	institutions of higher education
Request duplicate certificate to operate due to school name or address change	$100
Request duplicate agent permit, to replace lost/stolen/misplaced permit	$100
~~Application fee for each additional branch~~	~~$300~~
Application fee for each additional site	$100
Application fee for each additional program or modification to an existing program	$100

E. A school that submits a payment that is returned for any reason must resubmit the required payment, any applicable late fee, and the assessed returned check fee of $35 via a money order or certified bank check only.

VA.R. Doc. No. R16-4393; Filed March 29, 2016, 12:00 p.m.

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TITLE 12. HEALTH

STATE BOARD OF HEALTH

Fast-Track Regulation

Title of Regulation: **12VAC5-481. Virginia Radiation Protection Regulations (amending 12VAC5-481-10, 12VAC5-481-3390 through 12VAC5-481-3450; adding 12VAC5-481-3451, 12VAC5-481-3452, 12VAC5-481-3453).**

Statutory Authority: §§ 32.1-12 and 32.1-229 of the Code of Virginia.

Public Hearing Information: No public hearings are scheduled.

Public Comment Deadline: May 18, 2016.

Effective Date: June 5, 2016.

Agency Contact: Steve Harrison, Director, Office of Radiological Health, Department of Health, 109 Governor Street, Richmond, VA 23219, telephone (804) 864-8151, FAX (804) 864-8155, or email steve.harrison@vdh.virginia.gov.

Basis: Section 32.1-229 of the Code of Virginia authorizes the State Board of Health to require the licensure and inspection of radioactive materials facilities and mandates inspections of mammography facilities. Section 32.1-229.1 of the Code of Virginia requires the State Board of Health to promulgate regulations for the registration, inspection, and certification of x-ray machines.

Purpose: The Virginia Department of Health (VDH), Office of Radiological Health (ORH) proposes to amend 12VAC5-481, Virginia Radiation Protection Regulations, to reflect changes in and new x-ray modalities pertaining to the medical field, amend existing and add new definitions, and update the regulations to meet the current Virginia Register Form, Style, and Procedure Manual.

Rationale for Using Fast-Track Rulemaking Process: Practitioners have requested that regulations providing for the use of therapeutic radiation machines be instituted in the Commonwealth in order to remain up to date with regard to current practices. The regulated community has requested that regulations be put into place for the proper operation of therapeutic and electronic brachytherapy equipment. This initiative was discussed and endorsed at the November 2014 Radiation Advisory Board meeting. Accordingly, ORH does not view this initiative as being controversial in nature.

Substance: The Conference of Radiation Control Program Directors (CRCPD) develops Suggested State Regulations (SSRs) upon which an individual state may base its regulations. The x-ray regulations were based upon the SSRs when adopted in 2006; this amendment will ensure that Virginia's regulations are brought up to date by incorporating the most recent CRCPD SSRs in totality. This action adds or amends provisions concerning radiation therapy machines, including electronic brachytherapy, as follows:

1. Adds new terms and definitions in 12VAC5-481-10, including conventional simulator, electronic brachytherapy, electronic brachytherapy device, electronic brachytherapy source, intensity modulated radiation therapy (IMRT), mobile electronic brachytherapy service, qualified inspector, qualified medical physicist, radiation therapy system, target-skin distance (TSD), and virtual simulator.

2. Amends definitions in 12VAC5-481-10, including beam-limiting device, leakage radiation, light field, prescribed dose, and therapeutic radiation machine.

3. Amends the following sections in Part XV, Therapeutic Radiation Machines: 12VAC5-481-3390, General administrative requirements for facilities using therapeutic radiation machines; 12VAC5-481-3400, General technical requirements for facilities using therapeutic radiation machines; 12VAC5-481-3410, Quality management program; 12VAC5-481-3420, Therapeutic radiation machines of less than 500 kV; 12VAC5-481-3430, Therapeutic radiation machines - photon therapy systems (500 kV and above) and electron therapy systems (500 kV and above), and electron therapy systems (500kv and above); and 12VAC5-481-3450, Shielding and safety design requirements.

4. Adds the following new sections to Part XV, Therapeutic Radiation Machines: 12VAC5-481-3451, Quality assurance for radiation therapy simulation systems; 12VAC5-481-3452, Electronic brachytherapy;

and 12VAC5-481-3453, Other use of electronically-produced radiation to deliver therapeutic radiation dosage.

Issues: The advantage of this action is that health care providers regulated by VDH will operate under clear worker and machine performance standards. Another advantage for health care professionals and patients is that regulations governing the application of radiation will meet nationally recognized performance standards, which will promote quality of care. There are no disadvantages to the public in promulgating the proposed regulation.

The advantage of the proposed regulation to the agency is that the proper regulation of therapeutic radiation producing machines will now be addressed. There are no disadvantages to the agency in promulgating the proposed regulation. There are no disadvantages to the public or the Commonwealth as a result of this initiative.

Department of Planning and Budget's Economic Impact Analysis:

Summary of the Proposed Amendments to Regulation: The State Health Commissioner proposes to amend the Virginia Radiation Protection Regulations to 1) add new definitions, amend existing definitions and update other sections of this regulation so that it accurately reflects current practice for therapeutic radiation machines and 2) update the regulation so that it conforms to the current Virginia Register Form, Style and Procedure Manual.

Result of Analysis. Benefits likely outweigh costs for all proposed regulatory changes.

Estimated Economic Impact. The Commissioner proposes to add eleven new definitions and amend a further five to account for new therapeutic radiation machine techniques and procedures. For instance, the Commissioner proposes to add a definition for "radiation therapy systems" and amend the definition of "therapeutic radiation machine." The Commissioner also proposes to add language to the regulatory text to clarify current procedures and requirements for the regulated community. Some of these changes will, for instance, replace general language that requires facilities that own machines covered by this regulation to have a quality management program with specific language that lays out exactly what is currently required of such a program.

All of these amendments, as well as the amendments that bring regulatory language into conformity with the state's regulatory style manual, are clarifying rather than substantive. No affected entity is likely to incur costs on account of any of these changes. To the extent that this regulation was out of date and out of sync with current radiation machine practices and terminology, these changes will benefit readers who will likely find the regulation easier to understand and comply with.

Businesses and Entities Affected. Virginia Department of Health staff reports that this x-ray program currently registers approximately 21,464 x-ray machines. Of these 21,464, approximately 90 are therapeutic radiation machines. Staff further reports that approximately 1,500 registrants meet the criteria for small business.

Localities Particularly Affected. No locality will be particularly affected by this regulatory change.

Projected Impact on Employment. These regulatory changes are unlikely to have any effect on employment in the Commonwealth.

Effects on the Use and Value of Private Property. These proposed regulatory changes are unlikely to affect the use or value of private property in the Commonwealth.

Real Estate Development Costs. These proposed regulatory changes are unlikely to affect real estate development costs in the Commonwealth.

Small Businesses:

Definition. Pursuant to § 2.2-4007.04 of the Code of Virginia, small business is defined as "a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million."

Costs and Other Effects. Small businesses are unlikely to incur any costs on account of these proposed regulatory changes.

Alternative Method that Minimizes Adverse Impact. Small businesses are unlikely to incur any costs on account of these proposed regulatory changes.

Adverse Impacts:

Businesses. Businesses are unlikely to incur any costs on account of these proposed regulatory changes.

Localities. Localities in the Commonwealth are unlikely to see any adverse impacts on account of this proposed regulatory change.

Other Entities. No entities are likely to incur any costs on account of these regulatory changes.

Agency's Response to Economic Impact Analysis: The Virginia Department of Health concurs with the economic impact analysis submitted by the Department of Planning and Budget.

Summary:

To reflect changes in and new x-ray modalities for the medical field, including therapeutic and electonic brachytherapy equipment, this action (i) amends and adds defined terms and (ii) updates the regulatory text to clarify current procedures and requirements.

Part I
General Provisions

12VAC5-481-10. Definitions.

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

"A_1" means the maximum activity of special form radioactive material permitted in a Type A package. This value is listed in Table 1 of 12VAC5-481-3770.

"A_2" means the maximum activity of radioactive material, other than special form radioactive material, LSA, and SCO material, permitted in a Type A package. This value is listed in Table 1 of 12VAC5-481-3770.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"Agreement state" means any state with which the NRC or the Atomic Energy Commission has entered into an effective agreement under subsection 274b of the Atomic Energy Act of 1954, as amended (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 composed wholly or partly of licensed material exist in concentrations:

1. In excess of the derived air concentrations (DACs) specified in 12VAC5-481-3690; or

2. To such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6% of the annual limit on intake (ALI) or 12 DAC hours.

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

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

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

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

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

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

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

"Annual limit on intake" or "ALI" means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent of 0.05 Sv (5 rem) or a committed dose equivalent of 0.5 Sv (50 rem) to any individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Tables 1 and 2 in 12VAC5-481-3690.

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

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

"ANSI" means the American National Standards Institute.

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

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

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

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

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

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

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

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

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

"Authorized medical physicist" means an individual who:

1. Meets the requirements in 12VAC5-481-1760 and 12VAC5-481-1790; or

2. Is identified as an authorized medical physicist or teletherapy physicist on:

a. A specific medical use license issued by the NRC or another agreement state;

b. A medical use permit issued by an NRC master material licensee;

c. A permit issued by an NRC or another agreement state broad scope medical use licensee; or

d. A permit issued by an NRC master material license broad scope medical use permittee.

"Authorized nuclear pharmacist" means a pharmacist who:

1. Meets the requirements in 12VAC5-481-1770 and 12VAC5-481-1790;

2. Is identified as an authorized nuclear pharmacist on:

a. A specific license issued by the NRC or another agreement state that authorizes medical use or the practice of nuclear pharmacy;

b. A permit issued by an NRC master material licensee that authorizes medical use or the practice of nuclear pharmacy;

c. A permit issued by an NRC or another agreement state broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or

d. A permit issued by an NRC master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy;

3. Is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or

4. Is designated as an authorized nuclear pharmacist in accordance with 12VAC5-481-440 I 2.

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

1. Meets the requirements in 12VAC5-481-1790 and any of the following:

a. 12VAC5-481-1910;

b. 12VAC5-481-1940;

c. 12VAC5-481-1980;

d. 12VAC5-481-1990;

e. 12VAC5-481-2000;

f. 12VAC5-481-2010;

g. 12VAC5-481-2030;

h. 12VAC5-481-2040; or

2. Is identified as an authorized user on:

a. A specific license issued by the NRC or another agreement state that authorizes medical use;

b. A permit issued by an NRC master material licensee that authorizes medical use;

c. A permit issued by an NRC or another agreement state broad scope medical use licensee that authorizes medical use; or

d. A permit issued by an NRC master material license broad scope medical use permittee that authorizes medical use.

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

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

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

"Barrier" (See "Protective barrier").

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

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

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

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

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

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

"Beneficial to the product" see "Beneficial attribute."

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

"Bioassay" means the determination of kinds, quantities or concentrations, and, in some cases, the locations of radioactive material in the human body, whether by direct measurement, in-vivo counting, or by analysis and evaluation of materials excreted or removed from the human body. For purposes of these regulations, "radiobioassay" is an equivalent term.

"Board" means the State Board of Health.

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

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

"Byproduct material" means:

1. Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material;

2. The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition;

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

b. Any material that:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"CFR" means Code of Federal Regulations.

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

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

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

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

"cm" means centimeters.

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

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

where:

s = Standard deviation of the observed values;

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

x_i = i_{th} observation in sample;

n = Number of observations in sample.

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

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

"Commencement of construction" means 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" or "$H_{T,50}$" means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

"Committed effective dose equivalent" or "$H_{E,50}$" 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 ($H_{E,50} = \Sigma\ (w_T\ H_{T,50})$).

"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:

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

where:

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

D(z) = Dose at position z;

T = Nominal tomographic section thickness;

n = Number of tomograms produced in a single scan.

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

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

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

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

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

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

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

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

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

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

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

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

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

"Conveyance" means:

1. For transport by public highway or rail any transport vehicle or large freight container;

2. For transport by water any vessel, or any hold, compartment, or defined deck area of a vessel including any transport vehicle on board the vessel; and

3. For transport by any aircraft.

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

"Cradle" means either:

1. A removable device that supports and may restrain a patient above an x-ray table; or

2. A device:

a. Whose patient support structure is interposed between the patient and the image receptor during normal use;

b. Which is equipped with means for patient restraint; and

c. Which is capable of rotation about its long (longitudinal) axis.

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

"Criticality safety index" or "CSI" means the dimensionless number (rounded up to the next tenth) assigned to and placed on the label of a fissile material package, to designate the degree of control of accumulation of packages containing fissile material during transportation. Determination of the criticality safety index is described in Part XIII (12VAC5-481-2950 et seq.).

"CS" (See "Contrast scale").

"CT" (See "Computed tomography").

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

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

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

"CTN" (See "CT number").

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

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

where:

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

μ_x = Linear attenuation coefficient of the material of interest;

μ_w = Linear attenuation coefficient of water.

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

"Curie" means a unit of quantity of activity. One curie (Ci) is that quantity of radioactive material that 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.

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

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

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

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

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

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

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

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

"Derived air concentration" or "DAC" means the concentration of a given radionuclide in air which, if breathed by the reference man for a working year of 2,000 hours under conditions of light work, results in an intake of one ALI. For purposes of these regulations, the condition of light work is an inhalation rate of 1.2 cubic meters of air per hour for 2,000 hours in a year. DAC values are given in 12VAC5-481-3690.

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

"Detector" (See "Radiation detector").

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"Fissile material" means the radionuclides uranium-233, uranium-235, plutonium-239, and plutonium-241, or any combination of these radionuclides. "Fissile material" means the fissile nuclides themselves, not material containing fissile nuclides. Unirradiated natural uranium and depleted uranium and natural uranium or depleted uranium, that has been irradiated in thermal reactors only, are not included in this definition. Certain exclusions from fissile material controls are provided in 10 CFR 71.15.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"Image receptor" means any device, such as a fluorescent screen, radiographic film, x-ray image intensifier tube, solid-state detector, or gaseous detector that transforms incident x-ray photons either into a visible image or into another form that can be made into a visible image by further

transformations. In those cases where means are provided to preselect a portion of the image receptor, the term "image receptor" shall mean the preselected portion of the device.

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

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

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

"Individual" means any human being.

"Individual monitoring" means the assessment of:

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

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

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

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

"Inhalation class" (See "Class").

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"kBq" means kilabecquerels.

"Kerma" or "K" means the quantity defined by the International Commission on Radiation Units and Measurements. The kerma is the quotient of dEtr by dm, where dEtr is the sum of the initial kinetic energies of all charged particles liberated by uncharged particles in a mass dm of materials; thus K=dEtr/dm, in units of J/kg, where the

special name for the units of kerma is gray (Gy). When the materials is air, the quantity is referred to as "air kerma."

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

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

"kV" means kilovolts.

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

"kWs" means kilowatt second.

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

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

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

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

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

1. The useful beam; and

2. Radiation produced when the exposure switch or timer is not activated.

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

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

2. For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in an hour for operation at the maximum-rated peak tube potential; or

3. For all other diagnostic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

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

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

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

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

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

"Limits" (See "Dose limits").

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

Percent line-voltage regulation = 100 $(V_n-V_l)/V_l$

where:

V_n = No-load line potential; and

V_l = Load line potential.

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

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

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

"Logging assistant" means any individual who, under the personal supervision of a logging supervisor, handles sealed sources or tracers that are not in logging tools or shipping containers or who performs surveys required by Part XIV (12VAC5-481-3140 et seq.) of this chapter.

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

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

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

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

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

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

1. LSA-I

a. Uranium and thorium ores, concentrates of uranium and thorium ores, and other ores containing naturally occurring radioactive radionuclide that are not intended to be processed for the use of these radionuclides;

b. Solid unirradiated natural uranium or depleted uranium or natural thorium or their solid or liquid compounds or mixtures;

c. Radioactive material, for which the A_2 value is unlimited; or

d. Other radioactive material in which the activity is distributed throughout and the estimated average specific activity does not exceed 30 times the value for exempt material activity concentration determined in accordance with 12VAC5-481-3720.

2. LSA-II

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

b. Other material in which the activity 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.

3. LSA-III

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

a. The radioactive material is distributed throughout a solid or a collection of solid objects, or is essentially uniformly distributed in a solid compact binding agent (e.g., concrete, bitumen, or ceramic);

b. The radioactive material is relatively insoluble, or it is intrinsically contained in a relatively insoluble material, so that, even under loss of packaging, the loss of radioactive material per package by leaching, when placed in water for seven days, would not exceed 0.1 A_2; and

c. The estimated average specific activity of the solid does not exceed 2.0 E-03 A_2/g.

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

"Lung class" (See "Class").

"mA" means milliampere.

"mAs" means milliampere second.

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

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

"MBq" means megabecquerels.

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

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

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

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

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

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

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

"Misadministration" means either:

1. An x-ray teletherapy radiation dose:

a. Involving the wrong patient;

b. Involving the wrong mode of treatment;

c. Involving the wrong treatment site;

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

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

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

2. An x-ray brachytherapy radiation dose:

a. Involving the wrong patient;

b. Involving the wrong treatment site; or

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

"mm" means millimeters.

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

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

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

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

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

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

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

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

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

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

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

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

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

"Natural radioactivity" means radioactivity of naturally occurring nuclides.

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

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

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

"Negative pressure respirator" or "tight fitting" means a respirator in which the air pressure inside the facepiece is

negative during inhalation with respect to the ambient air pressure outside the respirator.

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

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

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

where:

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

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.

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

"Nonstochastic effect" means a health effect, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect. For purposes of these regulations, "deterministic effect" is an equivalent term.

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

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

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

"Nominal treatment distance" means:

1. For electron irradiation, the distance from the scattering foil, virtual source, or exit window of the electron beam to the entrance surface of the irradiated object along the central axis of the useful beam.

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

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

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

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

"Occupational dose" means the dose received by an individual in the course of employment in which the individual's assigned duties for the licensee or registrant involve exposure to sources of radiation, whether or not the sources of radiation are in the possession of the licensee, registrant, or other person. Occupational dose does not include doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with 12VAC5-481-1870, from voluntary participation in medical research programs, or as a member of the public.

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

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

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

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

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

1. Fissile material package or Type AF package, Type BF package, Type B(U)F package, or Type B(M)F package

means a fissile material packaging together with its fissile material contents.

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

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

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

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

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

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

"Particle accelerator" (See "Accelerator").

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"Pigtail" (See "Source assembly").

"Pill" (See "Sealed source").

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

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

"Position indicating device" means a device on dental x-ray equipment used to indicate the beam position and to establish

a definite source-surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.

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

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

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

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

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

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

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

"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. The prescribed dose is an estimation from measured data from a specified therapeutic machine using assumptions that are clinically acceptable for that treatment technique and historically consistent with the clinical calculations previously used for patients treated with the same clinical technique; or

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

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

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

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

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

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

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

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

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

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

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

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

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

"Public dose" means the dose received by a member of the public from exposure to sources of radiation released by the licensee or registrant, or to any other source of radiation under the control of the licensee or registrant. "Public dose" does not include occupational dose, or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with 12VAC5-481-1870, or from voluntary participation in medical research programs.

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

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

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

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

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

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

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

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

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

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

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

"Radiation dose" (See "Dose").

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

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

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

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

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

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

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

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

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

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

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

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

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

"Radiobioassay" (See "Bioassay").

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

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

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

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

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

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

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

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

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

"Radiography" means:

1. For radioactive materials: See "Industrial radiography."

2. For x-ray: A technique for generating and recording an x-ray pattern for the purpose of providing the user with an image after termination of the exposure.

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

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

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

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

"Reference man" means a hypothetical aggregation of human physical and physiological characteristics determined by international consensus. These characteristics may be used by researchers and public health employees to standardize results of experiments and to relate biological insult to a common base. A description of the reference man is contained in the International Commission on Radiological Protection report, ICRP Publication 23, "Report of the Task Group on Reference Man."

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

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

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

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

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

"Reportable event" means the administration of either:

1. A diagnostic x-ray exposure where an actual or suspected acute or long-term functional damage to an organ or a physiological system has occurred. Exempt from this reporting requirement is any event when any functional damage to a patient organ or a physiological system that was an expected outcome when the causative procedures were prescribed;

2. A procedure where the patient or operator is injured as a result of a mechanical injury;

3. A teletherapy x-ray or electron dose where the calculated weekly administered dose differs from the weekly prescribed dose by 15% or more; or

4. A brachytherapy x-ray dose where the calculated administered dose differs from the prescribed dose by 10% or more.

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

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

"Residual radioactive material" means (i) waste (that the U.S. Secretary of Energy determines to be radioactive) in the form of tailings resulting from the processing of ores for the

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

"Residual radioactivity" means radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee's control. This includes radioactivity from all licensed and unlicensed sources used by the licensee, but excludes background radiation. It also includes radioactive materials remaining at the site as a result of routine or accidental releases of radioactive materials at the site and previous burials at the site, even if those burials were made in accordance with the provisions of Part IV (12VAC5-481-600 et seq.) of this chapter.

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

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

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

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

"Roentgen" means the special unit of exposure. One roentgen (R) equals 2.58E-4 coulombs per kilogram of air (see "Exposure" and 12VAC5-481-240).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"Shallow dose equivalent " or "H_s," which applies to the external exposure of the skin or an extremity, means the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm2).

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

"Shielded-room radiography" means industrial radiography conducted in a room shielded so that radiation levels at every

location on the exterior meet the limitations specified in 12VAC5-481-640.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"Source material" means:

1. Uranium or thorium, or any combination thereof, in any physical or chemical form; or

2. Ores that contain by weight one-twentieth of 1.0% (0.05%) or more of uranium, thorium or any combination of uranium and thorium. Source material does not include special nuclear material.

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

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

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

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

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

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

3. It satisfies the test requirements specified by the NRC. A special form encapsulation designed in accordance with the NRC requirements in effect on June 30, 1983, and constructed prior to July 1, 1985, 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 NRC, pursuant to the provisions of § 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:

$$\frac{175\ grams\ contained\ U235}{350} + \frac{50\ grams\ U-235}{200} + \frac{50\ grams\ Pu}{200} = 1$$

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

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

"Stability" means structural stability.

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

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

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

"Stochastic effect" means a health effect that occurs randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects. For purposes of ~~these regulations~~ this chapter, "probabilistic effect" is an equivalent term.

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

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

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

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

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

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

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

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

a. The nonfixed contamination on the accessible surface averaged over 300 cm², or the area of the surface if less than 300 cm², does not exceed four becquerel per cm² (1 E-04 μCi/cm²) for beta and gamma and low toxicity alpha emitters, or 0.4 becquerel per cm² (1 E-05 μCi/cm²) for all other alpha emitters;

b. The fixed contamination on the accessible surface averaged over 300 cm², or the area of the surface if less than 300 cm², does not exceed 4 E+04 becquerel per cm² (1.0 μCi/cm²) for beta and gamma and low toxicity alpha emitters, or 4 E+03 becquerel per cm² (0.1 μCi/cm²) for all other alpha emitters; and

c. The nonfixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm², or the area of the surface if less than 300 cm², does not exceed 4 E+04 becquerel per cm² (1 μCi/cm²) for beta and gamma and low toxicity alpha emitters, or 4 E+03 Becquerel per cm² (0.1 μCi/cm²) for all other alpha emitters.

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

a. The nonfixed contamination on the accessible surface averaged over 300 cm², or the area of the surface if less than 300 cm², does not exceed 400 becquerel per cm² (1 E-02 μCi/cm²) for beta and gamma and low toxicity alpha emitters or 40 becquerel per cm² (1 E-03 μCi/cm²) for all other alpha emitters;

b. The fixed contamination on the accessible surface averaged over 300 cm², or the area of the surface if less than 300 cm², does not exceed 8 E+05 becquerel per cm² (20 μCi/cm²) for beta and gamma and low toxicity alpha emitters, or 8 E+04 becquerel per cm² (2 μCi/cm²) for all other alpha emitters; and

c. The nonfixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm², or the area of the surface if less than 300 cm², does not exceed 8 E+05 becquerel per cm² (20 μCi/cm²)

for beta and gamma and low toxicity alpha emitters, or 8 E+04 becquerel per cm² (2 μCi/cm²) for all other alpha emitters.

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

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

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

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

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

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

"Technique factors" means the following conditions of operation:

1. For capacitor energy storage equipment, peak tube potential in kilovolts (kV) and quantity of charge in milliampere-seconds (mAs);

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

3. For CT equipment designed for pulsed operation, peak tube potential in kilovolts (kV), scan time in seconds, and either tube current in milliamperes (mA), x-ray pulse width in seconds, and the number of x-ray pulses per scan, or the product of tube current, x-ray pulse width, and the number of x-ray pulses in milliampere-seconds (mAs);

4. For CT equipment not designed for pulsed operation, peak tube potential in kilovolts (kV), and either tube current in milliamperes (mA) and scan time in seconds, or the product of tube current and exposure time in milliampere-seconds (mAs) and the scan time when the scan time and exposure time are equivalent; and

5. For all other equipment, peak tube potential in kilovolts (kV), and either tube current in milliamperes (mA) and exposure time in seconds, or the product of tube current and exposure time in milliampere-seconds (mAs).

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

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

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

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

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

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

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

"These regulations" mean all parts of this chapter.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"Type A quantity" means a quantity of radioactive material, the aggregate radioactivity of which does not exceed A_1 for special form radioactive material or A_2 for normal form radioactive material, where A_1 and A_2 are given in Table A-1 of 12VAC5-481-3770 or may be determined by procedures described in Table A-1 of 12VAC5-481-3770.

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

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

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

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

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

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

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

"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 with the naturally occurring distribution of uranium isotopes, which is approximately 0.711 weight percent uranium-235, and the remainder by weight essentially uranium-238.

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

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

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

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

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

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

"Very high radiation area" means an area, accessible to individuals, in which radiation levels from radiation sources

external to the body could result in an individual receiving an absorbed dose in excess of five Gy (500 rad) in one hour at one meter from a source of radiation or one meter from any surface that the radiation penetrates.

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

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

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

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

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

"Waste collector" means an entity, operating under a specific license, whose principal purpose is to collect and consolidate waste generated by others, and to transfer this waste, without processing or repackaging the collected waste, to another licensed waste collector, licensed waste processor, or licensed land disposal facility.

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

"Waste generator" means an entity, operating under a license, that (i) possesses any material or component that contains radioactivity or is radioactively contaminated for which the licensee foresees no further use, and (ii) transfers this material or component to a licensed land disposal facility or to a licensed waste collector or processor for handling or treatment prior to disposal. A licensee performing processing or decontamination services may be a "waste generator" if the transfer of low-level radioactive waste from its facility is defined as "residual waste."

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

"Waste processor" means an entity, operating under a specific license, whose principal purpose is to process, repackage, or otherwise treat low-level radioactive material or waste generated by others prior to eventual transfer of waste to a licensed low-level radioactive waste land disposal facility.

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

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

"Week" means seven consecutive days starting on Sunday.

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

Organ Dose Weighting Factors

Organ or Tissue	w_T
Gonads	0.25
Breast	0.15
Red bone marrow	0.12
Lung	0.12
Thyroid	0.03
Bone surfaces	0.03
Remainder	0.30[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 that may contain sources of radiation into well-bores or cavities for the purpose of obtaining information about the well or adjacent formations.

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

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

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

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

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

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

"Written directive" means an 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 subdivision 6 of this definition, 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 control" means a device that controls input power to the x-ray high-voltage generator or the x-ray tube. It includes equipment such as timers, phototimers, automatic brightness stabilizers, and similar devices, which control the technique factors of an x-ray exposure.

"X-ray exposure control" means a device, switch, button or other similar means by which an operator initiates ~~and/or~~ 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 that is installed in a fixed location.

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

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

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

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

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

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

12VAC5-481-3390. 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 ~~and reporting misadministrations within 10 days~~. The registrant or the registrant's agent shall ensure that the requirements of Part XV (12VAC5-481-3380 et seq.) of this chapter are met in the operation of the therapeutic radiation ~~machine(s)~~ machines.

B. A therapeutic radiation machine that does not meet the provisions of ~~these regulations~~ this chapter 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 12VAC5-481-3420 or 12VAC5-481-3430 shall require the authorized user to be a physician who:

1. Is certified in:

a. ~~Radiology~~ Radiation oncology or therapeutic radiology by the American Board of Radiology or radiology (combined diagnostic and therapeutic radiology program) by the American Board of Radiology prior to 1976;

b. Radiation oncology by the American Osteopathic Board of Radiology;

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 and patient treatment settings;

(3) Using administrative controls to prevent ~~miss-administrations~~ 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 or 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~~ 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 subdivisions 1 and 2 of this subsection, the registrant for any therapeutic radiation machine subject to 12VAC5-481-3420 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~~ qualified medical physicist. The registrant for any therapeutic radiation machine subject to 12VAC5-481-3420 and 12VAC5-481-3430 shall require the ~~radiation therapy~~ qualified medical physicist to~~: 1. Be~~ be registered with the agency, under the provisions of Part II (12VAC5-481-260 et seq.) of this chapter, as a provider of radiation services in the area of calibration and surveys of external beam radiation therapy units~~;~~ and ~~2. Shall meet the requirements of 12VAC5-481-340 B 2~~ to:

1. Be certified by the American Board of Radiology in:

a. Therapeutic radiological physics;

b. Roentgen-ray and gamma-ray physics;

c. X-ray and radium physics; or

d. Radiological physics;

2. Be certified by the American Board of Medical Physics in Radiation Oncology Physics;

3. Be certified by the Canadian College of Medical Physics; or

4. Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university and have completed one year of full-time training in medical physics and an additional year of full-time work experience

under the supervision of a qualified medical physicist at a medical institution. This training and work experience shall be conducted in clinical radiation facilities that provide high-energy external beam radiation therapy (photons and electrons with energies greater than or equal to one MV/one MeV). To meet this requirement, the individual shall have performed the tasks listed in 12VAC5-481-3400 A, 12VAC5-481-3420 P, 12VAC5-481-3420 Q, 12VAC5-481-3430 T, and 12VAC5-481-3430 U under the supervision of a qualified medical physicist during the year of work experience.

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~~ qualified medical 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~~ therapeutic radiation machine authorized user. This provision specifically prohibits deliberate exposure of an individual for training, demonstration or other ~~nonhealing arts~~ non-healing-arts purposes.

H. Visiting authorized user. Notwithstanding the provisions of subsection G of this section, 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, where applicable; and

2. The visiting authorized user meets the requirements established for an authorized ~~user(s)~~ user in subdivisions ~~1 and 2~~ C 1 and C 2 of this ~~subsection~~ section; and

3. The registrant ~~maintains copies of all records specified by this subsection for five years from the date of the last visit~~ shall maintain copies of the written permission required in subdivision 1 of this subsection and documentation that the visiting authorized user met the requirements of subdivision 2 of this subsection 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 of this chapter, these individuals are also subject to the requirements of 12VAC5-481-640, 12VAC5-481-680, and 12VAC5-481-760.

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 of this chapter, as well as the name(s) of person(s) who performed such activities;

3. Records of maintenance ~~and/or~~ or modifications performed on the therapeutic radiation machine after September 20, 2006, as well as the ~~name(s)~~ names of ~~person(s)~~ persons 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 of this chapter shall be retained until disposal is authorized by the agency unless another retention period is specifically authorized in Part XV of this chapter. 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.

12VAC5-481-3400. General technical requirements for facilities using therapeutic radiation machines.

A. ~~Surveys~~ 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 12VAC5-481-3440. The radiation protection survey shall be performed by, or under the direction of, a ~~radiation therapy~~ qualified medical physicist

or a ~~private inspector~~ qualified 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 12VAC5-481-640; and

b. Radiation levels in unrestricted areas do not exceed the limits specified in 12VAC5-481-720.

2. In addition to the requirements of ~~12VAC5-481-3400 A 1~~ subdivision 1 of this subsection, 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~~ qualified medical physicist or a ~~private inspector~~ qualified 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~~;~~, the model number and serial number of the therapeutic radiation machine~~;~~, the ~~instrument(s)~~ instruments 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 subdivision 1 or 2 of this subsection indicate any radiation levels in excess of the respective limit specified in subdivision 1 of this subsection, 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 subsection A of this section indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by 12VAC5-481-720, 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 12VAC5-481-720;

2. Perform the survey required by subsection A of this section again; and

3. Include in the report required by subsection D of this section the results of the initial survey, a description of the modification made to comply with subdivision 1 of this subsection, and the results of the second survey; or

4. Request and receive a registration amendment under 12VAC5-481-720 that authorizes radiation levels in unrestricted areas greater than those permitted by 12VAC5-481-720.

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 qualified inspector or qualified medical physicist other than the person performing the original survey prior to the equipment being used except as described in subsection A of this section:

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 subdivision ~~C~~ 1 of this ~~section~~ subsection. 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 subdivision ~~C~~ 1 of this ~~section~~ subsection;

3. The registrant shall maintain a record of each dosimetry system calibration, intercomparison, and comparison for the duration of the license ~~and/or~~ 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 subdivisions ~~C~~ 1 and 2 of this ~~section~~ subsection; 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~~ qualified medical physicist.

D. Reports of external beam radiation therapy surveys and measurements. The registrant for any therapeutic radiation machine subject to 12VAC5-481-3420 or 12VAC5-481-3430 shall furnish a copy of the records required in subsections A and B of this section to the agency within 30 days following completion of the action that initiated the record requirement.

12VAC5-481-3410. Quality management program.

~~The facility shall implement a quality management program. The facility shall include in the quality management program written notification to the agency within 72 hours of discovery of a reportable event or a misadministration~~ Each registrant or applicant subject to 12VAC5-481-3420 and 12VAC5-481-3430 shall develop, implement, and maintain a quality management program to provide high confidence that radiation will be administered as directed by the authorized user.

A. Scope and applicability. The quality management program shall address, at a minimum, the following specific objectives:

1. Written directives.

a. A written directive shall be dated and signed by an authorized user prior to the administration of radiation. If because of the patient's condition a delay caused by providing 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 as soon as possible in writing in the patient's record and a revised written directive is signed by an authorized user within 48 hours of the oral revision.

b. The written directive shall contain the patient's or human research subject's name, type and energy of the beam, total dose, dose per fraction, treatment site, and number of fractions.

c. A written revision to an existing written directive may be made provided that the revision is dated and signed by an authorized user prior to the administration of the therapeutic radiation machine dose or the next fractional dose.

d. The registrant shall retain a copy of the written directive for three years.

2. Procedures for administrations. The registrant shall develop, implement, and maintain written procedures to provide high confidence that:

a. Prior to the administration of each course of radiation treatment, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive;

b. Each administration is in accordance with the written directive;

c. Therapeutic radiation machine final plans of treatment and related calculations are in accordance with the respective written directives by:

(1) Checking both manual and computer-generated dose calculations to verify they are correct and in accordance with the written directive; and

(2) Verifying that any computer-generated calculations are correctly transferred into the consoles of authorized therapeutic medical units;

d. Any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken; and

e. The registrant retains a copy of the procedures for administrations for the duration of the registration.

B. Reports and notifications of misadministrations.

1. A registrant shall report any event resulting from the treatment of a patient or human research subject in which the administration of therapeutic radiation machine radiation results, or will result in, unintended permanent functional damage to an organ or a physiological system as determined by a physician.

2. Other than events that result from the treatment of a patient or human research subject, a registrant shall report any event in which the administration of a therapeutic radiation machine therapy dose:

a. Involves the wrong patient, wrong treatment modality, or wrong treatment site;

b. The calculated weekly administered dose differs from the weekly prescribed dose by more than 30%; or

c. The calculated total administered dose differs from the total prescribed dose by more than 20% of the total prescribed dose.

3. The registrant shall notify the agency by telephone no later than the next calendar day after the discovery of a misadministration.

4. The registrant shall submit a written report to the agency within 15 days after the discovery of a misadministration. The written report shall include:

a. The registrant's name;

b. The name of the prescribing physician;

c. A brief description of the event;

d. Why the event occurred;

e. The effect, if any, on the individual who received the misadministration;

f. Actions, if any, that have been taken or are planned to prevent recurrence; and

g. Certification that the registrant notified the individual, or the individual's responsible relative or guardian, and if not, why not.

5. The report shall not contain the individual's name or any other information that could lead to the identification of the individual.

6. The registrant shall provide notification of the event to the referring physician and also notify the individual who is the subject of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the registrant either that he will inform the individual or that, based on medical judgment, telling the individual would be harmful. The registrant is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the registrant shall notify the individual as soon as possible thereafter. The registrant may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the misadministration, because of any delay in notification. To meet the requirements of this subdivision, the notification of the individual who is the subject of the misadministration may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the registrant shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the registrant upon request. The registrant shall provide such a written description if requested.

7. Aside from the notification requirement, nothing in this section affects any rights or duties of registrants and physicians in relation to each other, to individuals affected by the misadministration, or to that individual's responsible relatives or guardians.

8. The registrant shall retain a record of a misadministration in accordance with subsection C of this section. A copy of the required record shall be provided to the referring physician if other than the registrant within 15 days after discovery of the misadministration.

C. Records of misadministrations. A registrant shall retain a record of misadministrations reported in accordance with subsection B of this section for three years. The record shall contain the following:

1. The registrant's name and the names of the individuals involved;

2. The social security number or other identification number, if one has been assigned, of the individual who is the subject of the misadministration;

3. A brief description of the event; why it occurred; and the effect, if any, on the individual;

4. The actions, if any, taken or planned to prevent recurrence; and

5. Whether the registrant notified the individual, or the individual's responsible relative or guardian and, if not, whether such failure to notify was based on guidance from the referring physician.

12VAC5-481-3420. Therapeutic radiation machines of less than 500 kV.

A. Leakage radiation. When the ~~X-ray~~ 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~~ 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. ~~>~~ Greater than 50 and ~~<~~ less than 500 kV ~~Systems~~ 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 subdivisions ~~A~~ 1 and 2 of this ~~section~~ subsection 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 5.0% 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 September 20, 2006, 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~~ 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 preselected 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. ~~Time~~r The timer shall be accurate to within 1.0% 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 this section, shall have:

1. An indication of whether electrical power is available at the control panel and if activation of the ~~X-ray~~ x-ray tube is possible;

2. An indication of whether ~~X-rays~~ x-rays are being produced;

3. A means for indicating ~~X-ray~~ 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 September 20, 2006, a positive display of specific ~~filter(s)~~ filters in the beam.

J. Multiple tubes. When a control panel may energize more than one ~~X-ray~~ x-ray tube:

1. It shall be possible to activate only one ~~X-ray~~ x-ray tube at any time;

2. There shall be an indication at the control panel identifying which ~~X-ray~~ 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~~ x-ray output to the prescribed exposure parameters within five seconds after the ~~X-ray~~ 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~~ 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 12VAC5-481-3450, 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 subdivision 3 of this subsection is opened while the ~~X-ray~~ 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 this section shall be performed by, or under the direct supervision of, a ~~radiation therapy~~ qualified medical 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 5.0% 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 subdivision 1 c of this subsection:

(1) Full calibration of therapeutic radiation machines with multienergy capabilities is required only for those modes ~~and/or~~ 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 subdivision 1 c (1) of this subsection.

2. To satisfy the requirement of subdivision 1 of this subsection, full calibration shall include all measurements recommended for annual calibration by ~~NCRP~~ the National Council on Radiation Protection and Measurements (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~~ 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~~ qualified medical 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 this section, which are capable of operation at greater than or equal to 50 kV~~.~~;

2. To satisfy the requirement of subdivision 1 of this subsection, 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~~ qualified medical 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 subdivision P 1 of this section. 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 subdivision P 1 of this section, shall be stated~~.~~;

3. The cause for a parameter exceeding a tolerance set by the ~~radiation therapy~~ qualified medical 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~~ qualified medical physicist's quality assurance check procedures, the system shall be recalibrated as required in subdivision P 1 of this section;

5. The registrant shall use the dosimetry system described in 12VAC5-481-3400 C 2 to make the quality assurance check required in subdivision 2 of this subsection;

6. The registrant shall have the ~~radiation therapy~~ qualified medical physicist review and sign the results of each radiation output quality assurance check within ~~one month~~ 30 days of the date that the check was performed;

7. The registrant shall ensure that safety quality assurance checks of therapeutic radiation machines subject to this section are performed at intervals not to exceed ~~one month~~ 30 days;

8. Notwithstanding the requirements of subdivisions 4 and 7 of this subsection, the registrant shall ensure that no therapeutic radiation machine is used to administer radiation to humans unless the quality assurance checks

required by subdivisions ~~6~~ 4 and 7 of this subsection have been performed within the 30-day period immediately prior to said administration;

9. To satisfy the requirement of subdivision 7 of this subsection, 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)~~ door, control console, and in the radiation therapy room;

d. Viewing systems; and

e. If applicable, electrically operated treatment room doors from inside and outside the treatment room; and

10. The registrant shall maintain a record of each quality assurance check required by subdivisions 1 and 7 of this subsection for three years. The record shall include~~:~~ the date of the quality assurance check; the manufacturer's name, the model number, and serial number of the therapeutic radiation machine; the manufacturer's name~~;~~, the model number, and serial number for the ~~instrument(s)~~ instruments 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 subsections P and Q of this section have been met;

2. Therapeutic radiation machines shall not be left unattended unless secured pursuant to subdivision I 5 of this section;

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 an 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 12VAC5-481-640.

S. Possession of survey ~~instrument(s)~~ instruments. Each facility location authorized to use a therapeutic radiation machine in accordance with this section 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 ~~mSv~~ µSv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. The survey ~~instrument(s)~~ instruments shall be operable and calibrated in accordance with 12VAC5-481-3440.

T. Electronic brachytherapy devices are subject to the requirements of 12VAC5-481-3452 and are exempt from the requirements of this section.

12VAC5-481-3430. Therapeutic radiation machines - photon therapy systems (500 kV and above) and electron therapy systems (500 kV and above).

A. Possession of survey ~~instrument(s)~~ instruments. Each facility location authorized to use a therapeutic radiation machine in accordance with this section shall ~~possess~~ have access to 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 ~~mSv~~ µSv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. The survey ~~instrument(s)~~ instruments shall be operable and calibrated in accordance with 12VAC5-481-3440.

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 subdivision 1 of this subsection, 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 September 20, 2006, 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 subdivisions 1 ~~through~~, 2, and 3 of this subsection 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)~~ devices shall not exceed 2.0% of the maximum absorbed dose on the central axis of the useful beam measured in a ~~10 centimeter by 10 centimeter radiation field, or for multileaf collimators, shall not exceed manufacturer's specifications~~ 100 square centimeter radiation field, or maximum available field size if less than 100 square centimeters;

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 2.0% 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~~ 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 and 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 subsection I of this section 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 September 20, 2006, that 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)~~ filters, interchangeable field flattening ~~filter(s)~~ filters, ~~and/or~~ or interchangeable beam scattering ~~foil(s)~~ foils in use; and

d. An interlock shall be provided to prevent irradiation if any filter ~~and/or~~ or beam scattering foil selection operation carried out in the treatment room does not agree with the filter ~~and/or~~ or beam scattering foil selection operation carried out at the treatment control panel.

E. Stray radiation in the useful beam. For equipment manufactured after September 20, 2006, the registrant shall determine during acceptance testing, or obtain from the manufacturer, data sufficient to ensure that ~~X-ray~~ x-ray stray radiation in the useful electron beam, absorbed dose at the surface during ~~X-ray~~ x-ray irradiation, and stray neutron radiation in the useful ~~X-ray~~ 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 this section 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 September 20, 2006, 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 September 20, 2006, 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 September 20, 2006, 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)~~ systems; 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 September 20, 2006, 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 subdivision 3 e (3) of this subsection 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~~ A bent-beam linear accelerator with beam flattening filter subject to this section shall be provided with an auxiliary ~~device(s)~~ device to monitor beam symmetry;

2. The ~~device(s)~~ device referenced in subdivision 1 of this subsection shall be able to detect field asymmetry greater than 10%; and

3. The ~~device(s)~~ device referenced in subdivision 1 of this subsection shall be configured to terminate irradiation if the specifications in subdivision 2 of this subsection 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 preselected 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 September 20, 2006, after termination of irradiation, it shall be necessary for the operator to reset the preselected dose monitor units before irradiation can be initiated.

I. Air kerma rate or absorbed dose rate. For equipment manufactured after September 20, 2006, 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 subsection F of this section 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 that 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)~~ conditions 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 4 Gy (400 rad); and

4. For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the maximum ~~value(s)~~ values specified in subdivisions 2 and 3 of this subsection for the specified operating conditions. Records of these maximum ~~value(s)~~ values 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 preselected 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 preselected 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 September 20, 2006, 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 preselected 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 preselected time has elapsed~~,~~ if the dose monitoring systems have not previously terminated irradiation.

N. Selection of radiation type. Equipment capable of both ~~X-ray~~ 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~~ (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~~ 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~~ 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 September 20, 2006, 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 September 20, 2006:

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~~ centimeter 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 5.0% from the dose monitor unit value selected;

c. An interlock shall be provided to prevent motion of more than five degrees or one ~~cm~~ centimeter 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 that 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 ~~12VAC5-481-3430 J~~ subsection J of this section; and

7. For equipment manufactured after September 20, 2006, 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 12VAC5-481-3450, 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 (12VAC5-481-3380 et seq.) of this chapter, 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 12VAC5-481-720, 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)~~ barrier;

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 subsection K of this section. 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 ~~from treatment room~~, or working on therapeutic radiation machine components which may have become activated due to photo-neutron production.

R. ~~Radiation therapy~~ Qualified medical physicist support.

1. The services of a ~~radiation therapy~~ qualified medical physicist shall be required in facilities having therapeutic radiation machines with energies of 500 kV and above. The ~~radiation therapy~~ qualified medical physicist shall be responsible for:

a. Full ~~calibration(s)~~ calibrations required by subsection T of this section and protection surveys required by 12VAC5-481-3400 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 subdivision U 5 of this section.;

e. Consultation with the authorized user in treatment planning, as needed; and

f. Performance of calculations or assessments regarding misadministrations.

2. If the radiation therapy qualified medical physicist is not a full-time employee of the registrant, the operating procedures required by subsection S of this section shall also specifically address how the radiation therapy qualified medical physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the radiation therapy qualified medical 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 12VAC5-481-3400 A, and subsections T and U of this section 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 this section shall be performed by, or under the direct supervision of, a radiation therapy qualified medical physicist.

2. Acceptance testing and commissioning shall be performed in accordance with the American Association of Physicists in Medicine (AAPM) AAPM Code of Practice for Radiotherapy Accelerators: Report of AAPM Report Number 47," prepared by Radiation Therapy Task Group 45" and the manufacturer's contractual specifications. Acceptance testing and commissioning 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: AAPM Report No. 46," prepared by Committee Task Group 40" and shall be performed in accordance with "AAPM Code of Practice for Radiotherapy Accelerators: Report of AAPM AAPM Report No. 47" prepared by 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 qualified medical 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 5.0% from the value obtained at the last full calibration and the difference cannot be reconciled. Therapeutic radiation machines with multienergy and/or or multimode capabilities shall only require measurements for those modes and/or 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 or energies, measurements shall be performed on the effected mode or energy that is in most frequent clinical use at the facility. The remaining energies or modes may be validated with quality assurance check procedures against the criteria in subdivision 4 a of this subsection.

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 qualified medical 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 this section at intervals not to exceed those specified in "Comprehensive QA for Radiation Oncology: Report of AAPM Report No. 46," prepared by AAPM Radiation Therapy Committee Task Group 40";

2. To satisfy the requirement of subdivision 1 of this subsection, 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 Report No. 46" prepared by 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 12VAC5-481-3400 C 1 to make the periodic quality assurance checks required in subdivision 2 of this subsection;

4. The registrant shall perform periodic quality assurance checks required by subdivision 1 of this subsection in accordance with procedures established by the ~~radiation therapy~~ qualified medical 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~~ qualified medical 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~~ qualified medical 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~~ qualified medical physicist within three treatment days; and

c. The ~~radiation therapy~~ qualified medical physicist shall review and sign the results of each radiation output quality assurance check at intervals not to exceed ~~one month~~ 30 days.

6. Therapeutic radiation machines subject to this section shall have applicable safety quality assurance checks listed in "Comprehensive QA for Radiation Oncology: ~~Report of~~ AAPM Report No. 46," prepared by AAPM Radiation Therapy Committee Task Group 40~~"~~ performed at intervals not to exceed one week;

7. To satisfy the requirement of subdivision 6 of this subsection, 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)~~ doors 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 subdivision 7 of this subsection that is not operating properly; and

9. The registrant shall maintain a record of each quality assurance check required by subdivisions 1 and 7 of this subsection 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)~~ instruments used to measure the radiation output of the therapeutic radiation machine; and the signature of the individual who performed the periodic quality assurance check.

V. Quality assurance checks for intensity modulated radiation therapy (IMRT) shall:

1. Include commissioning and testing of the treatment planning and delivery systems, routine quality assurance of the delivery system, and patient-specific validation of treatment plans;

2. Be performed in accordance with "Guidance document on delivery, treatment planning, and clinical implementation of IMRT: Report of the IMRT subcommittee of the AAPM radiation therapy committee: AAPM Report No. 82"; and

3. Be performed in accordance with the manufacturer's contractual specifications.

12VAC5-481-3450. Shielding and safety design requirements.

A. Each therapeutic radiation machine subject to 12VAC5-481-3420 or 12VAC5-481-3430 shall be provided with such primary ~~and/or~~ or secondary barriers as are necessary to ensure compliance with 12VAC5-481-640 and 12VAC5-481-720.

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. At a minimum, facility design information shall include:

1. All therapeutic radiation machines.

a. Basic facility information including name, telephone number, and agency registration number of the individual responsible for preparation of the shielding plan; name and telephone number of the facility supervisor; and the street address, including room number, of the therapeutic radiation machine facility. The plan shall also indicate whether this is a new structure or a modification to an existing structure.

b. The primary areas where all wall, floor, and ceiling areas are struck by the useful beam.

c. The secondary barriers where all wall, floor, and ceiling areas do not have primary barriers.

2. Therapeutic radiation machines less than or equal to 150 kV (photons only). In addition to the requirements listed in subdivision 1 of this subsection, therapeutic radiation machine facilities that produce only photons with a maximum energy less than or equal to 150 kV shall submit shielding plans that contain, at a minimum, the following additional information:

a. Equipment specifications, including the manufacturer and model number of the therapeutic radiation machine, as well as the maximum technique factors;

b. Maximum design workload for the facility including total weekly radiation output, expressed in gray (rad) or air kerma at one meter; total beam-on time per day or per week; average treatment time per patient; and the anticipated number of patients to be treated per day or per week;

c. A facility blueprint or drawing indicating scale (0.25 inch equals 1 foot is typical); direction of north; normal location of the therapeutic radiation machine's radiation port; the port's travel and traverse limits; general direction of the useful beam; locations of any windows and doors; and location of the therapeutic radiation machine control panel. If the control panel is located inside the therapeutic radiation machine treatment room, the location of the operator's booth shall be noted on the plan and the operator's station at the control panel shall be behind a protective barrier sufficient to ensure compliance with 12VAC5-481-640;

d. The structural composition and thickness or lead or concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room concerned;

e. The type of occupancy of all adjacent areas inclusive of space above and below the room concerned. If there is an exterior wall, the distance to the closest areas where it is likely that individuals may be present shall be included; and

f. At least one example calculation that shows the methodology used to determine the amount of shielding required for each physical condition (e.g., primary, secondary, and leakage barriers; restricted and unrestricted areas; and entry doors) and shielding material in the facility:

(1) If commercial software is used to generate shielding requirements, the software used and the version and revision date shall be identified.

(2) If the software used to generate shielding requirements is not in the open literature, quality control sample calculations to verify the result obtained with the software shall be submitted.

3. Therapeutic radiation machines over 150 kV. In addition to the requirements listed in subdivision 1 of this subsection, therapeutic radiation machine facilities that produce photons with a maximum energy in excess of 150 kV or electrons, or both, shall submit shielding plans that contain, at a minimum, the following additional information:

a. Equipment specifications including the manufacturer and model number of the therapeutic radiation machine, gray (rad) at the isocenter, and the energy and type of radiation produced (e.g., photon, electron). The target to isocenter distance shall be specified;

b. Maximum design workload for the facility including total weekly radiation output, expressed in gray (rad) at one meter; total beam-on time per day or per week; the average treatment time per patient; and the anticipated number of patients to be treated per day or per week;

c. Facility blueprint or drawing, including both floor plan and elevation views, indicating relative orientation of the therapeutic radiation machine; scale (0.25 inch equals 1 foot is typical); type, thickness, and minimum density of shielding material; direction of north, locations and size of all penetrations through each shielding barrier (ceiling, walls, and floor); and details of the door and maze;

d. The structural composition and thickness or concrete equivalent of walls, doors, partitions, floor, and ceiling of the room concerned;

e. The type of occupancy of all adjacent areas inclusive of space above and below the room concerned. If there is an exterior wall, the distance to the closest areas where it is likely that individuals may be present shall be included;

f. Description of all assumptions that were used in shielding calculations including, but not limited to, design energy (e.g., room may be designed for 6 MV unit although only a 4 MV unit is currently proposed), workload, presence of integral beam-stop in unit, occupancy and use of adjacent areas, fraction of time that useful beam will intercept each permanent barrier (walls, floor, and ceiling), and "allowed" radiation exposure in both restricted and unrestricted areas; and

g. At least one example calculation that shows the methodology used to determine the amount of shielding required for each physical condition (e.g., primary, secondary, and leakage barriers; restricted and unrestricted areas; small angle scatter; entry doors; and maze), and shielding material in the facility.

(1) If commercial software is used to generate shielding requirements, the software used and the version and revision date shall be identified; and

(2) If the software used to generate shielding requirements is not in the open literature, quality control

sample calculations to verify the result obtained with the software shall be submitted.

4. Neutron shielding. In addition to the requirements listed in subdivision 3 of this subsection, therapeutic radiation machine facilities that are capable of operating above 10 MV shall submit shielding plans that contain, at a minimum, the following additional information:

a. The structural composition, thickness, minimum density, and location of all neutron shielding material;

b. Description of all assumptions that were used in neutron shielding calculations including, but not limited to, neutron spectra as a function of energy, neutron fluence rate, absorbed dose and dose equivalent (due to neutrons) in both restricted and unrestricted areas;

c. At least one example calculation that shows the methodology used to determine the amount of neutron shielding required for each physical condition (e.g., restricted and unrestricted areas, entry doors, and maze), and neutron shielding material utilized in the facility.

(1) If commercial software is used to generate shielding requirements, the software used and the version and revision date shall be identified; and

(2) If the software used to generate shielding requirements is not in the open literature, control sample calculations to verify the result obtained with the software shall be submitted.

d. The methods and instrumentation that will be used to verify the adequacy of all neutron shielding installed in the facility.

12VAC5-481-3451. Quality assurance for radiation therapy simulation systems.

Quality assurance for a conventional or virtual simulator shall include acceptance testing and periodic verification of system performance and shall be performed in accordance with (i) "Comprehensive QA for Radiation Oncology: AAPM Report No. 46, Report of AAPM Radiation Therapy Committee Task Group No.40" for a conventional simulator or (ii) "Quality assurance for computed tomography simulators and the computed tomography-simulation process: AAPM Report No. 83, Report of the AAPM Radiation Therapy Committee Task Group No. 66" for a virtual simulator.

12VAC5-481-3452. Electronic brachytherapy.

A. Applicability. Electronic brachytherapy devices shall be subject to the requirements of this section and shall be exempt for the requirements of 12VAC5-481-3420.

1. An electronic brachytherapy device that does not meet the requirements of this section shall not be used for irradiation of patients; and

2. An electronic brachytherapy device shall only be utilized for human use applications specifically approved by the U.S. Food and Drug Administration (FDA) unless participating in a research study approved by the registrant's institutional review board (IRB).

B. Possession of survey instruments. Each facility location authorized to use an electronic brachytherapy device in accordance with this section shall have access to appropriately calibrated portable monitoring equipment. At 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 instruments shall be operable and calibrated in accordance with 12VAC5-481-3440 for the applicable electronic brachytherapy source energy.

C. Facility design requirements for electronic brachytherapy devices. In addition to shielding adequate to meet requirements of 12VAC5-481-3450, the treatment room shall meet the following design requirements:

1. If applicable, provision shall be made to prevent simultaneous operation of more than one therapeutic radiation machine in a treatment room.

2. Access to the treatment room shall be controlled by a door at each entrance.

3. Each treatment room shall have provisions to permit continuous aural communication and visual observation of the patient from the treatment control panel during irradiation. The electronic brachytherapy device shall not be used for patient irradiation unless the patient can be observed.

4. For electronic brachytherapy devices capable of operating below 50 kV, radiation shielding for the staff in the treatment room shall be available, either as a portable shield or as localized shielded material around the treatment site.

5. For electronic brachytherapy devices capable of operating at greater than 150 kV:

a. The control panel shall be located outside the treatment room; and

b. Electrical interlocks shall be provided for all doors to the treatment room that will:

(a) Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;

(b) Cause the source to be shielded when an entrance door is opened; and

(c) Prevent the source from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source on-off control is reset at the console.

D. Electrical safety for electronic brachytherapy devices.

1. The high voltage transformer shall be electrically isolated to prevent electrical and magnetic interference with the surrounding environment and ancillary equipment.

2. The high voltage transformer shall be isolated from personnel (e.g., an operator) and the environment by a protective housing that can only be accessed through a cover requiring a tool for access or with electrical interlocks to prevent operation while open.

3. The high voltage transformer shall have appropriate safety labels warning personnel of potential electrical shock or heat related injuries.

4. Equipment manufactured after March 2009 shall be in compliance with the most current revision of the following International Electrotechnical Commission (IEC) Documents:

a. IEC 60601-1:1998+A1+A2:1995;

b. IEC 60601-1-2:2001;

c. IEC 60601-2-8:1999; and

d. IEC 60601-2-17:2004.

E. Control panel functions. The control panel, in addition to the displays required by other provisions in this section, shall:

1. Provide an indication of whether electrical power is available at the control panel and if activation of the electronic brachytherapy source is possible;

2. Provide an indication of whether x-rays are being produced;

3. Provide a means for indicating electronic brachytherapy source potential and current;

4. Provide the means for terminating an exposure at any time; and

5. Include an access control (locking) device that will prevent unauthorized use of the electronic brachytherapy device.

F. Timer. A suitable irradiation control device (timer) shall be provided to terminate the irradiation after a pre-set time interval or integrated charge on a dosimeter-based monitor.

1. A timer shall be provided at the treatment control panel. The timer shall indicate planned setting and the time elapsed or remaining;

2. The timer shall not permit an exposure if set at zero;

3. The timer shall be a cumulative device 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;

4. The timer shall terminate irradiation when a preselected time has elapsed if any dose monitoring system has not previously terminated irradiation.

5. The timer shall permit setting of exposure times as short as 0.1 second; and

6. The timer shall be accurate to within 1.0% of the selected value or 0.1 second, whichever is greater.

G. Qualified medical physicist support.

1. The services of a qualified medical physicist shall be required in facilities having electronic brachytherapy devices. The qualified medical physicist shall be responsible for:

a. Evaluation of the output from the electronic brachytherapy source;

b. Generation of the necessary dosimetric information;

c. Supervision and review of treatment calculations prior to initial treatment of any treatment site;

d. Establishing the periodic and day-of-use quality assurance checks and reviewing the data from those checks as required in subsection K of this section;

e. Consultation with the authorized user in treatment planning, as needed; and

f. Performing calculations or assessments regarding patient treatments that may constitute a misadministration.

2. If the qualified medical physicist is not a full-time employee of the registrant, the operating procedures required by subsection H of this section shall also specifically address how the qualified medical physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the qualified medical physicist can be contacted.

H. Operating procedures.

1. Only individuals approved by the authorized user, radiation safety officer, or qualified medical physicist shall be present in the treatment room during treatment;

2. Electronic brachytherapy devices shall not be made available for medical use unless the requirements of 12VAC5-481-3400 A and subsections I and J of this section have been met;

3. The electronic brachytherapy device shall be inoperable, either by hardware or password, when unattended by qualified staff or service personnel;

4. During operation, the electronic brachytherapy device operator shall monitor the position of all persons in the treatment room and all persons entering the treatment room to prevent entering persons from unshielded exposure from the treatment beam;

5. If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used;

6. Written procedures shall be developed, implemented, and maintained for responding to an abnormal situation. These procedures shall include:

a. Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions; and

b. The names and telephone numbers of the authorized users, the qualified medical physicist, and the radiation

safety officer to be contacted if the device or console operates abnormally;

7. A copy of the current operating and emergency procedures shall be physically located at the electronic brachytherapy device control console. If the control console is integral to the electronic brachytherapy device, the required procedures shall be kept where the operator is located during electronic brachytherapy device operation;

8. Instructions shall be posted at the electronic brachytherapy device control console to inform the operator of the names and telephone numbers of the authorized users, the qualified medical physicist, and the radiation safety officer to be contacted if the device or console operates abnormally; and

9. The radiation safety officer, or his designee, and an authorized user shall be notified as soon as possible if the patient has a medical emergency, suffers injury, or dies. The radiation safety officer or the qualified medical physicist shall inform the manufacturer of the event.

I. Safety precautions for electronic brachytherapy devices.

1. A qualified medical physicist shall determine which persons in the treatment room require monitoring when the beam is energized;

2. An authorized user and a qualified medical physicist shall be physically present during the initiation of all patient treatments involving the electronic brachytherapy device;

3. A qualified medical physicist and either an authorized user or a nonauthorized user (physician or electronic brachytherapy device operator) under the supervision of an authorized user, who has been trained in the operation and emergency response for the electronic brachytherapy device, shall be physically present during continuation of all patient treatments involving the electronic brachytherapy device;

4. When shielding is required by subdivision C 4 of this section, the electronic brachytherapy device operator shall use a survey meter to verify proper placement of the shielding immediately upon initiation of treatment. Alternatively, a qualified medical physicist shall designate shield locations sufficient to meet the requirements of 12VAC5-481-640 for any individual, other than the patient, in the treatment room; and

5. All personnel in the treatment room shall remain behind shielding during treatment. A qualified medical physicist shall approve any deviation from this requirement and shall designate alternative radiation safety protocols, compatible with patient safety, to provide an equivalent degree of protection.

J. Electronic brachytherapy source calibration measurements.

1. Calibration of the electronic brachytherapy source output for an electronic brachytherapy device subject to this section shall be performed by or under the direct supervision of a qualified medical physicist;

2. Calibration of the electronic brachytherapy source output shall be made for each electronic brachytherapy source after any repair affecting the x-ray beam generation, or when indicated by the electronic brachytherapy source quality assurance checks;

3. Calibration of the electronic brachytherapy source output shall utilize a dosimetry system described in 12VAC5-481-3400 C;

4. Calibration of the electronic brachytherapy source output shall include, as applicable, determination of:

a. The output within 2.0% of the expected value, if applicable, or determination of the output if there is no expected value;

b. Timer accuracy and linearity over the typical range of use;

c. Proper operation of back-up exposure control devices;

d. Evaluation that the relative dose distribution about the source is within 5.0% of that expected; and

e. Source positioning accuracy to within one millimeter within the applicator;

5. Calibration of the x-ray source output required by subdivisions 1 through 4 of this subsection shall be in accordance with current published recommendations from a recognized national professional association with expertise in electronic brachytherapy, when available. In the absence of a calibration protocol published by a national professional association, the manufacturer's calibration protocol shall be followed; and

6. 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 electronic brachytherapy device and a unique identifier for its electronic brachytherapy source; the model numbers and serial numbers of the instrument used to calibrate the electronic brachytherapy device; and the name and signature of the qualified medical physicist responsible for performing the calibration.

K. Periodic and day-of-use quality assurance checks for electronic brachytherapy devices.

1. Quality assurance checks shall be performed on each electronic brachytherapy device:

a. At the beginning of each day of use;

b. Each time the device is moved to a new room or each day of use at each operating location for a self-contained electronic brachytherapy unit transported in a van or trailer; and

c. After each x-ray tube installation.

2. The registrant shall perform periodic quality assurance checks required by subdivision 1 of this subsection in accordance with procedures established by the qualified medical physicist.

3. To satisfy the requirements of subdivision 1 of this subsection, radiation output quality assurance checks shall include at a minimum:

a. Verification that output of the electronic brachytherapy source falls within 3.0% of expected values, as appropriate for the device, as determined by:

(1) Output as a function of time, or

(2) Output as a function of setting on a monitor chamber.

b. Verification of the consistency of the dose distribution to within 3.0% of that found during calibration required by subsection J of this section; and

c. Validation of the operation of positioning methods to ensure that the treatment dose exposes the intended location within one millimeter.

4. The registrant shall use a dosimetry system that has been intercompared within the previous 12 months with the dosimetry system described in 12VAC5-481-3400 C 1 to make the quality assurance checks required in subdivision 3 of this subsection.

5. The registrant shall review the results of each radiation output quality assurance check according to the following procedures:

a. An authorized user and qualified medical physicist shall be immediately notified if any parameter is not within its acceptable tolerance. The electronic brachytherapy device shall not be made available for subsequent medical use until the qualified medical physicist has determined that all parameters are within the acceptable tolerances;

b. If all radiation output quality assurance check parameters appear to be within the acceptable range, the quality assurance check shall be reviewed and signed by either the authorized user or qualified medical physicist within two days; and

c. The qualified medical physicist shall review and sign the results of each radiation output quality assurance check at intervals not to exceed 30 days.

6. To satisfy the requirements of subdivision 1 of this subsection, safety device quality assurance checks shall, at a minimum, assure:

a. Proper operation of radiation exposure indicator lights on the electronic brachytherapy device and on the control console;

b. Proper operation of viewing and intercom systems in each electronic brachytherapy facility, if applicable;

c. Proper operation of radiation monitors, if applicable;

d. The integrity of all cables, catheters, or parts of the device that carry high voltages; and

e. Connecting guide tubes, transfer tubes, transfer-tube-applicator interfaces, and treatment spacers are free from any defects that interfere with proper operation.

7. If the results of the safety device quality assurance checks required in subdivision 6 of this subsection indicate the malfunction of any system, a registrant shall secure the control console in the "OFF" position and not use the electronic brachytherapy device except as may be necessary to repair, replace, or check the malfunctioning system.

8. The registrant shall maintain a record of each quality assurance check required by subdivisions 3 and 7 of this subsection in an auditable form for three years.

a. The record shall include the date of the quality assurance check; the manufacturer's name, model number, and serial number for the electronic brachytherapy device; the name and signature of the individual who performed the periodic quality assurance check; and the name and signature of the qualified medical physicist who reviewed the quality assurance check; and

b. For radiation output quality assurance checks required by subdivision 3 of this subsection, the record shall also include the unique identifier for the electronic brachytherapy source and the manufacturer's name, model number, and serial number for the instrument used to measure the radiation output of the electronic brachytherapy device.

L. Therapy-related computer systems. The registrant shall perform acceptance testing on the treatment planning system of electronic brachytherapy-related computer systems in accordance with current published recommendations from a recognized national professional association with expertise in electronic brachytherapy, when available. In the absence of an acceptance testing protocol published by a national professional association, the manufacturer's acceptance testing protocol shall be followed.

1. Acceptance testing shall be performed by or under the direct supervision of a qualified medical physicist. At a minimum, the acceptance testing shall include, as applicable, verification of:

a. The source-specific input parameters required by the dose calculation algorithm;

b. The accuracy of dose, dwell time, and treatment time calculations at representative points;

c. The accuracy of isodose plots and graphic displays;

d. The accuracy of the software used to determine radiation source positions from radiographic images; and

e. If the treatment-planning system is different from the treatment-delivery system, the accuracy of electronic

transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

2. The position indicators in the applicator shall be compared to the actual position of the source or planned dwell positions, as appropriate, at the time of commissioning.

3. Prior to each patient treatment regimen, the parameters for the treatment shall be evaluated and approved by the authorized user and the qualified medical physicist for correctness through means independent of that used for the determination of the parameters.

M. Training.

1. A registrant shall provide instruction, initially and at least annually, to all individuals who operate the electronic brachytherapy device, as appropriate to the individual's assigned duties, in the operating procedures identified in subsection H of this section. If the interval between patients exceeds one year, retraining of the individuals shall be provided.

2. In addition to the requirements of 12VAC5-481-3390 C for therapeutic radiation machine authorized users and 12VAC5-481-3390 D for qualified medical physicists, the therapeutic radiation machine authorized users and qualified medical physicists shall also receive device-specific instruction initially from the manufacturer and annually from either the manufacturer or other qualified trainer. The training shall be of a duration recommended by a recognized national professional association with expertise in electronic brachytherapy, when available. In the absence of any training protocol recommended by a national professional association, the manufacturer's training protocol shall be followed. The training shall include, but not be limited to:

a. Device-specific radiation safety requirements;

b. Device operation;

c. Clinical use for the types of use approved by the U.S. Food and Drug Administration;

d. Emergency procedures, including an emergency drill; and

e. The registrant's quality assurance program.

3. A registrant shall retain a record of individuals receiving instruction required by subdivisions 1 and 2 of this subsection for three years. The record shall include a list of the topics covered, the date of the instruction, the names of the attendees, and the names of the individuals who provided the instruction.

N. Mobile electronic brachytherapy service. A registrant providing mobile electronic brachytherapy service shall, at a minimum:

1. Check all survey instruments before medical use at each address of use or on each day of use, whichever is more restrictive.

2. Account for the electronic brachytherapy source in the electronic brachytherapy device before departure from the client's address.

3. Perform at each location on each day of use all of the required quality assurance checks specified in subsection K of this section to assure proper operation of the device.

12VAC5-481-3453. Other use of electronically produced radiation to deliver therapeutic radiation dosage.

A person shall not utilize any device that is designed to electronically generate a source of ionizing radiation to deliver therapeutic radiation dosage and that is not appropriately regulated under any existing category of therapeutic radiation machine until:

1. The applicant or registrant has, at a minimum, provided the agency with:

a. A detailed description of the device and its intended application;

b. Facility design requirements, including shielding and access control;

c. Documentation of appropriate training for authorized user physicians and qualified medical physicists;

d. Methodology for measurement of dosages to be administered to patients or human research subjects;

e. Documentation regarding calibration, maintenance, and repair of the device, as well as instruments and equipment necessary for radiation safety;

f. Radiation safety precautions and instructions; and

g. Other information requested by the agency in its review of the application; and

2. The applicant or registrant has received written approval from the agency to utilize the device in accordance with the regulations and specific conditions the agency considers necessary for the medical use of the device.

DOCUMENTS INCORPORATED BY REFERENCE (12VAC5-481)

Dosimetry of X-ray and Gamma-Ray Beams for Radiation Therapy in the Energy Range 10 keV to 50 MeV: NCRP Report 69, 1981, National Council on Radiation Protection and Measurements, 7910 Woodmont Avenue, Washington, DC 20014

Comprehensive QA for Radiation Oncology: AAPM Report No. 46, 1994, American Association of Physicists in Medicine, Committee Task Group 40, Radiation Therapy Committee, published by the American Institute of Physics, One Physics Ellipse, College Park, MD 20740-3846

AAPM Code of Practice for Radiotherapy Accelerators: AAPM Report Number 47, 1994, American Association of Physicists in Medicine Radiation Therapy Task Group 45,

published by the American Institute of Physics, One Physics Ellipse, College Park, MD 20740-3846

Guidance document on delivery, treatment planning, and clinical implementation of IMRT: Report of the IMRT subcommittee of the AAPM radiation therapy committee: AAPM Report No. 82, Medical Physics, Vol. 30, No. 8, August 2003, American Association of Physicists in Medicine

Quality assurance for computed tomography simulators and the computed tomography-simulation process: Report of the AAPM Radiation Therapy Committee Task Group No. 66: AAPM Report No. 83, Medical Physics, Vol. 30, No. 10, October 2003, American Association of Physicists in Medicine

VA.R. Doc. No. R16-4305; Filed March 25, 2016, 1:12 p.m.

DEPARTMENT OF MEDICAL ASSISTANCE SERVICES

Withdrawal of Proposed Regulation

Titles of Regulations: **12VAC30-50. Amount, Duration, and Scope of Medical and Remedial Care Services (amending 12VAC30-50-160, 12VAC30-50-210).**

12VAC30-80. Methods and Standards for Establishing Payment Rates; Other Types of Care (amending 12VAC30-80-40).

The Department of Medical Assistance Services has WITHDRAWN the proposed regulatory action for 12VAC30-50, Amount, Duration, and Scope of Medical and Remedial Care Services; and 12VAC30-80, Methods and Standards for Establishing Payment Rates; Other Types of Care, which was published in 16:26 VA.R. 3459-3465 September 11, 2000. The agency has determined that this action is no longer relevant or necessary.

Agency Contact: William Lessard, Director, Division of Program Reimbursement, Department of Medical Assistance Services, 600 East Broad Street, Suite 1300, Richmond, VA 23219, telephone (804) 225-4593, or email william.lessard@dmas.virginia.gov.

VA.R. Doc. No. R00-1; Filed March 18, 2016, 11:41 a.m.

TITLE 15. JUDICIAL

VIRGINIA STATE BAR

Final Regulation

REGISTRAR'S NOTICE: The Virginia State Bar is claiming an exemption from the Administrative Process Act in accordance with § 2.2-4002 A 2 of the Code of Virginia, which exempts agencies of the Supreme Court.

Title of Regulation: **15VAC5-40. Bylaws of the Virginia State Bar and Council (repealing 15VAC5-40-10 through 15VAC5-40-430).**

Statutory Authority: § 54.1-3910 of the Code of Virginia.

Effective Date: March 25, 2016.

Agency Contact: Stephanie Blanton, Executive Assistant, Virginia State Bar, 1111 East Main Street, Suite 700, Richmond, VA 23219, telephone (804) 775-0576, or email blanton@vsb.org.

Summary:

Due to a determination that the Bylaws of the Virginia State Bar and Council are not regulations as defined by § 2.2-4101 of the Code of Virginia, 15VAC5-40 is repealed.

VA.R. Doc. No. R16-4610; Filed March 18, 2016, 3:05 p.m.

Final Regulation

REGISTRAR'S NOTICE: The Virginia State Bar is claiming an exemption from the Administrative Process Act in accordance with § 2.2-4002 A 2 of the Code of Virginia, which exempts agencies of the Supreme Court.

Title of Regulation: **15VAC5-80. Regulations under the Virginia Consumer Real Estate Settlement Protection Act (amending 15VAC5-80-10 through 15VAC5-80-50).**

Statutory Authority: § 55-525.30 of the Code of Virginia.

Effective Date: March 25, 2016.

Agency Contact: Stephanie Blanton, Executive Assistant, Virginia State Bar, 1111 East Main Street, Suite 700, Richmond, VA 23219, telephone (804) 775-0576, or email blanton@vsb.org.

Summary:

The amendments conform the regulation to changes enacted by Chapter 794 of the 2010 Acts of Assembly, which repealed Title 6.1 of the Code of Virginia and transferred the provisions regarding real estate settlements and settlement agents to new Chapters 27.2 (§ 55-525.8 et seq.) and 27.3 (§ 55-525.16 et seq.) of Title 55 of the Code of Virginia as part of the recodification of Title 6.1. The amendments update citations to the Code of Virginia and terminology.

CHAPTER 80

~~REGULATIONS UNDER THE VIRGINIA CONSUMER~~ ATTORNEY REAL ESTATE SETTLEMENT ~~PROTECTION ACT~~ AGENTS REGULATIONS

15VAC5-80-10. Authority; applicability; scope.

~~These regulations are~~ This chapter is issued by the Virginia State Bar pursuant to ~~and under the authority of the Virginia Consumer Real Estate Settlement Protection Act (§ 6.1 2.19 et seq.~~ Chapter 27.3 (§ 55-525.16 et seq.) of Title 55 of the Code of ~~Virginia) as enacted by the 1997 session of the General Assembly of~~ Virginia. ~~The Act~~ Chapter 27.3 does not apply to licensed attorneys who provide escrow, closing, or