy physicist.; and

b. The quality assurance check procedures shall specify the frequency at which tests or measurements are to be performed. The quality assurance check procedures shall specify that the quality assurance check shall be performed during the calibration specified in 12 VAC 5-481-3750 P 1. The acceptable tolerance for each parameter measured in the quality assurance check, when compared to the value for that

parameter determined in the calibration specified in 12 VAC 5-481-3750 P 1, shall be stated.

3. The cause for a parameter exceeding a tolerance set by the radiation therapy physicist shall be investigated and corrected before the system is used for patient irradiation;

4. Whenever a quality assurance check indicates a significant change in the operating characteristics of a system, as specified in the radiation therapy physicist's quality assurance check procedures, the system shall be recalibrated as required in 12 VAC 5-481-3750 P 1;

5. The registrant shall use the dosimetry system described in 12 VAC 5-481-3730 C 2 to make the quality assurance check required in 12 VAC 5-481-3750 Q 2;

6. The registrant shall have the radiation therapy physicist review and sign the results of each radiation output quality assurance check within one month of the date that the check was performed;

7. The registrant shall ensure that safety quality assurance checks of therapeutic radiation machines subject to 12 VAC 5-481-3750 are performed at intervals not to exceed one month;

8. Notwithstanding the requirements of 12 VAC 5-481-3750 Q 4 and 12 VAC 5-481-3750 Q 7, the registrant shall ensure that no therapeutic radiation machine is used to administer

radiation to humans unless the quality assurance checks required by 12 VAC 5-481-3750 Q 6 and 12 VAC 5-481-3750 Q 7 have been performed within the 30 day period immediately prior to said administration;

9. To satisfy the requirement of 12 VAC 5-481-3750 Q 7, safety quality assurance checks shall ensure proper operation of:

a. Electrical interlocks at each external beam radiation therapy room entrance;

b. The "BEAM-ON" and termination switches;

c. Beam condition indicator lights on the access door(s), control console, and in the radiation therapy room;

d. Viewing systems;

e. If applicable, electrically operated treatment room doors from inside and outside the treatment room;

10. The registrant shall maintain a record of each quality assurance check required by 12 VAC 5-481-3750 Q 1 and 12 VAC 5-481-3750 Q 7 for three years. The record shall include: the date of the quality assurance check; the manufacturer's name, model number, and serial number of the therapeutic radiation machine; the manufacturer's name; model number and

serial number for the instrument(s) used to measure the radiation output of the therapeutic radiation machine; and the signature of the individual who performed the periodic quality assurance check.

R. Operating procedures.

1. The therapeutic radiation machine shall not be used for irradiation of patients unless the requirements of 12 VAC 5-481-3750 P and 12 VAC 5-481-3750 Q have been met;

2. Therapeutic radiation machines shall not be left unattended unless secured pursuant to 12 VAC 5-481-3750 I 5;

3. When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used;

4. The tube housing assembly shall not be held by an individual during operation unless the assembly is designed to require such holding and the peak tube potential of the system does not exceed 50 kV. In such cases, the holder shall wear protective gloves and apron of not less than 0.5 millimeters lead equivalency at 100 kV;

5. A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console; and

6. No individual other than the patient shall be in the treatment room during exposures from therapeutic radiation machines operating above 150 kV. At energies less than or equal to 150 kV, any individual, other than the patient, in the treatment room shall be protected by a barrier sufficient to meet the requirements of 12 VAC 5-481-640 of these regulations.

S. Possession of survey instrument(s). Each facility location authorized to use a therapeutic radiation machine in accordance with 12 VAC 5-481-3750 shall possess appropriately calibrated portable monitoring equipment. As a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 μSv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. The survey instrument(s) shall be operable and calibrated in accordance with 12 VAC 5-481-3770.

12 VAC 5-481-3760. Therapeutic radiation machines - photon therapy systems (500 kV and above) and electron therapy systems (500 kV and above).

A. Possession of survey instrument(s). Each facility location authorized to use a therapeutic radiation machine in accordance with 12 VAC 5-481-3760 shall possess appropriately calibrated portable monitoring equipment. As a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 μSv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. The survey instrument(s) shall be operable and calibrated in accordance with 12 VAC 5-481-3770.

B. Leakage radiation outside the maximum useful beam in photon and electron modes.

1. The absorbed dose due to leakage radiation (excluding neutrons) at any point outside the maximum sized useful beam, but within a circular plane of radius two meters which is perpendicular to and centered on the central axis of the useful beam at the nominal treatment distance (i.e. patient plane), shall not exceed a maximum of 0.2% and an average of 0.1% of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding 100 square centimeters at a minimum of 16 points uniformly distributed in the plane;

2. Except for the area defined in 12 VAC 5-481-3760 B 1, the absorbed dose due to leakage radiation (excluding neutrons) at one meter from the electron path between the electron source and the target or electron window shall not exceed 0.5% of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding 100 square centimeters;

3. For equipment manufactured after the effective date of these regulations, the neutron absorbed dose outside the useful beam shall be in compliance with International Electrotechnical Commission (IEC) Document 601-2-1 (most current revision); and

4. For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in 12 VAC 5-481-3760 B 1 through 12 VAC 5-481-3760 B 3 for the specified operating conditions. Records on leakage radiation measurements shall be maintained at the installation for inspection by the

agency.

C. Leakage radiation through beam limiting devices.

1. Photon radiation. All adjustable or interchangeable beam limiting devices shall attenuate the useful beam such that at the nominal treatment distance, the maximum absorbed dose anywhere in the area shielded by the beam limiting device(s) shall not exceed 2% of the maximum absorbed dose on the central axis of the useful beam measured in a 10 centimeter by 10 centimeter radiation field;

2. Electron radiation. All adjustable or interchangeable electron applicators shall attenuate the radiation, including but not limited to photon radiation generated by electrons incident on the beam limiting device and electron applicator and other parts of the radiation head, such that the absorbed dose in a plane perpendicular to the central axis of the useful beam at the nominal treatment distance shall not exceed:

a. A maximum of 2% and average of 0.5% of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line seven centimeters outside the periphery of the useful beam; and

b. A maximum of 10% of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line two centimeters outside the periphery of the useful beam.

3. Measurement of leakage radiation.

a. Photon radiation. Measurements of leakage radiation through the beam limiting devices shall be made with the beam limiting devices closed and any residual aperture blocked by at least two tenth value layers of suitable absorbing material. In the case of overlapping beam limiting devices, the leakage radiation through each set shall be measured independently at the depth of maximum dose. Measurements shall be made using a radiation detector of area not exceeding 10 square centimeters;

b. Electron radiation. Measurements of leakage radiation through the electron applicators shall be made with the electron beam directed into the air and using a radiation detector of area up to but not exceeding one square centimeter suitably protected against radiation which has been scattered from material beyond the radiation detector. Measurements shall be made using one centimeter of water equivalent build up material.

D. Filters/wedges.

1. Each wedge filter that is removable from the system shall be clearly marked with an identification number. For removable wedge filters, the nominal wedge angle shall appear on the wedge or wedge tray (if permanently mounted to the tray). If the wedge or wedge tray is significantly damaged, the wedge transmission factor shall be redetermined;

2. If the absorbed dose rate information required by 12 VAC 5-481-3760 I relates exclusively to operation with a field flattening filter or beam scattering foil in place, such foil or filter shall be removable only by the use of tools;

3. For equipment manufactured after the effective date of these regulations which utilizes wedge filters, interchangeable field flattening filters, or interchangeable beam scattering foils:

a. Irradiation shall not be possible until a selection of a filter or a positive selection to use "no filter" has been made at the treatment control panel, either manually or automatically;

b. An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position;

c. A display shall be provided at the treatment control panel showing the wedge filter(s), interchangeable field flattening filter(s), and/or interchangeable beam scattering foil(s) in use; and

d. An interlock shall be provided to prevent irradiation if any filter and/or beam scattering foil selection operation carried out in the treatment room does not agree with the filter and/or beam scattering foil selection operation carried out at the

treatment control panel.

E. Stray radiation in the useful beam. For equipment manufactured after the effective date of these regulations, the registrant shall determine during acceptance testing, or obtain from the manufacturer, data sufficient to ensure that X-ray stray radiation in the useful electron beam, absorbed dose at the surface during X-ray irradiation and stray neutron radiation in the useful X-ray beam are in compliance with International Electrotechnical Commission (IEC) Document 601-2-1 (most current revision).

F. Beam monitors. All therapeutic radiation machines subject to 12 VAC 5-481-3760 shall be provided with redundant beam monitoring systems. The sensors for these systems shall be fixed in the useful beam during treatment to indicate the dose monitor unit rate.

1. Equipment manufactured after the effective date of these regulations shall be provided with at least two independently powered integrating dose meters. Alternatively, common elements may be used if the production of radiation is terminated upon failure of any common element.

2. Equipment manufactured on or before the effective date of these regulations shall be provided with at least one radiation detector. This detector shall be incorporated into a useful beam monitoring system;

3. The detector and the system into which that detector is incorporated shall meet the following

requirements:

a. Each detector shall be removable only with tools and, if movable, shall be interlocked to prevent incorrect positioning;

b. Each detector shall form part of a beam monitoring system from whose readings in dose monitor units the absorbed dose at a reference point can be calculated;

c. Each beam monitoring system shall be capable of independently monitoring, interrupting, and terminating irradiation; and

d. For equipment manufactured after the effective date of these regulations, the design of the beam monitoring systems shall ensure that the:

(1) Malfunctioning of one system shall not affect the correct functioning of the other system(s); and

(2) Failure of either system shall terminate irradiation or prevent the initiation of radiation.

e. Each beam monitoring system shall have a legible display at the treatment control panel. For equipment manufactured after the effective date of these regulations, each display shall:

(1) Maintain a reading until intentionally reset;

(2) Have only one scale and no electrical or mechanical scale multiplying factors;

(3) Utilize a design such that increasing dose is displayed by increasing numbers; and

(4) In the event of power failure, the beam monitoring information required in 12 VAC 5-481-3760 F 3 e (3) displayed at the control panel at the time of failure shall be retrievable in at least one system for a 20 minute period of time.

G. Beam symmetry.

1. Bent-beam linear accelerators subject to 12 VAC 5-481-3760 shall be provided with auxiliary device(s) to monitor beam symmetry;

2. The device(s) referenced in 12 VAC 5-481-3760 g 1 shall be able to detect field asymmetry greater than 10%; and

3. The device(s) referenced in 12 VAC 5-481-3760 g 1 shall be configured to terminate irradiation if the specifications in 12 VAC 5-481-3760 g 2 cannot be maintained.

H. Selection and display of dose monitor units.

1. Irradiation shall not be possible until a new selection of a number of dose monitor units has been made at the treatment control panel;

2. The pre-selected number of dose monitor units shall be displayed at the treatment control panel until reset manually for the next irradiation;

3. After termination of irradiation, it shall be necessary to reset the dosimeter display before subsequent treatment can be initiated; and

4. For equipment manufactured after the effective date of these regulations, after termination of irradiation, it shall be necessary for the operator to reset the pre-selected dose monitor units before irradiation can be initiated.

I. Air kerma rate/absorbed dose rate. For equipment manufactured after the effective date of these regulations, a system shall be provided from whose readings the air kerma rate or absorbed dose rate at a reference point can be calculated. (The radiation detectors specified in 12 VAC 5-481-3760 F may form part of this system.) In addition:

1. The dose monitor unit rate shall be displayed at the treatment control panel;

2. If the equipment can deliver under any conditions an air kerma rate or absorbed dose rate at the nominal treatment distance more than twice the maximum value specified by the manufacturer, a device shall be provided which terminates irradiation when the air kerma rate or absorbed dose rate exceeds a value twice the specified maximum. The dose rate at which the irradiation will be terminated shall be a record maintained by the registrant;

3. If the equipment can deliver under any fault condition(s) an air kerma rate or absorbed dose rate at the nominal treatment distance more than 10 times the maximum value specified by the manufacturer, a device shall be provided to prevent the air kerma rate or absorbed dose rate anywhere in the radiation field from exceeding twice the specified maximum value and to terminate irradiation if the excess absorbed dose at the nominal treatment distance exceeds four Gy (400 rad); and

4. For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the maximum value(s) specified in 12 VAC 5-481-3760 I 2 and 12 VAC 5-481-3760 I 3 for the specified operating conditions. Records of these maximum value(s) shall be maintained at the installation for inspection by the agency.

J. Termination of irradiation by the beam monitoring system or systems during stationary beam radiation therapy.

1. Each primary system shall terminate irradiation when the pre-selected number of dose monitor units has been detected by the system;

2. If the original design of the equipment included a secondary dose monitoring system, that system shall be capable of terminating irradiation when not more than 15% or 40 dose monitor units above the pre-selected number of dose monitor units set at the control panel has been detected by the secondary dose monitoring system; and

3. For equipment manufactured after the effective date of these regulations, an indicator on the control panel shall show which monitoring system has terminated irradiation.

K. Termination of irradiation. It shall be possible to terminate irradiation and equipment movement or go from an interruption condition to termination condition at any time from the operator's position at the treatment control panel.

L. Interruption of irradiation. If a therapeutic radiation machine has an interrupt mode, it shall be possible to interrupt irradiation and equipment movements at any time from the treatment control panel. Following an interruption it shall be possible to restart irradiation by operator action without any reselection of operating conditions. If any change is made of a pre-selected value during an interruption, irradiation and equipment movements shall be automatically terminated.

M. Timer. A suitable irradiation control device shall be provided to terminate the irradiation after a pre-set time interval.

1. A timer shall be provided which has a display at the treatment control panel. The timer shall have a pre-set time selector and an elapsed time indicator;

2. The timer shall be a cumulative timer that activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator;

3. The timer shall terminate irradiation when a pre-selected time has elapsed, if the dose monitoring systems have not previously terminated irradiation.

N. Selection of radiation type. Equipment capable of both X-ray therapy and electron therapy shall meet the following additional requirements:

1. Irradiation shall not be possible until a selection of radiation type (X-rays or electrons) has been made at the treatment control panel;

2. The radiation type selected shall be displayed at the treatment control panel before and during irradiation;

3. An interlock system shall be provided to ensure that the equipment can principally emit only the radiation type that has been selected;

4. An interlock system shall be provided to prevent irradiation with X-rays, except to obtain an image, when electron applicators are fitted;

5. An interlock system shall be provided to prevent irradiation with electrons when accessories specific for X-ray therapy are fitted; and

6. An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

O. Selection of energy. Equipment capable of generating radiation beams of different energies shall meet the following requirements:

1. Irradiation shall not be possible until a selection of energy has been made at the treatment control panel;

2. The nominal energy value selected shall be displayed at the treatment control panel until reset manually for the next irradiation. After termination of irradiation, it shall be necessary to reset the nominal energy value selected before subsequent treatment can be initiated;

3. Irradiation shall not be possible until the appropriate flattening filter or scattering foil for the selected energy is in its proper location; and

4. For equipment manufactured after the effective date of these regulations, the selection of energy shall be in compliance with International Electrotechnical Commission (IEC) Document 601-2-1.

P. Selection of stationary beam radiation therapy or moving beam radiation therapy. Therapeutic radiation machines capable of both stationary beam radiation therapy and moving beam radiation therapy shall meet the following requirements:

1. Irradiation shall not be possible until a selection of stationary beam radiation therapy or moving beam radiation therapy has been made at the treatment control panel;

2. The mode of operation shall be displayed at the treatment control panel;

3. An interlock system shall be provided to ensure that the equipment can operate only in the mode that has been selected;

4. An interlock system shall be provided to prevent irradiation if any selected parameter in the treatment room does not agree with the selected parameter at the treatment control panel;

5. Moving beam radiation therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental movement. For equipment manufactured after the effective date of these regulations:

a. An interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any 10 degrees of rotation or one cm of linear motion differs by more than 20% from the selected value;

b. Where angle terminates the irradiation in moving beam radiation therapy, the dose monitor units delivered shall differ by less than 5% from the dose monitor unit value selected;

c. An interlock shall be provided to prevent motion of more than five degrees or one cm beyond the selected limits during moving beam radiation therapy;

d. An interlock shall be provided to require that a selection of direction be made at the treatment control panel in all units which are capable of both clockwise and counter-clockwise moving beam radiation therapy.

e. Moving beam radiation therapy shall be controlled with both primary position sensors and secondary position sensors to obtain the selected relationships between incremental dose monitor units and incremental movement.

6. Where the beam monitor system terminates the irradiation in moving beam radiation therapy, the termination of irradiation shall be as required by 12 VAC 5-481-3760 J; and

7. For equipment manufactured after the effective date of these regulations, an interlock system shall be provided to terminate irradiation if movement:

a. Occurs during stationary beam radiation therapy; or

b. Does not start or stops during moving beam radiation therapy unless such stoppage is a pre-planned function.

Q. Facility design requirements for therapeutic radiation machines operating above 500 kV. In addition to shielding adequate to meet requirements of 12 VAC 5-481-3780, the following design requirements are made:

1. Protective barriers. All protective barriers shall be fixed, except for access doors to the treatment room or movable beam interceptors;

2. Control panel. In addition to other requirements specified in Part XV (12 VAC 5-481-3710 et seq.), the control panel shall also:

a. Be located outside the treatment room;

b. Provide an indication of whether electrical power is available at the control panel and if activation of the radiation is possible;

c. Provide an indication of whether radiation is being produced; and

d. Include an access control (locking) device that will prevent unauthorized use of the therapeutic radiation machine;

3. Viewing systems. Windows, mirrors, closed-circuit television or an equivalent viewing system shall be provided to permit continuous observation of the patient following positioning and during irradiation and shall be so located that the operator may observe the patient from the treatment control panel. The therapeutic radiation machine shall not be used for patient irradiation unless at least one viewing system is operational;

4. Aural communications. Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel. The therapeutic radiation machine shall not be used for irradiation of patients unless continuous two-way aural communication is possible;

5. Room entrances. Treatment room entrances shall be provided with warning lights in a readily observable position near the outside of all access doors, which will indicate when the useful beam is "ON" and when it is "OFF";

6. Entrance interlocks. Interlocks shall be provided such that all access controls are activated before treatment can be initiated or continued. If the radiation beam is interrupted by any access control, it shall not be possible to restore the machine to operation without resetting

the access control and reinitiating irradiation by manual action at the control panel;

7. Beam interceptor interlocks. If the shielding material in any protective barrier requires the presence of a beam interceptor to ensure compliance with 12 VAC 5-481-720 A and 12 VAC 5-481-720 B of these regulations, interlocks shall be provided to prevent the production of radiation, unless the beam interceptor is in place, whenever the useful beam is directed at the designated barrier(s);

8. Emergency cutoff switches. At least one emergency power cutoff switch shall be located in the radiation therapy room and shall terminate all equipment electrical power including radiation and mechanical motion. This switch is in addition to the termination switch required by 12 VAC 5-481-3760 K. All emergency power cutoff switches shall include a manual reset so that the therapeutic radiation machine cannot be restarted from the unit's control console without resetting the emergency cutoff switch;

9. Safety interlocks. All safety interlocks shall be designed so that any defect or component failure in the safety interlock system prevents or terminates operation of the therapeutic radiation machine; and

10. Surveys for residual radiation. Surveys for residual activity shall be conducted on all therapeutic radiation machines capable of generating photon and electron energies above 10 MV prior to machining, removing, or working on therapeutic radiation machine components which may have become activated due to photo-neutron production.

R. Radiation therapy physicist support.

1. The services of a radiation therapy physicist shall be required in facilities having therapeutic radiation machines with energies of 500 kV and above. The radiation therapy physicist shall be responsible for:

a. Full calibration(s) required by 12 VAC 5-481-3760 T and protection surveys required by 12 VAC 5-481-3730 A;

b. Supervision and review of dosimetry;

c. Beam data acquisition and transfer for computerized dosimetry, and supervision of its use;

d. Quality assurance, including quality assurance check review required by 12 VAC 5-481-3760 U 5.

e. Consultation with the authorized user in treatment planning, as needed; and

f. Performance of calculations/assessments regarding misadministrations.

2. If the radiation therapy physicist is not a full-time employee of the registrant, the operating

procedures required by 12 VAC 5-481-3760 S shall also specifically address how the radiation therapy physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the radiation therapy physicist can be contacted.

S. Operating procedures.

1. No individual, other than the patient, shall be in the treatment room during treatment or during any irradiation for testing or calibration purposes;

2. Therapeutic radiation machines shall not be made available for medical use unless the requirements of 12 VAC 5-481-3730 A, 12 VAC 5-481-3760 T and 12 VAC 5-481-3760 U have been met;

3. Therapeutic radiation machines, when not in operation, shall be secured to prevent unauthorized use;

4. When adjustable beam limiting devices are used, the position and shape of the radiation field shall be indicated by a light field.

5. If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used; and

6. A copy of the current operating and emergency procedures shall be maintained at the

therapeutic radiation machine control console.

T. Acceptance testing, commissioning and full calibration measurements.

1. Acceptance testing, commissioning and full calibration of a therapeutic radiation machine subject to 12 VAC 5-481-3760 shall be performed by, or under the direct supervision of, a radiation therapy physicist.

2. Acceptance testing and commissioning shall be performed in accordance with "AAPM Code of Practice for Radiotherapy Accelerators: Report of AAPM Radiation Therapy Task Group 45" and shall be conducted before the first medical use following installation or reinstallation of the therapeutic radiation machine.

3. Full calibration shall include measurement of all parameters required by Table II of "Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy Committee Task Group 40" and shall be performed in accordance with "AAPM Code of Practice for Radiotherapy Accelerators: Report of AAPM Radiation Therapy Task Group 45". Although it shall not be necessary to complete all elements of a full calibration at the same time, all parameters (for all energies) shall be completed at intervals not exceeding 12 calendar months, unless a more frequent interval is required in Table II.

4. The radiation therapy physicist shall perform all elements of a full calibration necessary to determine that all parameters are within acceptable limits:

a. Whenever quality assurance check measurements indicate that the radiation output differs by more than 5% from the value obtained at the last full calibration and the difference cannot be reconciled. Therapeutic radiation machines with multi-energy and/or multi-mode capabilities shall only require measurements for those modes and/or energies that are not within their acceptable range; and

b. Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam. If the repair, replacement or modification does not affect all modes and/or energies, measurements shall be performed on the effected mode/energy that is in most frequent clinical use at the facility. The remaining energies/modes may be validated with quality assurance check procedures against the criteria in 12 VAC 5-481-3760 T 4 a.

5. The registrant shall maintain a record of each calibration in an auditable form for the duration of the registration. The record shall include: the date of the calibration; the manufacturer's name, model number and serial number for the therapeutic radiation machine; the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine; and the signature of the radiation therapy physicist responsible for performing the calibration.

U. Periodic quality assurance checks.

1. Periodic quality assurance checks shall be performed on all therapeutic radiation machines subject to 12 VAC 5-481-3760 at intervals not to exceed those specified in "Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy Committee Task Group 40";

2. To satisfy the requirement of 12 VAC 5-481-3760 U 1, quality assurance checks shall include determination of central axis radiation output and a representative sampling of periodic quality assurance checks contained in "Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy Committee Task Group 40". Representative sampling shall include all referenced periodic quality assurance checks in an interval not to exceed 12 consecutive calendar months;

3. The registrant shall use a dosimetry system that has been inter-compared within the previous 12 months with the dosimetry system described in 12 VAC 5-481-3730 C 1 to make the periodic quality assurance checks required in 12 VAC 5-481-3760 U 2;

4. The registrant shall perform periodic quality assurance checks required by 12 VAC 5-481-3760 U 1 in accordance with procedures established by the radiation therapy physicist;

5. The registrant shall review the results of each periodic radiation output check according to the following procedures:

a. The authorized user and radiation therapy physicist shall be immediately notified if

any parameter is not within its acceptable tolerance. The therapeutic radiation machine shall not be made available for subsequent medical use until the radiation therapy physicist has determined that all parameters are within their acceptable tolerances;

b. If all quality assurance check parameters appear to be within their acceptable ranges, the quality assurance check shall be reviewed and signed by either the authorized user or radiation therapy physicist within three treatment days; and

c. The radiation therapy physicist shall review and sign the results of each radiation output quality assurance check at intervals not to exceed one month.

6. Therapeutic radiation machines subject to 12 VAC 5-481-3760 shall have safety quality assurance checks listed in "Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy Committee Task Group 40" performed at intervals not to exceed one week;

7. To satisfy the requirement of 12 VAC 5-481-3760 U 6, safety quality assurance checks shall ensure proper operation of:

a. Electrical interlocks at each external beam radiation therapy room entrance;

b. Proper operation of the "BEAM-ON", interrupt and termination switches;

c. Beam condition indicator lights on the access doors, control console, and in the radiation therapy room;

d. Viewing systems;

e. Electrically operated treatment room door(s) from inside and outside the treatment room;

f. At least one emergency power cutoff switch. If more than one emergency power cutoff switch is installed and not all switches are tested at once, each switch shall be tested on a rotating basis. Safety quality assurance checks of the emergency power cutoff switches may be conducted at the end of the treatment day in order to minimize possible stability problems with the therapeutic radiation machine.

8. The registrant shall promptly repair any system identified in 12 VAC 5-481-3760 U 7 that is not operating properly; and

9. The registrant shall maintain a record of each quality assurance check required by 12 VAC 5-481-3760 U 1 and 12 VAC 5-481-3760 U 7 for three years. The record shall include: the date of the quality assurance check; the manufacturer's name, model number, and serial number of the therapeutic radiation machine; the manufacturer's name, model number and serial number for the instrument(s) used to measure the radiation output of the therapeutic

radiation machine; and the signature of the individual who performed the periodic quality assurance check.

12 VAC 5-481-3770. Calibration of survey instruments.

A. The registrant shall ensure that the survey instruments used to show compliance with Part XV (12 VAC 5-481-3710 et seq.) have been calibrated before first use, at intervals not to exceed 12 months, and following repair.

B. To satisfy the requirements of 12 VAC 5-481-3770 A, the registrant shall:

1. Calibrate all required scale readings up to 10 mSv (1000 mrem) per hour with an appropriate radiation source that is traceable to the National Institute of Standards and Technology (NIST);

2. Calibrate at least two (2) points on each scale to be calibrated. These points should be at approximately 1/3 and 2/3 of full-scale; and

C. To satisfy the requirements of 12 VAC 5-481-3770 B, the registrant shall:

1. Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 10%; and

2. Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 20% if a correction factor or graph is conspicuously attached to the instrument.

D. The registrant shall retain a record of each calibration required in 12 VAC 5-481-3770 A for three years. The record shall include:

1. A description of the calibration procedure; and

2. A description of the source used and the certified dose rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, the signature of the individual who performed the calibration, and the date of calibration.

E. The registrant may obtain the services of individuals licensed by the agency, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State to perform calibrations of survey instruments. Records of calibrations that contain information required by 12 VAC 5-481-3770 D shall be maintained by the registrant.

12 VAC 5-481-3780. Shielding and safety design requirements.

A. Each therapeutic radiation machine subject to 12 VAC 5-481-3750 or 12 VAC 5-481-3760 shall be provided with such primary and/or secondary barriers as are necessary to ensure compliance with 12

VAC 5-481-640 and 12 VAC 5-481-720 of these regulations.

B. Facility design information for all new installations of a therapeutic radiation machine or installations of a therapeutic radiation machine of higher energy into a room not previously approved for that energy shall be submitted for agency approval prior to actual installation of the therapeutic radiation machine. The minimum facility design information that must be submitted is contained in Appendix O.

PART XVI

REGULATION AND LICENSING OF TECHNOLOGICALLY ENHANCED NATURALLY OCCURRING RADIOACTIVE MATERIALS (TENORM)

*/ ~~This section duplicates the requirements of SSR Part III; states having equivalent requirements may elect to refer to appropriate regulations.~~

12 VAC 5-481-3790. Purpose.

This Part establishes radiation protection standards for the possession, use, transfer, and disposal of Technologically Enhanced Naturally Occurring Radioactive Materials (TENORM).

12 VAC 5-481-3800. ~~Sec. N.2 – –~~ Scope.

A~~a~~. These regulations apply to any person who receives, owns, possesses, uses, processes, transfers, distributes, or disposes of TENORM.

B~~b~~. The regulations in this Part address the introduction of TENORM into products in which neither the TENORM, nor the radiation emitted from the TENORM, is considered to be beneficial to the products.

C~~c~~. The manufacture and distribution of products containing TENORM, in which the TENORM and/or its emitted radiation is considered to be a beneficial attribute, are licensed under the provisions of Part III of these regulations.

D~~d~~. This Part does not apply to radionuclides for which NRC retains exclusive jurisdiction.

12 VAC 5-481-3810. ~~Sec. N.4 –~~ Exemptions.

A~~a~~. Persons who receive, own, possess, use, process, transfer, distribute, or dispose of TENORM are exempt from the requirements of Part XVI with respect to any combination of ^{226}Ra-226 and ^{228}Ra-228 if the materials contain, or are contaminated at, concentrations less than ~~[~~185 bequerel per kilogram (5 pCi/gm)~~]~~ excluding natural background. This does not apply to consumer or retail ~~products which~~products that are discussed in 12 VAC 5-481-3890 C~~N.22c.~~ and 12 VAC 5-481-~~N.23~~3900. Using purposeful dilution to render TENORM waste exempt shall not be allowed without prior agency approval.

B~~b~~. Persons who receive products or materials containing TENORM distributed in accordance with a specific license issued by the Agency pursuant to 12 VAC 5-481-3870 A~~N.20a.~~, or to an equivalent license issued by another Licensing State, are exempt from these regulations

with regard to those products or materials.

C. The distribution, including custom blending, possession, and use of fertilizers containing TENORM, is exempt from the requirements of this Part.

D~~d~~. TENORM waste regulated by CERCLA or RCRA (Resources Conservation and Recovery Act) are exempt from this Part.

E~~e~~. The transportation and storage incident to transportation are governed by other parts~~Parts D and T~~ of these regulations.

12 VAC 5-481-3820. ~~Sec. N.5 –~~ Standards for Radiation Protection for TENORM.

A~~a~~. No person licensed under 12 VAC 5-481-3860~~N.10~~ or 12 VAC 5-481-3870~~N.20~~ shall conduct operations, use, or transfer TENORM in a manner such that a member of the public will receive an annual Total Effective Dose in

~~e~~excess of 1 millisievert per year (100 mrem/yr.) from all licensed sources including TENORM.

B~~b~~. Persons subject to a license under this Part shall comply with radiation protection standards set out in Part IV of these regulations.

~~5.~~ */

~~c.~~C. Doses from indoor radon and its progeny shall not be included in Total Effective Dose Equivalent calculations.

D~~d~~. No person shall release TENORM for unrestricted use in such a manner that the reasonably maximally exposed individual will receive an annual total effective dose equivalent from the released TENORM in excess of ~~[some fraction of~~ 1 millisievert per year (100 mrem/yr.~~)~~ **/ ~~]~~ excluding natural background.

12 VAC 5-481-3830. ~~Sec. N.6 -~~ Protection of Workers During Operations.

Each person subject to a specific license under Part XVI shall conduct operations in compliance with the standards for radiation protection set out in other parts~~Parts D and J~~ of these regulations.

12 VAC 5-481-3840.~~Sec. N.7 -~~ Release for Unrestricted Use.

Each person subject to a license under this Part shall:

A~~a~~. Not transfer or release for unrestricted use facilities or equipment contaminated with TENORM in excess of levels in Appendix R of this Part ***/ ~~;~~ ~~;~~

~~b.~~B. Not transfer or release for unrestricted use equipment contaminated with TENORM in excess of a surface gamma radiation level of 200 micro rem per hour at 1 cm ~~[insert state screening level micro rems /hour including/ee~~xcluding natural background~~]~~; and

C~~c~~. Not transfer land for unrestricted use where the concentration of ~~-~~^{226}Ra-226 or ^{228}Ra-228 in soil averaged over any 100 square meters exceeds the background level by more than 185 Bequerel per kilogram (5 pCi/gm), averaged over any 15 cm layer of soil below the surface, unless compliance with 12 VAC 5-481-3820 B~~N.5 b~~ through 12 VAC 5-481-3820 D~~d~~ can be demonstrated.

12 VAC 5-481-3850.~~Sec. N.8 –~~ Disposal and Transfer of Waste for Disposal.

A.~~a.~~ Each person subject to a license under this Rule shall manage and dispose of wastes containing TENORM:

~~i~~1. By transfer of the wastes for disposal to a facility licensed under requirements ~~-~~for uranium or thorium byproduct materials in either 40 CFR 192 or 10 CFR 40 Appendix R; or

~~ii~~2. By transfer of the wastes for disposal to a disposal facility licensed by the US Nuclear Regulatory Commission, an agreement state, or a Licensing State; or

~~iii~~3. In accordance with alternate methods authorized by the Agency upon application or

upon the Agency's initiative, consistent with 12 VAC 5-481-3820~~N.5~~ and where applicable the Clean Water Act, Safe Drinking Water Act and other requirements of the US Environmental Protection Agency for disposal of such wastes.

B~~b~~. Equipment contaminated with TENORM in excess of levels specified in Appendix R, which is to be disposed of as waste, shall be disposed of:

~~i~~1. So as to prevent any reintroduction into commerce or unrestricted use; and

~~ii~~2. Within disposal areas specifically designed to meet the criteria of 12 VAC 5-481-3850 A~~N.8a~~.

~~c~~C. Transfers of waste containing TENORM for disposal shall be made only to a person specifically authorized by the Nuclear Regulatory Commission, an Agreement State or a licensing state, to receive such waste.

D~~d~~. Records of disposal, including manifests, shall be maintained pursuant to the provisions of Part IV of these regulations.

12 VAC 5-481-3860. ~~Sec. N.10 -~~ General License.

A~~a~~. Subject to the requirements of 12 VAC 5-481-3820~~N.5~~ through 12 VAC 5-481-3850~~N.8~~ and

12 VAC 5-481-~~N.10~~3860, a general license is hereby issued to possess, own, use, ~~-~~transfer, distribute or dispose of TENORM without regard to quantity.

B~~b~~. This general license does not authorize the manufacturing of products containing TENORM in concentrations greater than those specified in 12 VAC 5-481-3810 A~~N.4a.~~ nor the receipt and disposal of wastes from other persons.

C~~c~~. The decontamination of equipment, facilities, and land shall be performed only by persons specifically licensed by the agency or another licensing state to conduct such work. However, employees or contractors under control and supervision of a general licensee can perform routine maintenance on equipment, facilities, and land owned or controlled by the general licensee. Maintenance that provides a different pathway for exposure than is found in daily operations and that increases the potential for additional exposure is not considered routine.

~~[~~D~~d.*~~. ~~(This section may be omitted at the states option)~~ Any person subject to the general license issued by this section shall notify the Agency. Such notification shall include:

1~~i~~. Name and address of the licensee;

2~~ii~~. Location and description of the facility or operation;

~~*~~ ~~This subsection may be omitted at the option of the adopting state.~~

3iii. Description of the TENORM including estimates of the amount and extent of TENORM.]

Ee. Transfer of material or real property.

i1. The transfer of TENORM not exempt from these regulations from one general licensee to another general licensee is authorized if:

a.(1) The equipment and facilities contaminated with TENORM are to be used by the recipient for the same purpose; or

b.(2) The transfer of control or ownership of land contaminated with TENORM includes [an annotation of the deed records, or notice to owners of surface and mineral rights, to indicate the][notice to owners of surface and mineral rights]**[/] to indicate the presence of TENORM.

2ii. Transfers not made in accordance with 12 VAC 5-481-3860 E 1N.10e.i. require prior approval by the Agency.

3iii. Transfers made under 12 VAC 5-481-3860 E 1N.10e.i. do not relieve the general

**[/] This option is provided for those states in which notations to recorded deeds are prohibited.

licensee who makes the transfer from the responsibilities of assessing the extent of TENORM contamination or material present, informing the general licensee receiving the TENORM of these assessments, and maintaining records required by these regulations.

4~~iv~~. A general licensee intending to transfer material or real property for unrestricted use shall document compliance with the requirements of 12 VAC 5-481-3840~~N.7~~ of this regulation. ~~Records of such compliance shall be kept [state's option].~~

F~~f~~. Distribution of TENORM products between general licensees. The distribution of TENORM products not exempt from these regulations from one general licensee to another general licensee is authorized provided the product is accompanied by labels or manifests which identify the type and amount of TENORM.

G~~g~~. The Department of Health~~[name of regulating agency]~~ may, by written notice, require any person authorized by a general license to apply for and obtain a specific license. The notice shall state the reason or reasons for requiring a specific license.

12 VAC 5-481-3870. ~~Sec. N.20 -~~ Specific Licenses.

Unless otherwise exempt, a specific license is required to:

Aa. Manufacture and distribute any material or product containing TENORM unless authorized by 12 VAC 5-481-3860 FN.10f, exempted under the provisions of 12 VAC 5-481-3810N.4, or licensed under the provisions of Part III of these regulations;

Bb. Except as provided in 12 VAC 5-481-3860 CN.10c., decontaminate equipment or land not otherwise exempted under the provisions of 12 VAC 5-481-3810N.4 or facilities contaminated with TENORM in excess of the levels set forth in 12 VAC 5-481-N.73840, as applicable; for purposes of this subsection, the term "decontaminate" shall not include maintenance which incidentally results in removal of contamination;

Cc. Receive TENORM from other persons for disposal.

12 VAC 5-481-3880.Sec. N.21 – Filing Application for Specific Licenses.

*[*]

Aa. Applications for specific licenses shall be filed in a manner and on a form prescribed by the Agency.

Bb. 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.

*[*] This section duplicates the requirements of SSRCR Part III; states having equivalent requirements may elect to refer to appropriate regulations.

Cc. Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on the licensee's behalf.

Dd. An application for a license may include a request for a license authorizing one or more activities.

Ee. Each application for a specific license shall be accompanied by athe fee of $50.00.prescribed in [cite the appropriate regulation].

Ff. In an application, the applicant may incorporate by reference information contained in previous applications, statements, or reports filed with the Agency provided such references are clear and specific. *

Gg. Applications and documents submitted to the Agency may be made available for public inspection [state's option: include references to applicable freedom of information statute, trade secrets, etc.].

12 VAC 5-481-3890.Sec. N.22 — Requirements for the Issuance of Specific Licenses. *

* This section duplicates the requirements of SSR Part III; states having equivalent requirements may elect to refer to appropriate regulations.

Aa. A license application will be approved if the Agency determines that:

1i. The applicant is qualified by reason of training and experience to use the TENORM in question for the purpose requested in accordance with these rules in such a manner as to protect the public health and safety or property;

2ii. The applicant's proposed equipment, facilities, and procedures are adequate to protect the public health and safety or property;

3iii. The issuance of the license will not be inimical to the health and safety of the public;

4iv. The applicant satisfied all applicable special requirements in this Part; and

5v. The applicant has met the financial surety requirements of 12 VAC 5-481-4000N.50.

6vi. The applicant has adequately addressed the following items in the application:

a.(1) Procedures and equipment for monitoring and protecting workers;

b.(2) An evaluation of the radiation levels and concentrations of contamination expected during normal operations;

c.~~(3)~~ Operating and emergency procedures, including procedures for waste reduction and quality assurance of items released for unrestricted use; ~~-~~and

d.~~(4)~~ A method for managing the radioactive material removed from contaminated equipment and facilities.

B~~b~~. An application for a specific license to decontaminate equipment, land, or facilities contaminated with TENORM in excess of the levels set forth in 12 VAC 5-481-3810 A~~N.4a.~~, 12 VAC 5-481-3840 B~~N.7b.~~, or Appendix R of this Part, as applicable, and to dispose of the resulting waste will be approved if:

1~~i~~. The applicant satisfies the general requirements specified in 12 VAC 5-481-3890 A~~N.22a.~~; and

2~~ii~~. The applicant has adequately addressed the following items in the application:

a.~~(1)~~ Procedures and equipment for monitoring and protection of workers;

b.~~(2)~~ An evaluation of the radiation levels and concentrations of contamination expected during normal operations;

c.~~(3)~~ Operating and emergency procedures, including procedures for waste reduction and quality assurance of items released for unrestricted use; and

d.~~(4)~~ Method of disposing of the TENORM removed from contaminated equipment, facilities, and/or land.

C~~c~~. An application for a specific license to transfer materials or manufacture or distribute products containing TENORM to persons exempted from these regulations pursuant to 12 VAC 5-481-3860 B~~N.4b~~. will be approved if:

1~~i~~. The applicant satisfies the general requirements specified in 12 VAC 5-481-3890 A~~N.22a.~~;

2~~ii~~. The TENORM is not contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being; and

3~~iii~~. The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, and conditions of handling, storage, use, and disposal of the TENORM material or product to demonstrate that the material or product will meet the safety criteria set forth in 12 VAC 5-481-3900~~N.23~~. The information shall include:

a.~~(1)~~ A description of the material or product and its intended use or uses;

b.~~(2)~~ The type, quantity, and concentration of TENORM in each material or product;

c.~~(3)~~ The chemical and physical form of the TENORM in the material or product, and changes in chemical and physical form that may occur during the useful life of the material or product;

d.~~(4)~~ An analysis of the solubility in water and body fluids of the TENORM in the material or product;

e.~~(5)~~ The details of manufacture and design of the material or product relating to containment and shielding of the TENORM and other safety features under normal and severe conditions of handling, storage, use, reuse, and disposal of the material or product;

f.~~(6)~~ The degree of access of human beings to the material or product during normal handling, use, and disposal;

g.~~(7)~~ The total quantity of TENORM expected to be distributed annually in the material or product;

h.~~(8)~~ The expected useful life of the material or product;

i.~~(9)~~ The proposed method of labeling or marking each unit of the material or product with identification of the manufacturer or initial transferor of the product and the radionuclides and quantity of TENORM in the material or product;

j.~~(10)~~ The procedures for prototype testing of the material or product to demonstrate the effectiveness of the containment, shielding, and other safety features under both normal and severe conditions of handling, storage, use, reuse, and disposal;

k.~~(11)~~ The results of the prototype testing of the material or product, including any change in the form of the TENORM contained in it, the extent to which the TENORM may be released to the environment, any change in radiation levels, and any other changes in safety features;

l.~~(12)~~ The estimated external radiation doses and dose commitments relevant to the safety criteria in 12 VAC 5-481-3900~~N.23~~ and the basis for such estimates;

m.~~(13)~~ A determination that the probabilities with respect to doses referred to in 12 VAC 5-481-3900~~N.23~~ meet the safety criteria;

n.~~(14)~~ The quality control procedures to be followed in the production of production lots of the material or product, and the quality control standards the material

or product will be required to meet; and

o.~~(15)~~ Any additional information, including experimental studies and tests, required by the Agency to facilitate a determination of the radiation safety of the material or product.

~~[~~D~~d~~. Notwithstanding the provisions of 12 VAC 5-481-3900 B~~N.23b.~~, the Agency may deny an application for a specific license if the end uses of the product are frivolous or cannot be reasonably foreseen.~~]~~

12 VAC 5-481-3900. ~~Sec. N.23 - -~~ Safety Criteria for Products.

An applicant for a license under 12 VAC 5-481-3890 C~~N.22c.~~ shall demonstrate that the product is designed and will be manufactured so that:

~~a~~A. In normal use and disposal of a single exempt item~~, *[1]-~~, and in normal handling and storage of the quantities of exempt items likely to accumulate in one location during marketing, distribution, installation, and servicing of the product, it is unlikely that the TEDE in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from the product will exceed the doses in Column I of 12 VAC 5-481-3910~~N.24~~.

B~~b~~. In use and disposal of a single exempt item and in handling and storage of the quantities of

exempt items likely to accumulate in one location during marketing, distribution, installation, and servicing of the product, the probability is low~~w~~ [*/] ~~-~~w (not more than one failure per year for each 10,000 exempt units distributed) that the containment, shielding, or other safety features of the product would fail under such circumstances that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column II of the table in 12 VAC 5-481-3910~~N.24~~ and the probability is negligible [*/] ~~-~~ (not more than one such failure per year for each one millions exempt units distributed) that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column III of the table in 12 VAC 5-481-3910~~N.24~~.~~**~~[/] It is the intent of this paragraph that as the magnitude of the potential dose increases above that permitted under normal conditions, the probability that any individual will receive such a dose must decrease. The probabilities have been expressed in general terms to emphasize the approximate nature of the estimates that are to be made. The above values may be used a guidelines in estimating compliance with the criteria.

C~~c~~. It is unlikely that there will be a significant reduction in the effectiveness of the containment, shielding, or other safety features of the product from wear and abuse likely to occur in normal handling and use of the product during its useful life.

12 VAC 5-481-3910~~Sec. N.24 – –~~ Table of Organ Doses.

Part of Body	Column I*	Column II*	Column III*

	Dose	Dose	Dose
Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye	0.05 mSv (0.005 rem)	5 mSv (0.5 rem)	150 mSv (15 rem)
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter	0.75 mSv (0.075 rem)	75 mSv (7.5 rem)	2000 mSv (200 rem-)
Other organs	0.15mSv (0.015 rem)	15 mSv (1.5 rem)	500 mSv (50 rem)
*Dose limit is the dose above background from the product.			

12 VAC 5-481-3920. ~~Sec. N.25 - -~~Issuance of Specific Licenses.

A.~~a~~. Upon a determination that an application meets the requirements- of these regulations~~[applicable authorizing statutes and rules of the Agency]~~, the Agency will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.

B~~b~~. The Agency may incorporate in any license at the time of issuance, or thereafter by

amendment, such additional requirements and conditions with respect to the licensee's receipt, possession, use, and transfer of TENORM subject to this Part as it deems appropriate or necessary in order to:

1i. Protect public health and safety or property;

2ii. Require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be appropriate or necessary; and

3iii. Prevent loss, theft, or loss of control of TENORM subject to this Part.

12 VAC 5-481-3930. ~~Sec. N.26 .~~ Conditions of Specific Licenses Issued Under 12 VAC 5-481-3890~~N.22~~.

A.~~a.~~ General Terms and Conditions

1i. Each license issued pursuant to this Part shall be subject to all the provisions of the Radiation Control Act in the *Code of Virginia* Title 32.1 Chapter 6, Article 8, ~~[applicable Act],~~ now or hereafter in effect, and to all rules, regulations, and orders of the Agency.

2ii. No license issued or granted under this Part and no right to possess or utilize TENORM granted by any license issued pursuant to this Part shall be transferred,

assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the Agency shall, after securing full information, find that the transfer is in accordance with the provisions of the Radiation Control Act ~~[applicable Act]~~, and shall give its consent in writing.

3~~iii~~. Each person licensed by the Agency pursuant to this Part shall confine use and possession of the TENORM licensed to the locations and purposes authorized in the license.

4~~iv~~. Each person licensed by the Agency pursuant to this Part is subject to the general license provisions of 12 VAC 5-481-3830~~N.6~~, 12 VAC 5-481-3840~~N.7~~, and 12 VAC 5-481-3850~~N.8~~.

5~~v~~. Each licensee shall:

a~~(1)~~. Notify the Agency, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapters of Title II (Bankruptcy) of the United States Code (11 U.S.C.) by or against a ~~:~~

~~(a) A~~ licensee,~~;~~

(b) aAn entity ([as that term is defined in 11 U.S.C. 101 (14))] controlling a licensee or listing the license or licensee as property of the estate; or

(c) aAn affiliate ([as that term is defined in 11 U.S.C. 101 (2))] of the licensee.

b.(2) Indicate in their Bankruptcy notification :

(a) Tthe bankruptcy court in which the petition for bankruptcy was filed; and

(b) T the date of the filing of the petition.

[Bb. This section may be omitted or modified as appropriate based on state quality control standards. Quality Control, Labeling, and Reports of Transfer. *[/] Each person licensed under 12 VAC 5-481-3890 CN.22c. shall:

1i. Carry out adequate control procedures in the manufacture of the product to assure that each production lot meets the quality control standards approved by the Agency;

2ii. Label or mark each unit so that the manufacturer, processor, producer, or initial

*[/] State option; this section may be omitted or modified as appropriate based on state quality control standards.

transferor of the material or product and the TENORM in the product can be identified; and

3~~iii~~. Maintain records [identifying, by name and address, each person to whom TENORM is transferred for use under 12 VAC 5-481-3810 B~~N.4b.~~ or the equivalent regulations of another Licensing State, and stating the kinds, quantities, and uses of TENORM transferred. An annual summary report stating the total quantity of each radionuclide transferred under the specific license shall be filed with the Agency. Each report shall cover the year ending December 31, and shall be filed within 90 days thereafter. If no transfers of TENORM have been made pursuant to 12 VAC 5-481-3890 C~~N.22c.~~ during the reporting period, the report shall so indicate.~~]~~*~~*/~~

12 VAC 5-481-3940. ~~Sec. N.27 –~~ Expiration and Termination of Specific Licenses.

A~~a~~. Except as provided in 12 VAC 5-481-3940 D 6~~N.27d.vi.~~ and 12 VAC 5-481-3950 B~~N.28b.~~, each specific license shall expire at the end of the specified day in the month and year stated therein.

B~~b~~. Each licensee shall notify the Agency in writing and request termination of the license when the licensee decides to terminate all activities involving TENORM authorized under the license. This notification and request for termination of the license must include the reports

~~*/ Implementing state may require reporting as appropriate for each category of licensee.~~

and information specified in 12 VAC 5-481-3940 D 4~~N.27d.iv~~. The licensee is subject to the provisions of 12 VAC 5-481-3940 D~~N.27d.~~ and 12 VAC 5-481-3940 E~~N.27e.~~, as applicable.

C~~c~~. No less than 30 days before the expiration date specified in a specific license, the licensee shall

either:

1~~i~~. Submit an application for license renewal under 12 VAC 5-481-3950~~N.28~~; or

2~~ii~~. Notify the Agency in writing, under 12 VAC 5-481-3940 B~~N.27b.~~, if the licensee decides to discontinue all activities involving TENORM.

D~~d~~. If a licensee does not submit an application for license renewal under 12 VAC 5-481-3950~~N.28~~, the licensee shall, on or before the expiration date specified in the license:

1~~i~~. Terminate use of TENORM;

2~~ii~~. Remove TENORM contamination consistent with the requirements of 12 VAC 5-481-3840.~~N.7;~~

3~~iii~~. Properly dispose of TENORM; and

4~~iv~~. Submit a report of disposal of TENORM and radiation surveys to confirm the

absence of TENORM or to establish the levels of residual TENORM contamination. The licensee shall, as appropriate:

a.~~(1)~~ Report levels of radiation in units of microroentgens per hour of beta and gamma radiation at one centimeter and gamma radiation at one meter from surfaces and report levels of radioactivity in units of disintegrations per minute (or microcuries) per 100 square centimeters removable and fixed on surfaces, microcuries or Becquerel per milliliter in water, and picocuries or Becquerels per gram in contaminated solids such as soils or concrete; and

b.~~(2)~~ Specify the instruments used and certify that each instrument is properly calibrated and tested.

5~~v~~. If levels of residual activity are less than those established in 12 VAC 5-481-3840~~N.7~~, the licensee shall so certify. If the Agency determines that this certification and the information submitted under 12 VAC 5-481-3940 D 4~~N.27d.iv.~~ is adequate and surveys confirm the findings, the Agency will notify the licensee in writing that the license is terminated.

6~~vi~~. If levels of residual TENORM are not in conformance with criteria established in 12 VAC 5-481-3840~~N.7~~, the license continues in effect beyond the expiration date, if necessary, with respect to possession of residual TENORM until the Agency notifies the licensee in writing that the license is terminated. During this time, the licensee is

subject to the provisions of 12 VAC 5-481-3940 E~~N.27e~~. In addition to the information submitted under 12 VAC 5-481-3940 D 4~~N.27d.iv.~~, the licensee shall submit a plan, if appropriate, for decontaminating the location(s) and disposing of the residual TENORM.

E~~e~~. Each licensee who possesses residual TENORM under 12 VAC 5-481-3940 D 6~~N.27d.vi~~, following the expiration date specified in the license, shall:

1~~i~~. Be limited to actions involving TENORM related to preparing the locations for release for unrestricted use; and

2~~ii~~. Continue to control entry to restricted areas until the locations are suitable for release for unrestricted use and the Agency notifies the licensee in writing that the license is terminated.

12 VAC 5-481-3950. ~~Sec. N.28 – ~~Renewal of Specific Licenses.

A~~a~~. Applications for renewal of specific licenses shall be filed in accordance with 12 VAC 5-481-3880~~N.21~~.

B~~b~~. In any case in which a licensee, not less than ~~[~~30 days ~~]~~ ~~*~~ prior to expiration of an existing

~~*~~ ~~State option; appropriate time for review.~~

license, has filed an application in proper form for renewal or for a new license authorizing the same activities, such existing license shall not expire until final action by the Agency.

12 VAC 5-481-3960.~~Sec. N.29 - -~~ Amendment of Specific Licenses at Request of Licensee.

Applications for amendment of a license shall be filed in accordance with 12 VAC 5-481-3880~~N.21~~ and shall specify the respects in which the licensee desires the license to be amended and the grounds for such amendment.

12 VAC 5-481-3970.~~Sec. N.30 - -~~ Agency Action on Applications to Renew and Amend Specific Licenses.

In considering an application by a licensee to renew or amend the license, the Agency will apply the criteria set forth in 12 VAC 5-481-3890~~N.2~~2.

12 VAC 5-481-3980. ~~Sec. N.31 - -~~ Modification and Revocation of Specific Licenses.

A~~a~~. The terms and conditions of all licenses shall be subject to amendment, revision, or modification or the license may be suspended or revoked by reason of amendments to the Radiation Control Act~~[applicable Act]~~, or by reason of rules, regulations, and orders issued by the Agency.

B~~b~~. Any license may be revoked, suspended, or modified, in whole or in part, for any material

false statement in the application or any statement of fact required under provisions of the Radiation Control Act~~[applicable Act]~~, or because of conditions revealed by such application or statement of fact or any report, record, or inspection or other means which would warrant the Agency to refuse to grant a license on an original application, or for violation of, or failure to observe any of the terms and conditions of the Radiation Control Act~~[applicable Act]~~, or of the license, or of any rule, regulation, or order of the Agency.

C~~c~~. Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, the Agency shall not modify, suspend or revoke a license prior to the institution of proceedings unless facts or conduct which may warrant such action shall have been called to the attention of the licensee in writing and the licensee shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

12 VAC 5-481-3990. ~~Sec. N.40 –~~ Reciprocal Recognition of Specific Licenses.

Subject to these regulations, any person who holds a specific license from an Agreement State or a Licensing 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 this State for a period not in excess of 180 days in any calendar year provided that:

A.~~a.~~ The licensing document does not limit the activity authorized by such document to specified installations or locations;

B~~b~~. The out-of-state licensee notifies the Agency in writing at least ~~[~~3~~]~~ 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 ~~[~~3~~]~~ 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 12 VAC 5-481-3990 A~~N.40a.~~;

C~~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 which may be inconsistent with applicable regulations of the Agency;

D~~d~~. The out-of-state licensee supplies such other information as the Agency may request; and

E~~e~~. The out-of-state licensee shall not transfer or dispose of TENORM possessed or used under the general license provided in 12 VAC 5-481-3990 A~~N.40a.~~ except by transfer to a person:

1.~~i.~~ Specifically licensed by the Agency or by another Licensing State to receive such

TENORM; or

2~~ii~~. Exempt from the requirements for a license for such TENORM under 12 VAC 5-481-3810~~N.4~~.

12 VAC 5-481-4000. ~~Sec. N.50 - -~~ Financial Surety Arrangements.

Pursuant to *Code of Virginia* Section 32.1-231~~[cite applicable State statute]~~, each licensee or applicant for a license under 12 VAC 5-481-3890~~N.22~~ shall post with the Agency financial surety, or security, to ensure the protection of the public health and safety and the environment in the event of abandonment, default, or other inability or unwillingness of the licensee to meet the requirements of the Act and these regulations. Financial surety arrangements shall:

A~~a~~. ~~Consist of [surety bonds],~~An acceptable bond for the purposes of this section shall be a bond issued by a fidelity or surety company authorized to do business in Virginia, a personal bond secured by such collateral as the Board may require or a cash bond; ~~[cash deposits], [certificates of deposit], [government securities], [irrevocable letters or lines of credit], [corporate guarantees], [insurance], [state funds],~~ ~~*/~~ ~~or any combination of these;~~

B~~b~~. Be in an amount sufficient to meet the applicant's or licensee's obligations under the Act and these regulations and shall be based upon Agency approved cost estimates;

~~*/ State option; may include corporate guarantees, insurance, state funds, as state deems appropriate.~~

Cc. Be established prior to issuance of the license or the commencement of operations to assure that sufficient funds will be available to carry out the decontamination and decommissioning of the facility;

Dd. Be continuous for the duration of the license and for a period coincident with the applicant or licensee's responsibility under the Act and these regulations;

Ee. Be available in Virginia[name of State] subject to judicial process and execution in the event required for the purposes set forth; and

Ff. Be established within 90 days of [the effective date of this regulation] for licenses in effect on that date.

12 VAC 5-481-4010. [Sec. N.51 – Effective Date.

The provisions and requirements of this Part shall take effect on January 1, 2002[effective date of the regulations] and shall apply to all facilities or sites owned or controlled by a person on that date. [Products introduced into commerce and disposals approved prior to that date are not subject to the provisions of this Part.

APPENDICES REMOVED~~]~~ */

~~*~~*/ ~~This provision may not be necessary if covered by generally applicable laws or rules of the state.~~

FORMS