PUBLIC HEARING DRAFT – REVISED 1 AUGUST 2013

PROPOSED AMENDMENTS TO

RULES AND REGULATIONS FOR THE CONTROL OF RADIATION

[R23-1.3-RAD]

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

DEPARTMENT OF HEALTH

June 1978

AS AMENDED:

February 1979
June 1981
October 1984
February 1990
February 1990 (E)
January 1991 (E)
August 1991
December 1993 (E)
February 1994
June 1995
June 1999
July 2001
January 2002 (re-filing in accordance with the provisions of §42-35-4.1 of the Rhode Island General Laws, as amended)
September 2004
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January 2007 (re-filing in accordance with the provisions of §42-35-4.1 of the Rhode Island General Laws, as amended)
June 2007
September 2007
January 2012 (re-filing in accordance with the provisions of §42-35-4.1 of the Rhode Island General Laws, as amended)
September 2012
September 2013 (Proposed)

COMPILER'S NOTES:
Proposed Additions: Double Underlined
Proposed Deletions: ~~Strikeouts~~

SUMMARY OF MOST RECENT AMENDMENT ACTIONS

These amendments to the *Rules and Regulations for the Control of Radiation* [*R23-1.3-RAD*] are promulgated pursuant to the authority conferred under ~~section~~§23-1.3-5(f) of the General Laws of Rhode Island, as amended, to insure conformance with established radiation control standards, rules and regulations for the protection of radiation workers and the general public~~, and for the purpose of adopting revised initial and annual radioactive materials license fees~~.

Pursuant to the provisions of ~~section 42-35-3(c)~~ §42-35-3(a)(3) and §42-35.1-4 of the General Laws of Rhode Island, as amended, the following ~~issues~~ were given ~~serious~~ consideration in arriving at the amended regulations:

(a) Alternative approaches to the regulations; ~~and~~

(b) Duplication or overlap with other state laws and regulations; and

(c) Significant economic impact on small business.

Based on the available information, no known alternative approach, duplication or overlap ~~were~~ was identified.

Upon promulgation of these amendments, these amended regulations shall supersede all previous *Rules and Regulations for the Control of Radiation*, promulgated by the Radiation Control Agency, Rhode Island Department of Health and filed with the Secretary of State.

PART A
DEFINITIONS, GENERAL PROVISIONS OF THE REGULATIONS; STANDARDS FOR PROTECTION AGAINST RADIATION; NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS; INSPECTIONS

A.0 DEFINITIONS

***

A_1 means the maximum activity of special form radioactive material permitted in a Type A package. This value is either listed in Appendix G to Part A or may be derived in accordance with the procedures described in Appendix G to Part A. [See Type A Quantity]

A_2 means the maximum activity of radioactive material, other than special form material, LSA and SCO material, permitted in a Type A package. This value is either listed in Appendix G to Part A or may be derived in accordance with the procedures described in Appendix G to Part A. [See Type A Quantity]

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Accessory component means:

(1) A component used with diagnostic X-ray systems, such as a cradle or film changer, that is not necessary for the compliance of the system with applicable provisions of Part F of these Regulations but which requires an initial determination of compatibility with the system; or

(2) A component necessary for compliance of the system with applicable provisions of Part F of these Regulations but which may be interchanged with similar compatible components without affecting the system's compliance, such as one of a set of interchangeable beam-limiting devices; or

(3) A component compatible with all X-ray systems with which it may be used and that does not require compatibility or installation instructions, such as a tabletop cassette holder.

***

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

***

Agency means Rhode Island Radiation Control Agency. [Office of Facilities Regulation - Radiation Control Program ~~Occupational and Radiological Health~~, Rhode Island Department of Health].

***

Air kerma means kerma in air (see definition of Kerma).

Air kerma rate (AKR) means the air kerma per unit time

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

***

Authorized medical physicist (for uses authorized pursuant to Subpart C.8) means an individual who:

(1) Meets the requirements in C.8.71 and C.8.74; or

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

(i) A specific medical use license or equivalent permit issued by the Agency, U.S. Nuclear Regulatory Commission~~,~~ or another Agreement State ~~or Licensing State~~; or

(ii) A permit issued by an Agency, Nuclear Regulatory Commission~~,~~ or another Agreement State ~~or Licensing State~~ specific medical use license of broad scope that is authorized to permit the use of radioactive material.

Authorized nuclear pharmacist means a pharmacist who:

(1) Meets the requirements in C.8.76 and C.8.74; or

(2) Is identified as an authorized nuclear pharmacist on:

(i) A specific license or equivalent permit that authorizes medical use, the practice of nuclear pharmacy, commercial nuclear pharmacy or the manufacture and distribution of radiopharmaceuticals issued by the Agency, U.S. Nuclear Regulatory Commission~~,~~ or another Agreement State ~~or Licensing State~~; or

(ii) A permit issued by an Agency, U.S. Nuclear Regulatory Commission~~,~~ or another Agreement State ~~or Licensing State~~ specific license of broad scope that is authorized to permit the use of radioactive material.

Authorized user means an individual who is:

(1) Identified as an Authorized User on an Agency, Agreement State~~, Licensing State~~ or U.S. Nuclear Regulatory Commission license. The Authorized User for medical use of radioactive material means a physician, dentist or podiatrist who:

(i) Meets the requirements in C.8.74 and C.8.64(a), C.8.65(a), C.8.66(a), C.8.67(a), C.8.69(a), or C.8.70(a); or

(ii) Is identified as an Authorized User on:

(a) A license or equivalent permit issued by the Agency, U.S. Nuclear Regulatory Commission~~,~~ or another Agreement State ~~or Licensing State~~; or

(b) A permit issued by an Agency, U.S. Nuclear Regulatory Commission~~,~~ or another Agreement State ~~or Licensing State~~ specific license of broad scope that is authorized to permit the medical use of radioactive material.

or

(2) Qualified as an Authorized User under an Agency registration by satisfying the training requirements of H.3.3 of these regulations.

***

Automatic exposure rate ~~control~~ (AERC) means a device which automatically controls one or more technique factors in order to obtain, at a preselected location(s), a required quantity of radiation per unit time. (See also Phototimer).

***

Byproduct material means:

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

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

(3) (i) Any discrete source of Radium-226 that is produced, extracted, or converted after extraction,

before, on or after 8 August 2005, for use for a commercial, medical, or research activity; or

(ii) Any material that:

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

(b) Is produced, extracted, or converted after extraction, before, on or after 8 August 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:

(i) The U.S Nuclear Regulatory Commission, 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

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

***

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

C-arm fluoroscope means a fluoroscopic X-ray system in which the image receptor and the X-ray tube housing assembly are connected or coordinated to maintain a spatial relationship. Such a system allows a change in the direction of the beam axis with respect to the patient without moving the patient.

***

Cantilevered tabletop means a tabletop designed such that the unsupported portion can be extended at least one hundred (100) cm beyond the support.

***

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

***

~~Certified components means components of X-ray systems which are subject to the X-Ray Equipment Performance Standard promulgated under Public Law 90-602, the Radiation Control for Health and Safety Act of 1968.~~

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

***

Certificate of Compliance (CoC) means the certificate issued by the U.S. Nuclear Regulatory Commission under 10 CFR 71, Subpart D which approves the design of a package for the transportation of radioactive material.

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

***

Coefficient of variation (C) means the ratio of the standard deviation to the mean value of a ~~set~~ 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 = Estimated standard deviation of the ~~observed value~~ population;

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

x_i = i_{th} observation in sample;

n = Number of observations in sample

***

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

***

Computed tomography (CT) means the production of a tomogram by the acquisition and computer processing of X-ray transmission data

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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 medical facility.

***

Construction means the installation of foundations, or in-place assembly, erection, fabrication, or testing for any structure, system, or component of a facility or activity subject to these Regulations that are related to radiological safety or security. The term "construction" does not include:

(1) Changes for temporary use of the land for public recreational purposes;

(2) Site exploration, including necessary borings to determine foundation conditions or other pre-construction monitoring to establish background information related to the suitability of the site, the environmental impacts of construction or operation, or the protection of environmental values;

(3) Preparation of the site for construction of the facility, including clearing of the site, grading, installation of drainage, erosion and other environmental mitigation measures, and construction of temporary roads and borrow areas;

(4) Erection of fences and other access control measures that are not related to the safe use of, or security of, radiological materials subject to these re4gulations;

(5) Excavation;

(6) Erection of support buildings (e.g., construction equipment storage sheds, warehouse and shop facilities, utilities, concrete mixing plants, docking and unloading facilities, and office buildings) for use in connection with the construction of the facility;

(7) Building of service facilities (e.g., paved roads, parking lots, railroad spurs, exterior utility and lighting systems, potable water systems, sanitary sewerage treatment facilities, and transmission lines);

(8) Procurement or fabrication of components or portions of the proposed facility occurring at other than the final, in-place location at the facility; or

(9) Taking any other action that has no reasonable nexus to radiological health and safety.

***

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.

***

Cradle means:

(1) A removable device which supports and may restrain a patient above an X-ray table; or

(2) A device;

(i) Whose patient support structure is interposed between the patient and the image receptor during normal use;

(ii) Which is equipped with means for patient restraint; and

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

***

Criticality Safety Index (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 10 CFR 71.22, 71.23 and 71.59.

***

CT dosimetry phantom means the phantom used for determination of the dose delivered by a CT X-ray system. The phantom shall be a right circular cylinder of polymethl-methacrylate of density 1.19±0.01 grams per cubic centimeter. The phantom shall be at least 14 centimeters in length and shall have diameters of 32.0 centimeters for testing any CT system designed to image any section of the body (whole body scanners) and 16.0 centimeters for any system designed to image the head (head scanners) or for any whole body scanner operated in the head scanning mode. The phantom shall provide means for the placement of a dosimeter(s) along its axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom. Means for the placement of a dosimeter(s) or alignment device at other locations may be provided for convenience. Any effect on the doses measured due to the removal of phantom material to accommodate dosimeters shall be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom.

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

***

CT gantry means the tube housing assemblies, beam-limiting devices, detectors, and the supporting structures, frames and covers ~~frames~~ which hold and/or enclose these components.

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~~CTN (See "CT number").~~

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

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

***

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

***

Deuterium means, for the purposes of 10 CFR 71.15 and 71.22, deuterium and any deuterium compounds, including heavy water, in which the ratio of deuterium atoms to hydrogen atoms exceeds 1:5000.

***

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.

***

~~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, "radiation dose" is an equivalent term.~~

Dose means the absorbed dose as defined by the International Commission on Radiation Units and Measurements. The absorbed dose, D, is the quotient of de by dm, where de is the mean energy imparted to matter of mass dm; thus D=de/dm, in units of J/kg, where the special name of the unit of absorbed dose is gray (Gy).

***

~~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").~~

***

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

***

~~Entrance exposure rate means the exposure free in air per unit time.~~

***

Exposure (X) means the quotient of dQ by dm where dQ is the absolute value of the total charge of the ions of one sign produced in air when all the electrons and positrons liberated or created by photons in air of mass dm

are completely stopped in air; thus X=dQ/dm, in units of C/kg. A second meaning of exposure is the process or condition during which the X-ray tube produces X-ray radiation.

***

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.

***

Fluoroscopic air kerma display device means a device, subsystems or component that provides the display of AKR and cumulative air kerma, respectively, required by Subpart F.4 of these Regulations. It includes radiation detectors, if any, electronic and computer components, associated software, and data displays.

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

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.

***

Graphite means, for the purposes of 10 CFR 71.15 and 71.22, graphite with a boron equivalent content less than five (5) parts per million and density greater than one and one-half (1.5) grams per cubic centimeter.

***

Half-value layer (HVL) means the thickness of specified material which attenuates the beam of radiation to an extent such that the ~~exposure~~ AKR ~~rate~~ 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 X-ray equipment means X-ray equipment that is designed to be hand-held during operation.

***

Image receptor means any device, such as a fluorescent screen, ~~or~~ radiographic film, X-ray image intensifier tube, solid-state detector, or gaseous detector which transforms incident X-ray photons either into a visible image or into another form which can be made into a visible image by further transformations. 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 mammography X-ray systems, that part of the system designed to support the image receptor during a mammographic examination and to provide a primary protective barrier.

***

Indian tribe means an Indian or Alaska native tribe, band, nation, pueblo, village, or community that the

Secretary of the Interior acknowledges to exist as an Indian tribe pursuant to the Federally Recognized Indian Tribe List Act of 1994, 25 U.S.C. 479a.

***

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

***

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.

***

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

***

Last image hold (LIH) radiograph 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.

***

Lateral fluoroscope means the X-ray tube and image receptor combination in a biplane system dedicated to the lateral projection. It consists of the lateral X-ray tube housing assembly and the lateral image receptor that are fixed in position relative to the table with the X-ray beam axis parallel to the plane of the table.

***

~~Licensing State means any state, which has been finally designated as such by the Conference of Radiation Control Program Directors, Inc., which reviews state regulations to establish equivalency with the Suggested State Regulations and ascertains whether a State has an effective program for control of natural occurring or accelerator produced radioactive material (NARM). The Conference will designate as Licensing States those states with regulations for control of radiation relating to, and an effective program for, the regulatory control of NARM.~~

***

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: ~~It is calculated using the following equation:~~

Percent line-voltage regulation = $100\ (V_n-V_1)/V_1$

where:

V_n = No-load line potential and

V_1 = Load line potential

***

Low specific activity (LSA) material means radioactive material with limited specific activity which is nonfissile or is excepted under 10 CFR 71.15, and which satisfies ~~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 shall be in one of three (3) groups:

(a) LSA-I

(1) Uranium and thorium ores, concentrates of uranium and thorium ores, and other ores containing ~~only~~ naturally occurring radioactive radionuclides[1] which are not intended to be processed for the use of these radionuclides ~~and uranium or thorium concentrates of such ores; or~~

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

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

(4) Other radioactive material in which the activity is distributed throughout and the estimated average specific activity does not exceed thirty (30) times the value for exempt material activity concentration determined in accordance with Appendix G to Part A of these Regulations. ~~Mill tailings, contaminated earth, concrete, rubble, other bulk debris, and activated material in which the radioactive material is essentially uniformly distributed, and the average specific activity does not exceed 10^{-6} A_2/g.~~

(b) LSA-II

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

(2) Other material in which the ~~radioactive material~~ activity is distributed throughout, and the average specific activity does not exceed 10^{-4} A_2/g for solids and gases, and 10^{-5} A_2/g for liquids.

(c) LSA-III Solids[2], excluding powders, that satisfy the requirements of 10 CFR 71.77, in which:

(1) 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[3]; and

(2) 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 7 days, would not exceed 0.1 A_2; and

(3) The average specific activity of the solid does not exceed 2×10^{-3} 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 ten (10) days.

***

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

***

Mode of operation means, for fluoroscopic 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

[1] ~~For example, uranium or thorium decay series radionuclides~~

[2] For example, consolidated wastes, ~~or~~ activated materials.

[3] For example, concrete, bitumen, or ceramic.

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.

***

Modulation transfer function means the modulus of the Fourier transform of the impulse response of the system.

***

Movable tabletop means a tabletop which, when assembled for use, is capable of movement with respect to its supporting structure within the plane of the tabletop.

***

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 Appendix H to Part A of these Regulations. 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 which 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 uranium means uranium isotopes with the naturally occurring distribution of uranium, which is approximately 0.711 weight percent uranium-235, and the remainder by weight essentially uranium-238.~~

***

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

***

Positron Emission Tomography (PET) radionuclide production facility means a facility operating a cyclotron or accelerator for the purpose of producing PET radionuclides.

***

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 6 September 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 10 CFR 71. ~~49 CFR Part 173, Subpart I~~. 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.

***

Primary protective barrier ~~(See "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 purposes.

***

~~Protective barrier means a barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:~~

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

~~(2) "Secondary protective barrier" means the material which attenuates stray radiation.]~~

***

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

***

Qualified Medical Physicist (for activities authorized pursuant to Part F) means an individual registered to provide Radiation Physics Services (Diagnostic X-ray Physics Services) in accordance with B.4 of these Regulations.

Qualified Medical Physicist (for activities authorized pursuant to Part H) means an individual qualified in accordance with H.3.4 of these Regulations.

***

Quick change X-ray tube means an X-ray tube designed for use in its associated tube housing such that:

(1) The tube cannot be inserted in its housing in a manner that would result in noncompliance of the system with the requirements of F.5 of these Regulations;

(2) The focal spot position will not cause noncompliance with the provisions of F.5 of these Regulations;

(3) The shielding within the tube housing cannot be displaced; and

(4) Any removal and subsequent replacement of a beam-limiting device during reloading of the tube in the tube housing will not result in noncompliance of the X-ray system with the applicable field limitation and alignment requirements of F.5 of these Regulations.

***

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

Radiography means a technique for generating and recording an X-ray pattern for the purpose of providing the user with an image(s) after termination of the exposure.

***

~~Radiotherapy Physicist means: (1) an individual who is registered with the Agency in accordance with Subpart B.4 to provide Radiotherapy Physics Services; or (2) an individual identified as the qualified radiotherapy physicist on an Agency Certificate of Registration.~~

***

Rated line voltage means the range of potentials, in volts, of the supply line specified by the manufacturer at which the X-ray machine is designed to operate.

Rated output current means the maximum allowable load current of the X-ray high-voltage generator

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

***

Recording means producing a ~~permanent~~ retrievable form of an image resulting from X-ray photon interactions ~~photons (e.g., film, video tape)~~.

***

Remanufacturing means modifying a CT system in such a way that the resulting dose and imaging performance become substantially equivalent to any CT X-ray system manufactured by the original manufacturer on or after 29 November 1984. Any reference in F.10 of these Regulations to "manufacture," "manufacturer," or "manufacturing" includes remanufacture, remanufacturer and remanufacturing, respectively.

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RIGL means the General Laws of Rhode Island, as amended.

***

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

***

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

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Sensitivity profile means the relative response of the CT X-ray system as a function of position along a line perpendicular to the tomographic plane.

***

Solid state X-ray imaging device means an assembly, typically in a rectangular panel configuration, that intercepts X-ray photons and converts the photon energy into a modulated electronic signal representative of the X-ray intensity over the area of the imaging device. The electronic signal is then used to create an image for display and/or storage.

***

Source-skin distance (SSD) means the distance from the source to the center of the entrant X-ray field in the plane tangent to the patient skin surface.

***

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

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

(b) The piece or capsule has at least one dimension not less than 5 millimeters (0.2 in.); and

(c) It satisfies the test requirements of 10 CFR 71.75 ~~specified by the Nuclear Regulatory Commission~~. A special form encapsulation designed in accordance with the Nuclear Regulatory Commission requirements in effect on 30 June 1983, (see 10 CFR Part 71, revised as of 1 January 1983), and constructed prior to 1

July 1985, ~~may continue to be used.~~ and a special form encapsulation designed in accordance with the ~~Nuclear Regulatory Commission~~ requirements of 10 CFR 71.4 in effect on 31 March 1996 (see 10 CFR Part 71, revised as of 1 January 1983), and constructed prior to 1 April 1, 1998, may continue to be used. Any other special form encapsulation must meet the specifications of this definition. ~~A special form encapsulation either designed or constructed after April 1, 1998, shall meet requirements of this definition applicable at the time of its design or construction.~~

***

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

***

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

***

Stationary tabletop means a tabletop which, when assembled for use, is incapable of movement with respect to its supporting structure within the plane of the tabletop.

***

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

***

Tomographic plane means that geometric plane which the manufacturer identified ~~is identified~~ as corresponding to the output tomogram.

***

Total effective dose equivalent (TEDE) means the sum of the ~~deep~~ effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

***

Tribal official means the highest ranking individual that represents Tribal leadership, such as the Chief, President, or Tribal Council leadership.

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.

***

Uranium, natural, depleted, enriched:

(1) Natural uranium means uranium with the naturally occurring distribution of uranium isotopes (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.

***

Useful beam means the radiation ~~emanating from~~ which passes through the tube housing port ~~or~~ and ~~the radiation head and passing through~~ the aperture of the beam limiting device when the exposure ~~controls are in a mode to cause the system to produce radiation~~ switch or timer is activated.

***

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 paragraphs (2), (3), and (4) of the definition of Byproduct material set forth in this section.

***

X-ray control means a device which controls input power to the X-ray high-voltage generator and/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 field means that area of the intersection of the useful beam and any one of a set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the ~~exposure rate~~ AKR is one-fourth of the maximum in the intersection.

X-ray subsystem means any combination of two or more components of an X-ray system for which there are requirements specified in Subparts A.0. F.3, F.4 and F.5 of these Regulations.

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

***

***

A.1 GENERAL PROVISIONS

***

A.1.8 **Communications.** All communications and reports concerning these regulations, and applications filed thereunder, should be addressed to the Agency at its office located at:

Rhode Island Department of Health
~~Office of Occupational and Radiological Health~~
Office of Facilities Regulation
Radiation Control Program
Three Capitol Hill- Room ~~206~~ 305
Providence, RI 02908-5097

***

***

A.2 STANDARDS FOR PROTECTION AGAINST RADIATION

***

A.2.3 **Occupational Dose Limits for Adults.**

***

(c) When the external exposure is determined by measurement with an external personal monitoring device, the deep-dose equivalent shall be used in place of the effective dose equivalent, unless the effective

dose equivalent is determined by a dosimetry method approved by the Agency. The assigned deep-dose equivalent shall be for the part of the body receiving the highest exposure. The assigned shallow-dose equivalent shall be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure. The deep-dose equivalent, lens-dose equivalent, and shallow-dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable.

***

***

A.2.15 **Criteria for License Termination Under Restricted Conditions.** A site will be considered acceptable for license termination under restricted conditions if:

***

(c) The licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site. Acceptable financial assurance mechanisms are:

(1) Funds placed into ~~an account~~ a trust segregated from the licensee's assets and outside the licensee's administrative control, and in which the adequacy of the trust funds is to be assessed based on an assumed annual one percent (1%) real rate of return on investment ~~as described in C.5.16(f)(1)~~;

(2) ~~Surety method, insurance, or other guarantee method as described in C.5.16 (f)(2);~~

~~(3)~~ A statement of intent in the case of Federal, State, or local Government licensees, as described in C.5.16 (f)(4); or

(~~4~~ 3)When a governmental entity is assuming custody and ownership of a site, an arrangement that is deemed acceptable by such governmental entity.

***

***

A.2.16 **Alternate Criteria for License Termination.**

(a) The Agency may terminate a license using alternate criteria greater than the dose criterion of A.2.14, A.2.15(b), and A.2.15(d)(1)(i)(a), if the licensee:

***

(5) Has provided sufficient financial assurance in the form of a trust fund to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site.

***

***

A.2.18 **Minimization of Contamination.**

(a) Applicants for licenses, other than renewals shall describe in the application how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste.

(b) Licensees shall, to the extent practical, conduct operations to minimize the introduction of residual radioactivity into the site, including the subsurface, in accordance with the existing radiation protection

requirements in A.2.3 through A.2.6, and A.2.8 through A.2.10 of these Regulations, and radiological criteria for license termination in A.2.13 through A.2.18 of these Regulations.

***

***

A.3 PRECAUTIONARY PROCEDURES

A.3.1 **Testing for Leakage or Contamination of Sealed Sources.**

(a) The licensee in possession of any sealed source shall assure that:

***

(2) Each sealed source that is not designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed six (6) months or at alternative intervals approved by the Agency, after evaluation of information specified by C.5.5(l)(4) and (5), an Agreement State~~, a Licensing State,~~ or the U.S. Nuclear Regulatory Commission.

(3) Each sealed source that is designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed three (3) months or at alternative intervals approved by the Agency, after evaluation of information specified by C.5.5(l)(4) and (5), an Agreement State~~, a Licensing State,~~ or the U.S. Nuclear Regulatory Commission.

***

(c) Tests for leakage or contamination from sealed sources shall be performed by persons specifically authorized by the Agency, another Agreement State~~, a Licensing State,~~ or the U.S. Nuclear Regulatory Commission to perform such services.

***

***

A.3.2 **General Survey and Monitoring Requirements.**

(a) Each licensee or registrant shall make, or cause to be made, surveys of areas, including the subsurface, that:

(1) Are necessary for the licensee or registrant to comply with this Part; and

(2) Are reasonable under the circumstances to evaluate:

(i) The magnitude and extent of radiation levels; and

(ii) Concentrations or quantities of ~~radioactive material~~ residual radioactivity; and

(iii) The potential radiological hazards of the radiation levels and residual radioactivity detected.

(b) Notwithstanding A.5.3, records from surveys describing the location and amount of subsurface residual radioactivity identified at the site must be kept with records important for decommissioning, and such records must be retained in accordance with C.5.16(g).

(~~b~~ c) The licensee or registrant shall ensure that instruments and equipment used for quantitative radiation measurements, for example, dose rate and effluent monitoring, are calibrated at intervals not to exceed twelve (12) months for the radiation measured, unless a different calibration interval is specified in the appropriate Part(s) of these regulations.

(~~c~~ d) All personnel dosimeters, except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to any extremity, that require processing to determine the radiation dose and that are used by licensees and registrants to comply with A.2.3, with other applicable provisions, or with

conditions specified in a license or registration shall be processed and evaluated by a dosimetry processor:

(1) Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and

(2) Approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

(~~d~~ e) Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.

***

***

A.4 WASTE DISPOSAL

A.4.1 **General Requirements.**

(a) A licensee shall dispose of licensed material only:

(1) By transfer to an authorized recipient as provided in A.4.6, Part C, or to the U.S. Department of Energy; or

(2) By decay in storage; or

(3) By release in effluents within the limits in A.2.11; or

(4) As authorized pursuant to A.4.2, A.4.3, A.4.4, ~~or~~ A.4.5 or A.4.8.

(b) A person shall be specifically licensed to receive waste containing licensed material from other persons for:

(1) Treatment prior to disposal; or

(2) Treatment or disposal by incineration; or

(3) Decay in storage; or

(4) Disposal at a land disposal facility licensed pursuant to 10 CFR 61 or the equivalent regulations of an Agreement State ~~or Licensing State~~; or

***

***

A.4.6 **Transfer for Disposal and Manifests.**

***

(e) Any licensee shipping byproduct material, as defined in paragraphs (3) and (4) of the definition of Byproduct material set forth in A.0, intended for ultimate disposal at a land disposal facility licensed under 10 CFR 61, or the equivalent regulations of an Agreement State, shall document the information required on the NRC's Uniform Low- Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with Appendix D to Part A.

***

***

A.4.8 **Disposal of 11e(3) and 11e(4) Byproduct Material.**

(a) Licensed material, as defined in paragraphs (3) and (4) of the definition of byproduct material set forth in A.0, may be disposed of in accordance with 10 CFR 61, or the equivalent regulations of an Agreement State,

even though it is not defined as low level radioactive waste. Therefore, any licensed byproduct material being disposed of at a facility, or transferred for ultimate disposal at a facility licensed under 10 CFR 61, or the equivalent regulations of an Agreement State, shall meet the requirements of A.4.6.

(b) A licensee may dispose of byproduct material, as defined in paragraphs (3) and (4) of the definition of byproduct material set forth in A.0, at a disposal facility authorized to dispose of such material in accordance with any Federal or State solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005.

***

***

A.5 RECORDS, REPORTS AND ADDITIONAL REQUIREMENTS

***

A.5.21 **Reports of Transactions Involving Nationally Tracked Sources.** Each licensee who manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report as specified in A.5.21(a) through (e) for each type of transaction.

(a) Each licensee who manufactures a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report shall include the following information:

(1) The name, address, and license number of the reporting licensee;

(2) The name of the individual preparing the report;

(3) The manufacturer, model, and serial number of the source;

(4) The radioactive material in the source;

(5) The initial source strength in becquerels (curies) at the time of manufacture; and

(6) The manufacture date of the source.

(b) Each licensee that transfers a nationally tracked source to another person shall complete and submit a National Source Tracking Transaction Report. The report shall include the following information:

(1) The name, address, and license number of the reporting licensee;

(2) The name of the individual preparing the report;

(3) The name and license number of the recipient facility and the shipping address;

(4) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

(5) The radioactive material in the source;

(6) The initial or current source strength in becquerels (curies);

(7) The date for which the source strength is reported;

(8) The shipping date;

(9) The estimated arrival date; and

(10) For nationally tracked sources transferred as waste under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification of the container with the nationally tracked source.

(c) Each licensee that receives a nationally tracked source shall complete and submit a National Source

Tracking Transaction Report. The report shall include the following information:

(1) The name, address, and license number of the reporting licensee;

(2) The name of the individual preparing the report;

(3) The name, address, and license number of the person that provided the source;

(4) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

(5) The radioactive material in the source;

(6) The initial or current source strength in becquerels (curies);

(7) The date for which the source strength is reported;

(8) The date of receipt; and

(9) For material received under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification with the nationally tracked source.

(d) Each licensee that disassembles a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report shall include the following information:

(1) The name, address, and license number of the reporting licensee;

(2) The name of the individual preparing the report;

(3) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

(4) The radioactive material in the source;

(5) The initial or current source strength in becquerels (curies);

(6) The date for which the source strength is reported;

(7) The disassemble date of the source.

(e) Each licensee who disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report shall include the following information:

(1) The name, address, and license number of the reporting licensee;

(2) The name of the individual preparing the report;

(3) The waste manifest number;

(4) The container identification with the nationally tracked source.

(5) The date of disposal; and

(6) The method of disposal.

(f) The reports discussed in A.5.21(a) through (e) shall be submitted by the close of the next business day after the transaction. A single report may be submitted for multiple sources and transactions. The reports shall be submitted to the National Source Tracking System by using:

(1) The on-line National Source Tracking System;

(2) Electronically using a computer-readable format;

(3) By facsimile;

(4) By mail to the address on the National Source Tracking Transaction Report Form (NRC Form 748); or

(5) By telephone with follow-up by facsimile or mail.

(g) Each licensee shall correct any error in previously filed reports or file a new report for any missed transaction within five (5) business days of the discovery of the error or missed transaction. Such errors may be detected by a variety of methods such as administrative reviews or by physical inventories required by regulation. In addition, each licensee shall reconcile the inventory[4] of nationally tracked sources possessed by the licensee against that licensee's data in the National Source Tracking System. The reconciliation shall be conducted during the month of January in each year. The reconciliation process shall include resolving any discrepancies between the National Source Tracking System and the actual inventory by filing the reports identified by A.5.21(a) through (e). By January 31 of each year, each licensee shall submit to the National Source Tracking System confirmation that the data in the National Source Tracking System is correct.

***

A.6 NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS; INSPECTIONS

***

A.6.2 **Posting of Notices to Workers.**

(a) Each licensee or registrant shall post current copies of the following documents:

(1) The regulations in this part;

(2) The license, certificate of registration, conditions or documents incorporated into the license by reference and amendments thereto;

(3) The operating procedures applicable to work under the license or registration;

(4) Any ~~notice of violation~~ Statement of Deficiencies involving radiological working conditions, proposed imposition of civil penalty, or order issued pursuant to the Act, and any response from the licensee or registrant.

***

***

A.7 COMPLIANCE PROCEDURES

To ensure compliance with these regulations, the Agency shall proceed in accordance with the provisions of this subpart, as appropriate.

A.7.1 **~~Notice of Violation~~ Statement of Deficiencies[5].**

(a) If, upon inspection or investigation, the administrator or his authorized representative finds that a registrant, licensee or other person subject to the Agency's jurisdiction has violated any of the provisions of the Act, these regulations, or any rules, orders or conditions imposed pursuant to the Act, he may issue a written

[4] Each licensee that possessed Category 1 and/or Category 2 nationally tracked source(s) prior to 31 January 2009 was required to report its initial inventory of Category 1 and/or Category 2 nationally tracked source(s) to the National Source Tracking System by 31 January 2009.

[5] The term *Notice of Violation* was use in these Regulations prior to the June 2013 edition. The change was made for consistency with other enforcement correspondence issued by the Office of Facilities Regulation. The terms *Notice of Violation* and *Statement of Deficiencies* shall be deemed to be equivalent for the purposes of these Regulations.

~~Notice of Violation~~ Statement of Deficiencies to the licensee, registrant, or other person subject to the Agency's jurisdiction.

(b) Each ~~Notice of Violation~~ Statement of Deficiencies shall describe the nature of the violation(s), including a reference to the provision(s) of the law, regulation, rule, order or condition alleged to have been violated.

(c) Each ~~Notice of Violation~~ Statement of Deficiencies shall require a consent agreement, whereby the registrant, licensee or other person subject to the Agency's jurisdiction shall provide a written ~~response~~ plan of correction to the Agency within ten (10) days of the service of the ~~notice of Violation~~ Statement of Deficiencies. The ~~response~~ plan of correction shall specify the corrective actions which the registrant, licensee or other person subject to the Agency's jurisdiction proposes to take, along with an estimate of the time required to implement such actions. If the ~~response~~ plan of correction is acceptable to the Agency, and the consent agreement is implemented, no further action will be taken.

A.7.2 **Order of Abatement.** If, upon inspection or investigation, the administrator or his authorized representative finds that a registrant, licensee or other person subject to the Agency's jurisdiction has violated any of the provisions of the Act, these regulations, or any rules, orders or conditions imposed pursuant to the Act, or a consent agreement, he may issue an Order of Abatement. Also, if a registrant, licensee or other person subject to the Agency's jurisdiction fails to respond within ten (10) days to a ~~Notice of Violation~~ Statement of Deficiencies, the Agency may issue an Order of Abatement.

***

***

A.7.4 **Orders of Suspension, Modification, and Revocation.**

***

(c) An order may be issued to revoke a registration or license when

(1) The registrant's or licensee's performance shows that he is not qualified to perform the activities covered by the registration or license; or

(2) The registrant or licensee refuses to correct violations; or

(3) A registrant or licensee does not comply with an Order of Abatement, or

(4) A registrant's or licensee's response to a ~~Notice of Violation~~ Statement of Deficiencies indicates inability or unwillingness to maintain compliance with regulatory requirements; or

***

***

PART A - APPENDIX B
ANNUAL LIMITS ON INTAKE (ALI) AND DERIVED AIR CONCENTRATIONS (DAC) OF RADIONUCLIDES FOR OCCUPATIONAL EXPOSURE; EFFLUENT CONCENTRATIONS; CONCENTRATIONS FOR RELEASE TO SANITARY SEWERAGE

***

LIST OF ELEMENTS

Name	Symbol	Atomic No.
*****	*****	*****
Nitrogen	N	7
*****	*****	*****
Oxygen	O	8
*****	*****	*****

***

***

Atomic Radionuclide No.	Class	Table I Occupational Values: Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values: Inhalation Col. 2 ALI (μCi)	Table I Occupational Values: Inhalation Col. 3 DAC (μCi/ml)	Table II Effluent Concentrations: Col. 1 Air (μCi/ml)	Table II Effluent Concentrations: Col. 2 Water (μCi/ml)	Table III Releases to Sewers: Monthly Average Concentration (μCi/ml)
***							
6 Carbon-14	Monoxide	-	2E+6	7E-4	2E-6	-	-
	Dioxide	-	2E+5	9E-5	3E-7	-	-
	Compounds	2E+3	2E+3	1E-6	3E-9	3E-5	3E-4
7 Nitrogen-13[2]	Submersion[1]	-	-	4E-6	2E-8	-	-
8 Oxygen-15[2]	Submersion[1]	-	-	4E-6	2E-8	-	-
***							

***

PART A

APPENDIX D

REQUIREMENTS FOR TRANSFER OF LOW-LEVEL RADIOACTIVE WASTE FOR DISPOSAL AT LAND DISPOSAL FACILITIES AND MANIFESTS

I. Manifest

***

As used in this appendix, the following definitions apply:

***

Decontamination facility means a facility operating under an Agency, U.S. Nuclear Regulatory Commission~~,~~ or Agreement State ~~or Licensing 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.

***

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

***

Waste collector means an entity, operating under an Agency, U.S. Nuclear Regulatory Commission, or other Agreement State ~~or Licensing State~~ 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 an Agency, U.S. Nuclear Regulatory Commission, or other Agreement State ~~or Licensing State~~ license, who (1) possesses any material or component that contains radioactivity or is radioactively contaminated for which the licensee foresees no further use, and (2) 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 processor means an entity, operating under an Agency, U.S. Nuclear Regulatory Commission, or other Agreement State ~~or Licensing State~~ 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.

***

***

PART A

APPENDIX H

NATIONALLY TRACKED SOURCE THRESHOLDS

The Terabecquerel (TBq) values are the regulatory standard. The curie (Ci) values specified are obtained by converting from the TBq value. The curie values are provided for practical usefulness only and are rounded after conversion.

RADIOACTIVE MATERIAL	CATEGORY 1 (TBq)	CATEGORY 1 (Ci)	CATEGORY 2 (TBq)	CATEGORY 2 (Ci)
Actinium-227	20	540	0.2	5.4
Americium-241	60	1,600	0.6	16
Americium-241/Be	60	1,600	0.6	16
Californium-252	20	540	0.2	5.4
Cobalt-60	30	810	0.3	8.1
Curium-244	50	1,400	0.5	14
Cesium-137	100	2,700	1	27
Gadolinium-153	1,000	27,000	10	270
Iridium-192	80	2,200	0.8	22
Plutonium-238	60	1,600	0.6	16
Plutonium-239/Be	60	1,600	0.6	16
Polonium-210	60	1,600	0.6	16
Promethium-147	40,000	1,100,000	400	11,000
Radium-226	40	1,100	0.4	11
Selenium-75	200	5,400	2	54
Strontium-90	1,000	27,000	10	270
Thorium-228	20	540	0.2	5.4
Thorium-229	20	540	0.2	5.4
Thulium-170	20,000	540,000	200	5,400
Ytterbium-169	300	8,100	3	81

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PART B
REGISTRATION OF X-RAY EQUIPMENT FACILITIES AND RADIATION PHYSICS SERVICES

***

B.2 EXEMPTIONS

B.2.1 Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from the registration and certification requirements of this Part, providing dose equivalent rate averaged over an area of ~~10~~ ten square centimeters (10 cm^2) does not exceed 0.5 mrem (5 uSv) per hour at five (5) cm from any accessible surface of such equipment. The production, testing, or factory servicing of such equipment shall not be exempt.

B.2.2 X-ray equipment while in transit or storage incident ~~thereto~~ to transit is exempt from the requirements of this Part. This exemption does not apply to the providers of X-ray equipment for mobile services.

B.2.3 Domestic television receivers and video display terminals are exempt from the requirements of this Part.

B.2.4 Inoperable X-ray equipment is exempt from the requirements of Part B of these Regulations. For the purposes Part B, inoperable X-ray equipment means X-ray equipment that cannot be energized when connected to a power supply without repair or modification.

B.3 ~~APPLICATION~~ GENERAL REGULATORY REQUIREMENTS FOR REGISTRATION OF X-RAY EQUIPMENT FACILITIES

~~Each person who owns or possesses and administratively controls an X-ray equipment facility, unless specifically exempted in B.2, shall:~~

B.3.1 **Submission of Application**

(a) Each person who owns or possesses and administratively controls an X-ray equipment facility, unless specifically exempted in B.2, shall apply for registration of such facility with the Agency prior to the operation of an X-ray equipment facility. Application for registration shall be completed on forms furnished by the Agency and shall contain all the information required by the form and accompanying instructions, including a designated e-mail address for receipt of official Agency correspondence in electronic format. The issuance of a Certificate of Registration for an X-ray equipment facility shall not preclude the Agency from subsequently reassigning the registered X-ray equipment to a more appropriate registration category and/or requiring the facility to periodically reregister all X-ray equipment at the facility. The registration category for ~~a reassigned and/or reregistered~~ an X-ray equipment facility will be determined in accordance with the provisions of ~~Appendix C to this Part~~ Appendix B to Part I of these Regulations.

~~(b) Prior to construction, the floor plans and equipment arrangement of all new facilities, or modifications of existing facilities, utilizing X-ray equipment and/or accelerators for shielded room radiography, research and development, or medical/veterinary diagnostic or therapeutic purposes, shall be submitted to the Agency for review. The required information for all X-ray equipment and accelerators, except therapeutic radiation machines, is denoted in Appendix A of this part.[6] The required information for therapeutic radiation machines~~

~~[6] Facilities may utilize the services of a person registered to provide Health Physics Services in developing the~~

~~is contained in Appendix A to Part H.~~

(b) **Designation of Individual Responsible for Radiation Protection**. An individual to be responsible for radiation protection[7] shall be designated on each application form. The qualifications of that individual shall be submitted to the Agency with the application. The RSO shall meet the applicable requirements of Appendix C and carry out the responsibilities in Appendix D to Part B of these Regulations.

~~(c) Prior to routine use, but in no case later than thirty (30) days subsequent to installation of the radiation producing equipment and/or modification of the existing facility, the shielding shall be reviewed and evaluated by a person registered with the Agency to provide Health Physics Services.~~

(c) **Designation of Facility Supervisor.**

(1) An individual responsible for directing the operation of the X-ray equipment facility shall be designated on each application form.

(2) The designation of a licensed practitioner of the healing arts shall be required on each healing arts application.

(3) The designation of an individual licensed in accordance with RIGL Chapter 5-25 to engage in veterinary medicine shall be required on each veterinary medicine application.

~~(d) A written report of the shielding evaluation shall be provided to the facility within ten (10) days of the evaluation. The report must specifically address any shielding and/or radiation protection deficiencies that were discovered during the evaluation and shall include recommendations for correcting these deficiencies. Any noted deficiencies shall be adequately addressed by the facility.~~

(d) **Additional Requirements for Medical Research on Humans.** In addition to the requirements of B.3.1(a), (b) and (c), the applicant shall submit, as a minimum, the following information:

(1) A detailed description of the proposed medical research, including a copy of the form that will be used to obtain informed consent from the human subjects and an evaluation of the potential radiation exposure to individuals participating in the medical research; and

(2) (i) Documentation that the research is conducted, funded, supported, or regulated by a Federal Agency which has implemented the Federal Policy for the Protection of Human Subjects; or

(ii) Documentation of prior review and approval of the research activities by an "Institutional Review Board" in accordance with the meaning of these terms as defined and described in the Federal Policy for the Protection of Human Subjects.

~~(e) Facilities must provide the Agency with a copy of the shielding evaluation report within ten (10) days of receipt of said report.~~

(e) **Additional Requirements for Mobile Service Operations.** In addition to the requirements of B.3.1(a), (b) and (c), the applicant shall submit the following information:

(1) The location where the X-ray equipment, records, etc. will be maintained for inspection. This shall be a street address, not a post office box number.

(2) A sketch or description of the normal configuration of each radiation machine's use, including the operator's position and any ancillary personnel's location during exposures. If a mobile van is used with a fixed unit inside, furnish the floor plan indicating protective shielding and the operator's location; and

(3) A current copy of the applicant's operating and safety procedures including radiological practices

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~~information required by Appendix A.~~

[7] This individual is frequently referred to as the Radiation Safety Officer (RSO).

for protection of patients, operators, employees, and the general public.

~~(f) An Agency finding that an X-ray equipment facility meets appropriate radiation protection standards shall not preclude the requirement of additional modifications, should a subsequent analysis of operating conditions and/or a radiation survey indicate that an individual is likely to receive a dose in excess of the limits prescribed in Sections A.2.3, A.2.9 and A.2.11 of these regulations.~~

(f) **Signature.** Each application shall be signed by the applicant or a person duly authorized to act on their behalf.

(g) Financial institutions that take possession of operable X-ray equipment as the result of foreclosure, bankruptcy, or other default of payment are subject to the requirements in this Part. X-ray equipment which is operable for the sole purpose of selling, leasing or transferring shall be registered in the Storage category.

~~B.3.2 Designate on the application form an individual to be responsible for radiation protection.~~

B.3.2 **Shielding Plan Review.** Except as otherwise provided in B.3.2(c), all new facilities and modifications of existing facilities utilizing ionizing radiation machines shall require shielding plan review by the Agency.

(a) Prior to construction, the floor plans, shielding specifications and equipment arrangement shall be submitted to the Agency for review and approval. The required information for all ionizing radiation machines, except therapeutic radiation machines, is denoted in Appendix A to Part B of these Regulations. The required information for therapeutic radiation machines is contained in Appendix A to Part H of these Regulations.

(b) The Agency may require the applicant to utilize the services of a person registered to provide General Radiation Physics Services in developing the information required by Appendix A to Part B of these Regulations.

(c) Shielding plan review by the Agency is not required for the following type of X-ray equipment facilities:

(1) Any type of X-ray equipment which provides sufficient self-shielding to reduce the radiation levels at all external surfaces of the equipment below those levels required by A.2.3, A.2.9 and A.2.11 of these regulations.

(2) Any X-ray equipment facility performing only dental intraoral and/or panoramic procedures whose estimated workload has been evaluated in accordance with NCRP Report 145 ["*Radiation Protection in Dentistry*" (2003)], and it has been documented that existing structural configuration will provide sufficient shielding to reduce the radiation levels to those required by A.2.3, A.2.9 and A.2.11 of these Regulations.

B.3.3 **Shielding Evaluation Required.**

(a) Prior to routine use, but in no case later than thirty (30) days subsequent to installation of the radiation producing equipment and/or modification of the existing facility, the shielding shall be reviewed and evaluated by a person registered with the Agency to provide General Radiation Physics Services.

(b) A written report of the shielding evaluation shall be provided to the facility within ten (10) days of the evaluation. The report shall specifically address any shielding and/or radiation protection deficiencies that were discovered during the evaluation and shall include recommendations for correcting these deficiencies. Any noted deficiencies shall be adequately addressed by the facility.

(c) Facilities shall provide the Agency with a copy of the shielding evaluation report within ten (10) days of receipt of said report.

(d) An Agency finding that an X-ray equipment facility meets appropriate radiation protection standards

shall not preclude the requirement of additional modifications, should a subsequent analysis of operating conditions and/or a radiation survey indicate that an individual is likely to receive a dose in excess of the limits prescribed in Sections A.2.3, A.2.9 and A.2.11 of these Regulations.

(e) **Retention of Information Used to Develop Shielding Plan.** After installation of radiation producing equipment, the registrant shall maintain for inspection by the Agency:

(1) The maximum rated technique factors of each machine;

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

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

(ii) The type and thickness of materials, or lead equivalency, of each protective barrier.

(3) All information required by B.3.3(e) shall be retained until disposal is authorized by the Agency. All required information shall be retained in an active file from at least the time of generation until the next Agency inspection. Information generated prior to the last Agency inspection may be microfilmed or otherwise archived as long as a complete copy of said information can be retrieved until such time as the Agency authorizes final disposal.

~~B.3.3~~B.3.4 All registrants shall prohibit any person from furnishing X-ray equipment servicing or radiation physics services as described in B.4.4 ~~of this Part~~ to ~~his~~ their X-ray equipment facility until such person provides evidence that ~~he is~~ they are registered with the Agency as a provider of services in accordance with Subpart B.4 of these Regulations.

B.4 APPLICATION FOR REGISTRATION OF X-RAY EQUIPMENT SERVICING AND RADIATION PHYSICS SERVICES

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B.4.2 Application for Registration shall be completed on forms furnished by the Agency and shall contain all information required by the Agency as indicated on the forms and accompanying instructions, including a designated e-mail address for receipt of official Agency correspondence in electronic format.

(a) An application for registration to provide X-ray equipment servicing will be accepted from either a firm or an individual.

(b) An application for registration to provide radiation physics services will only be accepted from an individual. If a firm employs more than one individual to provide radiation physics services, each individual shall be required to obtain a separate registration.

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B.4.5 **Restrictions on Provision of Services.**

(a) Persons offering the services described in B.4.4 shall not provide such services to any operational X-ray equipment facility or any facility utilizing radioactive materials in this state until such facility provides evidence that it has been registered or licensed with the Agency in accordance with Subpart B.3 or Part C of these Regulations. Persons providing the services described in B.4.4 to a preoperational X-ray facility or facility intending to utilize radioactive material shall inform the facility of the registration or licensing requirements of these regulations.

(b) An individual registered with the Agency as a provider of services in accordance with Subpart B.4

shall only perform services that are specifically authorized for that individual on the Certificate of Registration issued by the Agency.

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B.10 REGISTRATION FEES

In accordance with authority granted to the Agency in RIGL Chapter 23-1.3-5 ~~of the General Laws of Rhode Island~~, registration fees are payable to the Treasurer, State of Rhode Island by persons applying for registration. A current schedule of fees is available ~~from the Agency~~ in Appendix B to Part I of these Regulations. Upon approval of the application, the Agency will notify the applicant of the correct fee which is due. A Certificate of Registration will not be issued or renewed until the correct fee has been remitted. Fees which remain unpaid beyond the expiration date of the current Certificate of Registration may result in suspension of registration.

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PART B

APPENDIX A

INFORMATION ON RADIATION SHIELDING REQUIRED FOR PLAN REVIEWS

~~1. Shielding plans are not required for the following type of X-ray equipment facilities:~~

~~(a) Any type of X-ray equipment which provides sufficient self-shielding to reduce the radiation levels at all external surfaces of the equipment below those levels required by Sections A.2.3, A.2.9 and A.2.11 of these regulations.~~

~~(b) Any X-ray equipment facility performing only dental intraoral and/or panoramic procedures whose estimated workload has been evaluated in accordance with NCRP Report 35, and it has been determined that existing structural configuration will provide sufficient shielding to reduce the radiation levels to those required by Sections A.2.3, A.2.9 and A.2.11 of these regulations.~~

~~2. All X-ray equipment facility shielding plans must comply with the following requirements:~~

I. ALL X-RAY EQUIPMENT FACILITIES

(a) Basic facility information including: name, RPS registration number and telephone number of the individual responsible for the shielding specifications; name and telephone number of the facility supervisor; and the street address [including room #(s)] of the facility. ~~If applicable, also provide the individual's RPS registration number.~~ The plan should also indicate whether this is a new structure or a modification to existing structure(s). If the facility is currently registered, the Agency registration number shall be provided.

(b) All wall, floor, and ceiling areas struck by the useful beam shall have primary barriers.

(c) Secondary barriers, when required, shall be provided in all wall, floor, and ceiling areas. ~~not requiring primary barriers.~~

(d) Shielding in walls of diagnostic X-ray facilities shall extend to a minimum height of seven feet above the floor.

~~3. In addition to the requirements listed in Section 2 above, the plans for all X-ray facilities which produce only photons with a maximum energy less than or equal to 150 keV shall contain, as a minimum, the following additional information:~~

II. X-RAY EQUIPMENT FACILITIES UP TO 150 kV

In addition to the requirements listed in Section I above, the plans for all X-ray equipment facilities which produce only photons with a maximum energy less than or equal to 150 kV shall contain, as a minimum, the following additional information:

(a) Equipment specifications including the make and model of the X-ray equipment, ~~as well as~~ the maximum technique factors and the energy waveform (single phase, three phase, etc.).

(b) The maximum design workload for the facility in terms of milliamp-minutes or milliamp-seconds per week. The total anticipated number of patients per week or number of exposures~~/films~~ per ~~day and/or~~ week, as well as the type of examination(s) or treatment(s) which will be performed with the equipment, shall also be provided.

(c) A facility blueprint/drawing indicating: scale (0.25 inch = 1 foot is typical); direction of North; normal location of the X-ray system's radiation port(s); the port's travel and traverse limits; general direction(s) of the

useful beam; locations of any windows and doors; and the location of the X-ray control panel. If the control panel is located inside the X-ray room, the location of the operator's ~~booth~~ station shall be noted in the plan and the operator's station at the control panel shall be in ~~behind a protective barrier sufficient to assure~~ compliance with §A.2.3 of these Regulations.

(d) In X-ray facilities designed for medical use, a window (of lead equivalent at least equal to that required for the ~~adjacent~~ barrier), mirror or other remote viewing system shall be provided and so placed that the operator can see the patient during the exposure without having to leave the protected area.

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

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

(g) At least one example calculation which shows the methodology used to determine the amount of shielding required for each physical condition [i.e.: primary and secondary/ leakage barriers, restricted and unrestricted areas, small angle scatter, entry door(s) and maze] and shielding material in the facility. If commercial software is used to generate shielding requirements, also identify the software used and the version/revision date

~~4. In addition to the requirements listed in Item 2 above, the plans for all X-ray/ accelerator facilities which produce photons with a maximum energy in excess of 150 keV and/or electrons and/or neutrons, protons or other subatomic particles shall also contain the following information:~~

III. X-RAY EQUIPMENT FACILITIES OVER 150 kV

In addition to the requirements listed in Section I above, the plans for all X-ray equipment/accelerator facilities which produce photons with a maximum energy in excess of 150 kV and/or electrons and/or protons or other subatomic particles shall also contain the following information:

(a) Equipment specifications including: manufacturer and model number of the ~~radiotherapy~~ unit; rad (or rem) per minute at the isocenter; and the energy(s) and type(s) of radiation produced [i.e.: photon, electron, neutron]. The source to isocenter distance must be specified.

(b) Maximum design workload for the facility including total weekly radiation output [expressed in rad (or rem)/week @ 1 meter], total beam-on time per day or week. ~~All facilities designed for the administration of radiotherapy must also include the average treatment time per patient, along with the anticipated number of patients to be treated per day or week~~.

(c) Facility blueprint/drawing (including both floor plan and elevation views) indicating position and orientation of the X-ray/accelerator unit, scale (0.25 inch = 1 foot is typical), type(s) and thickness of shielding material(s), direction of North, the locations and size of all penetrations through each shielding barrier (ceiling, walls and floor), as well as details of the door(s) and maze.

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

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

(f) Description of all assumptions that were used in shielding calculations including, but not limited to, design energy [i.e.: room may be designed for 6 ~~MeV~~ MV unit although only a 4 ~~MeV~~ MV unit is currently proposed], presence of integral beam-stop in unit, workload, occupancy and use(s) of adjacent areas, fraction of

time that primary beam will intercept each permanent barrier (walls, floor and ceiling) and "allowed" radiation exposure in both restricted and unrestricted areas.

(g) At least one example calculation which shows the methodology used to determine the amount of shielding required for each physical condition [i.e.: primary and secondary/ leakage barriers, restricted and unrestricted areas, small angle scatter, entry door(s) and maze] and shielding material in the facility. If commercial software is used to generate shielding requirements, also identify the software used and the version/revision date.

IV. NEUTRON SHIELDING

In addition to the requirements listed in Sections I and III above, X-ray equipment/accelerator facilities which are capable of operating above 10 MV shall submit shielding plans which contain, as a minimum, the following additional information:

1. The structural composition, thickness, minimum density and location of all neutron shielding material.
2. 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.
3. At least one example calculation which shows the methodology used to determine the amount of neutron shielding required for each physical condition [i.e.: restricted and unrestricted areas, entry door(s) and maze] and neutron shielding material utilized in the facility. If commercial software is used to generate shielding requirements, also identify the software used and the version/revision date.
4. The method(s) and instrumentation which will be used to verify the adequacy of all neutron shielding installed in the facility.

V. REFERENCES

1. NCRP Report 144 “Radiation Protection for Particle Accelerator Facilities” (2003)
2. NCRP Report 145, “Radiation Protection in Dentistry” (2003).
3. NCRP Report 147, “Structural Shielding Design for Medical X-Ray Imaging Facilities” (2004)
4. NCRP Report 148, “Radiation Protection in Veterinary Medicine” (2004)

PART B

APPENDIX B

EDUCATION AND EXPERIENCE REQUIREMENTS FOR RADIATION PHYSICS SERVICES

1. **Radiotherapy Physics Services**. [Calibration and surveys of: therapeutic X-ray equipment; medical accelerators; teletherapy units, remote afterloader brachytherapy units and/or stereotactic radiosurgery units utilizing sealed radioactive sources.]

(a) Documentation of training sufficient to qualify as:

(1) An Authorized Medical Physicist pursuant to C.8.71 of these Regulations in the modality(s) for which registration is being requested; or

(2) A ~~Radiotherapy~~ Qualified Medical Physicist pursuant to H.3.4 of these Regulations

2. **Diagnostic X-ray Physics Services**. [Calibration and surveys of diagnostic X-ray equipment.]

(a) Certification by the American Board of Radiology in:

(1) Radiological physics;

(2) Roentgen-ray and gamma-ray physics; or

(3) X-ray and radium physics; or

(4) Diagnostic radiological physics; or

(5) Diagnostic medical physics; or

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3. **~~Health~~ General Radiation Physics Services.** [All ~~general~~ radiation physics services (except calibration of health physics instrumentation) for Agency registrants and/or radioactive materials licensees not covered in Sections 1 or 2 above.]

(a) Comprehensive certification by the American Board of Health Physics; or

(b) Certification by the American Board of Radiology in:

(1) Radiological physics;

(2) Roentgen-ray and gamma-ray physics; or

(3) X-ray and radium physics; or

(4) Diagnostic radiological physics; or

(5) Medical nuclear physics or nuclear medical physics; or

(c) Certification by the American Board of Medical Physics in Nuclear Medicine Physics or Medical Health Physics; or

(d) Hold a master's or doctor's degree in radiological physics or health physics or other related radiation discipline and submit documentation of appropriate experience in the area(s) for which registration is being requested. This experience must have been obtained under the supervision of an individual qualified to provide ~~Health~~ General Radiation Physics Services; or

(e) Hold a master's or doctor's degree in a physical science and submit documentation of at least one (1) year of appropriate full time training and experience in the area(s) for which registration is being requested. This experience must have been obtained under the supervision of an individual qualified to provide ~~Health~~ General Radiation Physics Services; or

(f) Hold a bachelor's degree in health physics or other related radiation discipline and submit documentation of at least one (1) year of appropriate full time experience in the area(s) for which registration is being requested. This experience must have been obtained under the supervision of an individual qualified to provide ~~Health~~ General Radiation Physics Services; or

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~~PART B~~

~~APPENDIX C~~

~~REGISTRATION CATEGORIES ANDFEES FOR FACILITIES AND SERVICES~~

~~CATEGORY I~~

~~(a) Facilities:~~

~~1. Facilities utilizing certified cabinet X-ray systems.~~

~~2. Facilities performing diagnostic radiography limited to veterinary procedures.~~

~~3. Facilities limited to storage of X-ray equipment, excluding X-ray equipment exempt from registration under these regulations.~~

~~(b) Individuals or facilities providing the following services:~~

~~1. Installation and/or servicing of X-ray equipment and associated components for Agency registrants.~~

~~2. NVLAP certified personnel dosimetry services for Agency registrants and/or radioactive materials licensees.~~

~~CATEGORY II~~

~~1. Facilities performing diagnostic radiography limited to chiropractic procedures.~~

~~2. Facilities performing diagnostic radiography limited to podiatric procedures.~~

~~3. Facilities performing diagnostic radiography limited to intra-oral dental procedures and/or extra-oral dental procedures, including panoramic and cephalometric procedures.~~

~~4. Facilities utilizing only specialized diagnostic radiography equipment including, but not limited to, CT scanners, therapy simulators, and dedicated mammography units.~~

~~5. Facilities performing only limited diagnostic radiographic procedures (ie: chest/extremities) and/or specific diagnostic radiographic procedures which are not included in any other human use registration category.~~

~~6. Facilities utilizing non-certified cabinet X-ray systems and/or X-ray units which are not included in any other non-human use registration category.~~

~~CATEGORY III~~

~~(a) Facilities:~~

~~1. Facilities performing industrial radiographic procedures.~~

~~2. Facilities performing radiation therapy procedures < 1 MeV.~~

~~3. Facilities performing radiation therapy procedures > 1 MeV.~~

~~4. Facilities operating particle accelerators not authorized for human use.~~

~~5. Facilities utilizing analytical X-ray equipment with an "open-beam" configuration.~~

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~~(b) Individuals providing the following services:~~

~~1. Calibration of health physics instrumentation for Agency registrants and/or radioactive materials licensees.~~

~~2. Health Physics Services for Agency registrants and/or radioactive materials licensees.~~

~~3. Diagnostic X-ray Physics Services for Agency registrants.~~

~~4. Radiotherapy Physics Services for Agency registrants. [Calibration and surveys of therapeutic X-ray equipment, including medical accelerators.]~~

~~5. Teletherapy Physics Services for Agency materials licensees. [Calibration and surveys of teletherapy units utilizing sealed radioactive sources.]~~

~~**CATEGORY IV**~~

~~1. Facilities performing general purpose diagnostic radiographic procedures outside of an institution licensed by the State of Rhode Island as a hospital.~~

~~2. Facilities performing general purpose and specialized diagnostic radiographic procedures outside of an institution licensed by the State of Rhode Island as a hospital.~~

~~**CATEGORY V**~~

~~1. Facilities performing general purpose diagnostic radiographic procedures in an institution licensed by the State of Rhode Island as a hospital.~~

~~2. Facilities performing general purpose and specialized diagnostic radiographic procedures in an institution licensed by the State of Rhode Island as a hospital.~~

~~Facilities or services which are submitted to the Radiation Control Agency for registration, but which do not appear to meet the specific description of any category listed in this Appendix, shall be assigned to either Category II (facilities) or Category III (services) until such time as the Agency has conducted a field inspection to determine the appropriate registration category.~~

PART B

APPENDIX C

RADIATION SAFETY OFFICER (RSO) REQUIREMENTS

(A) An RSO shall meet the following general requirements, as well as any applicable facility-specific requirements of this Appendix.

(a) Knowledge of potential radiation hazards and emergency precautions;

(b) Completed educational courses related to ionizing radiation safety or a radiation safety officer course;

(c) Experience in the use and familiarity of the type of equipment used.

(B) Specific RSO requirements by facility are as follows.

(a) Healing arts facilities subject to Part F of these Regulations shall have:

(1) A licensed practitioner RSO with documentation of a current unrestricted Rhode Island license; or

(2) A non-practitioner RSO who meets the following requirements:

(i) An individual who has a current unrestricted license, issued in accordance with RIGL Chapter 5-68.1, as a radiologic technologist, and has at least two (2) years of supervised use for the type(s) of radiation machines covered by the registration; or

(ii) An individual who has a current unrestricted license, issued in accordance with RIGL Chapter 5-34 as a nurse practitioner, and has at least two (2) years of supervised use for the type(s) of radiation machines covered by the registration; or

(iii) An individual who has a current unrestricted license, issued in accordance with RIGL Chapter 5-54, as a physician assistant, and has at least two (2) years of supervised use for the type(s) of radiation machines covered by the registration; or

(iv) An individual who has a current unrestricted license, issued in accordance with RIGL Chapter 5-31.1, as a dental hygienist, and has at least two (2) years of performing radiologic procedures under a dentist's instruction and direction; or;

(v) An individual who has a bachelor's (or higher) degree in a natural or physical science, health physics, radiological science, nuclear medicine, or nuclear engineering.

(b) Healing Arts facilities subject to Part H of these Regulations shall have an individual who meets the requirements for either an Authorized User physician or qualified medical physicist, as specified in Part H of these Regulations.

(c) Academic institutions and/or research and development facilities shall have an RSO who is a faculty or staff member with appropriate training in radiation protection, radiation engineering, or related disciplines. (If properly qualified, this individual may also serve as the RSO over the healing arts section of the facility.)]

(d) Industrial radiography facilities shall have an RSO who meets the requirements specified in §E.2.21 of these Regulations.

(e) Other industrial facilities shall have an RSO whose training and experience is sufficient to identify and control the anticipated radiation hazards.

PART B

APPENDIX D

DUTIES AND RESPONSIBILITIES OF THE RADIATION SAFETY OFFICER (RSO)

Specific duties and responsibilities of the Radiation Safety Officer (RSO) include, but are not limited to, the following:

1. Establishment and oversight of operating and safety procedures that maintain radiation exposures as low as reasonably achievable (ALARA), and periodic review to ensure that the procedures are current and conform with these Regulations;
2. Ensure that individual monitoring devices are properly used by occupationally-exposed personnel, that records are kept of the monitoring results, and that timely notifications are made as required by Part A of these Regulations;
3. Investigate and report to the Agency each known or suspected case of radiation exposure to an individual or radiation level detected in excess of limits established by these Regulations and each theft or loss of source(s) of radiation, determining the cause, and taking steps to prevent its recurrence;
4. Maintain a thorough knowledge of relevant management policies and administrative procedures of the registrant and keep management informed on a periodic basis of the performance of the registrant's radiation protection program, if applicable;
5. Authority to institute corrective actions including shut-down of operations when necessary in emergency situations or unsafe conditions;
6. Maintain records as required by these Regulations; and
7. Ensure that personnel are adequately trained and complying with these Regulations, the conditions of the Certificate of Registration, and the operating and safety procedures of the registrant.

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PART C
LICENSING OF RADIOACTIVE MATERIAL AND USE OF RADIONUCLIDES IN THE HEALING ARTS

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C.2 EXEMPTIONS

C.2.2 **Radioactive Material Other Than Source Material.**

(a) **Exempt Concentrations.**

(1) Except as provided in C.2.2(a)(2), any person is exempt from this part to the extent that such person receives, possesses, uses, transfers, owns or acquires products containing radioactive material introduced in concentrations not in excess of those listed in Appendix A.

(2) (i) A manufacturer, processor, or producer of a product or material is exempt from the requirements for a license set forth in these regulations to the extent that this person transfers radioactive material contained in a product or material in concentrations not in excess of those specified in Appendix B of this Part and introduced into the product or material by a licensee holding a specific license issued by the U.S. Nuclear Regulatory Commission expressly authorizing such introduction. This exemption does not apply to the transfer of radioactive material contained in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

(ii) No person may introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under C.2.2(a)(1) or equivalent regulations of the U.S. Nuclear Regulatory Commission or~~, any~~ other Agreement State ~~or Licensing State~~, except in accordance with a ~~specific license issued pursuant to C.5.5(a) or the general license provided in C.6.1~~ license issued by the U.S. Nuclear Regulatory Commission pursuant to §32.11 of 10 CFR Part 32.

(b) **Exempt Quantities.**

(1) (i) Except as provided in C.2.2(b)(2)~~,~~ ~~and~~ (3) and (4), any person is exempt from the requirements for a license set forth in these regulations to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material in individual quantities each of which does not exceed the applicable quantity set forth in Appendix B of this part.

(ii) Any person, who possesses byproduct material received or acquired before 25 September 1971, under the general license then provided in 10 CFR 31.4 or similar general license of a State, is exempt from the requirements for a license set forth in 10 CFR Parts 30 through 34, 36 and 39 to the extent that this person possesses, uses, transfers, or owns byproduct material.

(2) This paragraph does not authorize the production, packaging or repackaging of radioactive material for purposes of commercial distribution, or the incorporation of radioactive material into products intended for commercial distribution.

(3) No person may, for purposes of commercial distribution, transfer radioactive material in the individual quantities set forth in Appendix B of this part, knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt under C.2.2(b) or

equivalent regulations of the U.S. Nuclear Regulatory Commission~~, any~~ or other Agreement State ~~or Licensing State~~, except in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.18 of 10 CFR Part 32 ~~or by the Agency pursuant to C.5.5(b)~~ which license states that the radioactive material may be transferred by the licensee to persons exempt under C.2.2(b) or the equivalent regulations of the U.S. Nuclear Regulatory Commission~~, any~~ or other Agreement State ~~or Licensing State~~.

(4) No person may, for purposes of producing an increased radiation level, combine quantities of radioactive material covered by this exemption so that the aggregate quantity exceeds the limits set forth in Appendix B, except for radioactive material combined within a device placed in use before 3 May 1999, or as otherwise permitted by the regulations in this part.

(c) **Exempt Items.**

(1) **Certain Items Containing Radioactive Material**. Except for persons who apply radioactive material to, or persons who incorporate radioactive material into the following products, any person is exempt from these regulations to the extent that he receives, possesses, uses, transfers, owns, or acquires the following products:[8]

(i) Timepieces or hands or dials containing not more than the following specified quantities of radioactive material and not exceeding the following specified radiation dose rates:

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(h) one microcurie (37 kBq) of radium-226 per timepiece in intact time pieces acquired prior to ~~the effective date of these regulations~~ 30 November 2007.

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(ii) ~~Lock illuminators containing not more than 15 millicuries (555 MBq) of tritium or not more than 2 millicuries (74 MBq) of promethium-147 installed in automobile locks. The radiation dose rate from each lock illuminator containing promethium-147 will not exceed 1 millirad (10 μGy) per hour at 1 centimeter from any surface when measured through 50 milligrams per square centimeter of absorber.~~

(a) Static elimination devices which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 18.5 MBq (500 μCi) of polonium-210 per device.

(b) Ion generating tubes designed for ionization of air that contain, as a sealed source or sources, radioactive material consisting of a total of not more than 18.5 MBq (500 μCi) of polonium-210 per device or of a total of not more than 1.85 GBq (50 mCi) of hydrogen-3 (tritium) per device.

(c) Such devices authorized before 23 October 2012 for use under the general license then provided in §31.3 and equivalent regulations of Agreement States and manufactured, tested, and labeled by the manufacturer in accordance with the specifications contained in a specific license issued by the Commission.

(iii) Precision balances containing not more than 1 millicurie (37 MBq) of tritium per balance or not more than 0.5 millicurie (18.5 MBq) of tritium per balance part manufactured before 17 December 2007.

[8] Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

(iv) ~~Automobile shift quadrants containing not more than 25 millicuries (925 MBq) of tritium.~~ **[DELETED]**

(v) Marine compasses containing not more than 750 millicuries (27.8 GBq) of tritium gas and other marine navigational instruments containing not more than 250 millicuries (9.25 GBq) of tritium gas manufactured before 17 December 2007.

(vi) ~~Thermostat dials and pointers containing not more than 25 millicuries (925 MBq) of tritium per thermostat~~. **[DELETED]**

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(ix) ~~Spark gap irradiators containing not more than 1 microcurie (37 kBq) of cobalt-60 per spark gap irradiator for use in electrically ignited fuel oil burners having a firing rate of at least 3 gallons (11.4 liters) per hour.~~ **[DELETED]**

(2) **Self-luminous products containing radioactive material.**

(i) **Tritium, krypton-85, or promethium-147.** Except for persons who manufacture, process, or produce self-luminous products containing tritium, krypton-85, or promethium-147, any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, owns, or acquires tritium, krypton-85 or promethium-147 in self-luminous products manufactured, processed, produced, imported, or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to section 32.22 of 10 CFR part 32, which license authorizes the transfer of the product to persons who are exempt from regulatory requirements.

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

Any person who desires to manufacture, process, or produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147 for use under C.2.2(c)(2)(i) should apply for a license from the U.S. Nuclear Regulatory Commission pursuant to section §32.22 of 10 CFR part 32 and for a certificate of registration in accordance with section 32.210 of 10 CFR part 32.

(iii) The exemption in C.2.2(c)(2)(i) does not apply to tritium, krypton-85 or promethium-147 used in products for frivolous purposes or in toys or adornments.

(3) **Gas and aerosol detectors containing radioactive material.**

(i) Except for persons who manufacture, process, ~~or~~ produce or initially transfer for sale or distribution gas and aerosol detectors containing radioactive material, any person is exempt from the requirements for a license set forth in these regulations to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued ~~provided that detectors containing radioactive material shall have been manufactured, imported, or transferred in accordance with a specific license issued~~ by the U.S. Nuclear Regulatory Commission[9] pursuant to section 32.26 of 10 CFR Part 32, ~~or a~~

[9] Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other produce containing byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

~~Licensing State, pursuant to C.5.5(c),~~ which license authorizes the initial transfer of the product for use under this section ~~detectors to persons who are exempt from regulatory requirements~~.

(ii) This exemption also covers gas and aerosol detectors manufactured or distributed before 30 November 2007 ~~previously manufactured and distributed to general licensees~~ in accordance with a specific license issued by an Agreement State under comparable provisions to section 32.26 of 10 CFR Part 32, authorizing distribution to persons exempt from regulatory requirements. ~~shall be considered exempt under C.2.2(c)(3)(i), provided that the device is labeled in accordance with the specific license authorizing distribution of the generally licensed device, and provided further that they meet the requirement of C.5.5(c)~~.

(iii) ~~Gas and aerosol detectors containing NARM previously manufactured and distributed in accordance with a specific license issued by a Licensing State shall be considered exempt under C.2.2(c)(3)(i), provided that the device is labeled in accordance with the specific license authorizing distribution and provided further that they meet the requirements of C.5.5(c).~~

Any person who desires to manufacture, process, or produce gas and aerosol detectors containing radioactive material, or to initially transfer such products for use under C.2.2(c)(2)(i), should apply for a license from the U.S. Nuclear Regulatory Commission pursuant to section §32.26 of 10 CFR part 32 and for a certificate of registration in accordance with section 32.210 of 10 CFR part 32.

(4) **[DELETED]** ~~**Resins containing scandium-46 and designed for sand consolidation in oil wells.** Any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, owns or acquires synthetic plastic resins containing scandium-46 which are designed for sand consolidation in oil wells. Such resins shall have been manufactured or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or shall have been manufactured in accordance with the specifications contained in a specific license issued by the Agency or any Agreement State to the manufacturer of such resins pursuant to licensing requirements equivalent to those in sections 32.16 and 32.17 of 10 CFR part 32 of the regulations of the U.S. Nuclear Regulatory Commission. This exemption does not authorize the manufacture of any resins containing scandium-46.~~

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(e) **Certain Industrial Devices.**

(1) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing radioactive material designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing an ionized atmosphere, any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material, in these certain detecting, measuring, gauging, or controlling devices and certain devices for producing an ionized atmosphere, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to section 32.30 of 10 CFR part 32, which license authorizes the initial transfer of the device for use under this section. This exemption does not cover sources not incorporated into a device, such as calibration and reference sources.

(2) Any person who desires to manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing radioactive material for use under C.2.2(e)(1) should apply

for a license should apply for a license from the U.S. Nuclear Regulatory Commission pursuant to section §32.30 of 10 CFR part 32 and for a certificate of registration in accordance with section 32.210 of 10 CFR part 32.

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C.4 GENERAL LICENSES

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C.4.2 **General Licenses - Radioactive Material other than Source Material.** This section establishes general licenses for the possession and use of radioactive material and a general license for ownership of radioactive material. The general licenses provided in this section are subject to the provisions of C.2.2(a)(2), C.5.6(b), C.5.7(a)-(c), C.5.14, C.5.15, C.7.1 and Subpart A[10] unless indicated otherwise in the specific provision of the general license.

(a) **[RESERVED]** ~~**Certain Devices and Equipment.** A general license is hereby issued to transfer, receive, acquire, own, possess, and use radioactive material incorporated in the following devices or equipment which have been manufactured, tested and labeled by the manufacturer in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission for use pursuant to Section 31.3 of 10 CFR Part 31.~~

~~(1) **Static Elimination Device.** Devices designed for use as static eliminators which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries (18.5 MBq) of polonium-210 per device.~~

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

(b) **Certain Measuring, Gauging and Controlling Devices.**

(1) A general license is hereby issued to commercial and industrial firms and to research, educational and medical institutions, individuals in the conduct of their business, and state or local government agencies to own, receive, acquire, possess, use or transfer in accordance with the provisions of C.4.2(b)(2), (3), and (4), radioactive material, excluding special nuclear material, contained in devices designed and manufactured for the purpose of detecting, measuring, gauging, or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

(2) (i) The general license in C.4.2(b)(1) applies only to radioactive material contained in devices which have been manufactured or initially transferred and labeled in accordance with ~~the~~ specifications contained in a specific license issued by the Agency pursuant to C.5.5(d)~~, or in accordance with the specifications contained in~~ a specific license issued by the U.S. Nuclear Regulatory Commission under 10 CFR 31.52, an equivalent specific license issued by another Agreement State or an equivalent specific license issued by a state with provisions comparable to 10 CFR 32.51. ~~a Licensing State, which authorizes distribution of devices to persons generally licensed by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State~~[11]

[10] Attention is directed particularly to the provisions of Part A of these regulations which relate to the labeling of containers.

[11] ~~Regulations under the Federal Food, Drug, and Cosmetic Act authorizing the use of radioactive control devices in~~

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(3) Any person who owns, receives, acquires, possesses, uses or transfers radioactive material in a device pursuant to the general license in C.4.2(b)(1):

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(v) Shall immediately suspend operation of the device if there is a failure of, or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 0.005 microcurie (185 Bq) or more removable radioactive material. The device shall not be operated until it has been repaired by the manufacturer or other person holding a an applicable specific license from the Agency, the U.S. Nuclear Regulatory Commission~~, an~~ or another Agreement State ~~or a Licensing State~~. The device and any radioactive material from the device shall only be disposed of by transfer to a person authorized by a specific license to receive the radioactive material in the device or as otherwise approved by the Agency. A report containing a brief description of the event and the remedial action taken; and, in the case of detection of 0.005 microcurie or more removable radioactive material or failure of or damage to a source likely to result in contamination of the premises or the environs, a plan for ensuring that the premises and environs are acceptable for unrestricted use, shall be furnished to the Agency within 30 days. Under these circumstances, the criteria set out in A.2.14, "Radiological Criteria for Unrestricted Use", may be applicable, as determined by the Agency on a case-by-case basis;

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(vii) Except as provided in C.4.2(b)(3)(viii), ~~and~~ (x) and (xi), shall transfer or dispose of the device containing radioactive material only by transfer to a specific licensee of the Agency, the U.S. Nuclear Regulatory Commission~~, an~~ or another Agreement State ~~or a Licensing State~~ whose specific license authorizes him to receive the device or that authorizes waste collection. ~~Written Agency approval shall be obtained before transferring the device to any other specific licensee not specifically identified this subparagraph~~. Within 30 days after transfer of a device to a specific licensee or export shall furnish to the Agency a report containing:

(a) Identification of the device by manufacturer's (or initial transferor's) name, model number and serial number;

(b) The name, address and license number of the person receiving the device (license number not applicable if exported);

(c) The date of the transfer.

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(xi) Written Agency approval shall be obtained before transferring the device to any other specific licensee not specifically identified in C.4.2(b)(3)(vii). However, a holder of a specific license may transfer a device for possession and use under its own specific license, without prior approval, if the holder:

(a) Verifies that the specific license authorizes the possession and use, or applies for and obtains an amendment to the license authorizing the possession and use;

(b) Removes, alters, covers, or clearly and unambiguously augments the existing label

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~~food production require certain additional labeling thereon which is found in Section 179.21 of the Code of Federal Regulations, Title 21.~~

(otherwise required by C.4.2(b)(3)(i) so that the device is labeled in compliance with A.3.15. However the manufacturer, model number, and serial number must be retained;

(c) Obtains the manufacturer's or initial transferor's information concerning maintenance that would be applicable under the specific license (such as leak testing procedures); and

(d) Reports the transfer under C.4.2(b)(3)(vii).

***

(6) (i) Shall register, in accordance with C.4.2(b)(6)(ii) and (iii), devices containing at least 10 millicuries (370 MBq) of Cesium-137, 0.1 millicurie (3.7 MBq) of Strontium-90, 1 millicurie (37 MBq) of Cobalt-60, 0.1 millicurie(3.7 MBq) of radium-226 or 1 millicurie (37 MBq)) of Americium-241 or any other transuranic[12], based on the activity indicated on the label. Each address for a location of use, as described under C.4.2(b)(6)(iii)(d), represents a separate general licensee and requires a separate registration and fee.

(ii) If in possession of a device meeting the criteria of C.4.2(b)(6)(i), shall register these devices with the Agency and shall pay the fee required by I.3.6. The initial registration shall be submitted to the Agency within 30 days of initial receipt of the device, and shall be updated on an annual basis. Registration shall be done by verifying, correcting, and/or adding to the information provided on Agency Form GEN-4. In addition, a general licensee holding devices meeting the criteria of C.4.2(b)(6)(i) is subject to the bankruptcy notification requirement in C.5.7(f)(1).

(iii) In registering devices, the general licensee shall furnish on Agency Form GEN-4 the following information and such other information as may be required by that form:

(a) Name and mailing address of the general licensee, including a designated e-mail address for receipt of official Agency correspondence in electronic format.

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(e) **Calibration and Reference Sources.**

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(4) The general licenses in C.4.2(e)(1), (2) and (3) apply only to calibration or reference sources which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer or importer of the source by the U.S. Nuclear Regulatory Commission pursuant to Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70 or which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer by the Agency~~, any~~ or another Agreement State ~~or Licensing State~~ pursuant to licensing requirements equivalent to those contained in Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70 of the regulations of the U.S. Nuclear Regulatory Commission.

(5) The general licenses provided in C.4.2(e)(1), (2) and (3) are subject to the provisions of Part A, C.5.7, C.5.14, C.5.15, and C.7.1 of these regulations. In addition, persons who own, receive, acquire, possess, use, or transfer one or more calibration or reference sources pursuant to these general licenses:

(i) shall not possess at any one time, at any one location of storage or use, more than 5 microcuries (185 kBq) of americium-241, 5 microcuries (185 kBq) of plutonium, or 5 microcuries (185 kBq) of radium-226 in such sources;

[12] element with atomic number greater than uranium (92).

(ii) shall not receive, possess, use or transfer such source unless the source, or the storage container, bears a label which includes ~~one of~~ the following statement~~s as appropriate~~ or a substantially similar statement which contains the information called for in ~~one of~~ the following statement~~s as appropriate~~:

~~(~~a~~)~~ The receipt, possession, use and transfer of this source, Model ___, Serial No. ___, are subject to a general license and the regulations of the U.S. Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION - RADIOACTIVE MATERIAL - THIS SOURCE CONTAINS (RADIUM-226 or PLUTONIUM or AMERICIUM-241)[13] DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____

Name of manufacturer ~~of importer~~ or initial transferor

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

~~**CAUTION - RADIOACTIVE MATERIAL - THIS SOURCE CONTAINS RADIUM-226. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.**~~

~~_____~~

~~Name of manufacturer of importer~~

(f) **Special Requirements for License to Manufacture Calibration Sources Containing Americium-241, Plutonium or Radium-226 for Distribution to Persons Generally Licensed Under C.4.2(e).** An application for a specific license to manufacture calibration and reference sources containing americium-241, plutonium or radium-226 to persons generally licensed under C.4.2(e) will be approved subject to the following conditions:

(1) The applicant satisfies the general requirement of C.5.2, and

(2) The applicant satisfies the requirements of Sections 32.57, 32.58, 32.59, ~~32.60,~~ 32.102 of 10 CFR Part 32 and Section 70.39 of 10 CFR Part 70 or their equivalent.

(g) **General License for Use of Radioactive Material for Certain In-Vitro Clinical or Laboratory Testing.**

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(3) A person who receives, acquires, possesses or uses radioactive material pursuant to the general license established by C.4.2(g)(1) shall comply with the following:

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

(v) The general licensee shall dispose of the Mock Iodine-125 reference or calibration sources

[13] Showing only the name of the appropriate material.

described in C.4.2(g)(1)(viii) as required by A.4.1 of these regulations.

(4) The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to C.4.2(g)(1):

(i) Except as prepackaged units which are labeled in accordance with the provisions of an applicable specific license issued pursuant to C.5.5(h) or in accordance with the provisions of a specific license issued by the U.S. Nuclear Regulatory Commission~~, any~~ or another Agreement State ~~or Licensing State~~ which authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), iron-59, selenium-75, cobalt-57, or Mock Iodine-125 to persons generally licensed under C.4.2 or its equivalent, and

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(i) **General License for Radium-226 Contained in Products Manufactured Prior to 30 November 2007.**

(1) A general license is hereby issued to any person to acquire, receive, possess, use, or transfer, in accordance with the provisions of §§4.2(i)(2), (3) and (4), Radium-226 contained in the following products manufactured prior to 30 November 2007.

(i) Antiquities originally intended for use by the general public. For the purposes of §4.2(i), *antiquities* mean products originally intended for use by the general public and distributed in the late 19th and early 20th centuries, such as radium emanator jars, revigators, radium water jars, radon generators, refrigerator cards, radium bath salts, and healing pads;

(ii) Intact timepieces containing greater than 37 kBq (1 μCi), nonintact timepieces, and timepiece hands and dials no longer installed in timepieces;

(iii) Luminous items installed in air, marine, or land vehicles;

(iv) All other luminous products, provided that no more than one hundred (100) items are used or stored at the same location at any one time.

(v) Small radium sources containing no more than 37 kBq (1 μCi) of Radium-226. For the purposes of §4.2(i), *small radium sources* means discrete survey instrument check sources, sources contained in radiation measuring instruments, sources used in educational demonstrations (such as cloud chambers and spinthariscopes), electron tubes, lightning rods, ionization sources, static eliminators, or as designated by the Agency.

(2) Persons who acquire, receive, possess, use, or transfer radioactive material under the general license issued in §4.2(i)(1) are exempt from the provisions of Subparts A.1 - A.6 of these regulations to the extent that the receipt, possession, use, or transfer of radioactive material is within the terms of the general license. However, this exemption shall not be deemed to apply to any such person specifically licensed under these regulations.

(3) Any person who acquires, receives, possesses, uses, or transfers radioactive material in accordance with the general license in §4.2(i)(1):

(i) Shall notify the Agency should there be any indication of possible damage to the product so that it appears it could result in a loss of the radioactive material. A report containing a brief description of the event, and the remedial action taken, shall be furnished to the Agency within thirty (30) days.

(ii) Shall not abandon products containing Radium-226. The product, and any radioactive material from the product, may only be disposed of according to §A.4.1 or by transfer to a person authorized by a specific license to receive the Radium-226 in the product or as

otherwise approved by the Agency.

(iii) Shall not export products containing Radium-226 except in accordance with 10 CFR110.

(iv) Shall dispose of products containing Radium-226 at a disposal facility authorized to dispose of radioactive material in accordance with any Federal or State solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005, by transfer to a person authorized to receive Radium-226 by a specific license issued under these Regulations or equivalent regulations of the U.S. Nuclear Regulatory Commission or another Agreement State.

(v) Shall respond to written requests from the Agency to provide information relating to the general license within thirty (30) calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by providing the Agency with a written justification for the request.

(4) The general license in §4.2(i)(1) does not authorize the manufacture, assembly, disassembly, repair, or import of products containing Radium-226, except that timepieces may be disassembled and repaired.

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C.5 SPECIFIC LICENSES

C.5.1 **Filing Application for Specific Licenses.**

(a) Applications for specific licenses shall be filed in ~~triplicate~~ duplicate on a form prescribed by the Agency , and shall include a designated e-mail address for receipt of official Agency correspondence in electronic format.

(b) The Agency may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the Agency to determine whether the application should be granted or denied or whether a license should be modified or revoked.

(c) Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on ~~his~~ their behalf.

(d) An application for a license may include a request for a license authorizing one or more activities.

(e) In ~~his~~ the application, the applicant shall submit the required information to the Agency without reference to previously submitted documents unless permission has been obtained from the Agency, in advance, to incorporate by reference information contained in previous applications, statements, or reports filed with the Agency. All references shall be clear and specific and shall contain all of the information needed for a particular item on the application.

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C.5.2 **General Requirements for the Issuance of Specific Licenses.** A license application will be approved if the Agency determines that:

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(g) In the case of an application for a license to receive and possess radioactive material for the conduct of any activity which the Agency determines will significantly affect the quality of the environment, the Agency has concluded, after weighing the environmental, economic, technical and other benefits against environmental costs and considering available alternatives, that the action called for is the issuance of the proposed license,

with any appropriate conditions to protect environmental values. Commencement of construction prior to such conclusion shall be grounds for denial of a license to receive and possess radioactive material in such plant or facility. Commencement of construction, as defined in A.0, may include non-construction activities if the activity has a reasonable nexus to radiological safety and security.

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C.5.3 **Special Requirements for Issuance of Certain Specific Licenses for Radioactive Material.**

(a) **Human Use of Radioactive Material.** In addition to the requirements set forth in C.5.2 and C.8, a specific license for human use of radioactive material in institutions will be issued under the following conditions:

(1) If the application is for medical use sited in a medical institution, only the institution's management may apply. If the application is for medical use not sited in a medical institution, the applicant or a person duly authorized to act for and on their behalf ~~any person~~ may apply.

~~(2) The Agency finds the applicant equipped and committed to observe the safety standards established by the Agency in these regulations for the protection of the public health and safety.~~
(2) The application includes the facility diagram, equipment, and training and experience qualifications of the Radiation Safety Officer, Authorized User(s), authorized medical physicist(s), and authorized nuclear pharmacist(s).

(3) The application includes procedures required by §§C.8.49, C.8.56, C.8.58, and C.8.59, as applicable.

(4) An application for medical use of radioactive material as described in §C.8.79 must also include information regarding any radiation safety aspects of the medical use of the material that is not addressed in Subpart C.8 of these Regulations. The applicant shall also provide specific information on:

(i) Radiation safety precautions and instructions;

(ii) Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and

(iii) Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety.

(b) **[DELETED]** ~~**Human Use of Sealed Sources.** In addition to the requirements set forth in C.5.2 and C.8, a specific license for human use of sealed sources will be issued only if the applicant or, if the application is made by an institution, the individual user is a physician.~~

(c) **Use of Sealed Sources in Industrial Radiography.** In addition to the requirements set forth in C.5.2, a specific license for use of sealed sources in industrial radiography will be issued if:

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(4) The applicant submits a description of a program for inspections of the job performance of each radiographer and radiographer's assistant at intervals not to exceed six (6) months as described in E.2.10(e).

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(7) If an applicant intends to perform leak testing of sealed sources or exposure devices containing depleted uranium (DU) shielding, the applicant must describe the procedures for performing the test, and the qualifications of the person(s) authorized to do the leak testing. If the applicant intends to analyze its own wipe samples, the application must include a description of the procedures to be

followed. The description must include the:

(i) ~~Instrumentation~~ Instruments to be used;

(ii) Method(s) of ~~collecting the samples;~~ performing the analysis; and

(iii) ~~Qualifications~~ Pertinent experience of the person who will analyze the wipe samples~~; and~~

~~(iv) Method(s) of analyzing the samples~~.

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(10) The applicant identifies the location(s) where all records required by ~~this~~ Subpart E.2 and other parts of these Regulations will be maintained.

~~(11) If a license application includes underwater radiography, a description of:~~

~~(i) Radiation safety procedures and radiographer responsibilities unique to the performance of underwater radiography;~~

~~(ii) Radiographic equipment and radiation safety equipment unique to underwater radiography; and~~

~~(iii) Methods for gas-tight encapsulation of equipment; and~~

~~(12) If an application includes offshore platform and/or lay-barge radiography, a description of:~~

~~(i) Transport procedures for radioactive material to be used in industrial radiographic operations;~~

~~(ii) Storage facilities for radioactive material; and~~

~~(iii) Methods for restricting access to radiation areas.~~

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(e) **Production of PET Radioactive Drugs for Noncommercial Transfer**. An application from a medical facility or educational institution to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to licensees in its consortium authorized for medical use under C.8 shall include:

(1) A request for authorization for the production of PET radionuclides or evidence of an existing license issued under C.5, or equivalent regulations of the U.S. Nuclear Regulatory Commission or another Agreement State, for a PET radionuclide production facility within its consortium from which it receives PET radionuclides.

(2) Evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in C.5.5(j)(1)(ii).

(3) Identification of individual(s) authorized to prepare the PET radioactive drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an authorized nuclear pharmacist as specified in C.5.5(j)(2)(ii).

(4) Information identified in C.5.5(j)(1)(iii).on the PET drugs to be noncommercially transferred to members of its consortium.

(f) **Use of Radioactive Material in a Sealed Source or in a Device Containing a Sealed Source.**

(1) Except as provided in C.5.3(f)(2), (f)(3), and (f)(4), an application for a specific license to use radioactive material in the form of a sealed source or in a device that contains the sealed source shall either:

(i) Identify the source or device by manufacturer and model number as registered with the Agency, with the Nuclear Regulatory Commission under 10 CFR 32.210, with another

Agreement State, or for a source or a device containing radium-226 or accelerator-produced radioactive material with a State under provisions comparable to 10 CFR 32.210; or

(ii) Contain the information identified in 10 CFR 32.210(c).

(2) For sources or devices manufactured before 23 October 2012 that are not registered with the Agency, with the Nuclear Regulatory Commission under 10 CFR 32.210 or with another Agreement State, and for which the applicant is unable to provide all categories of information specified in 10 CFR 32.210(c), the applicant shall include:

(i) All available information identified in 10 CFR32.210(c) concerning the source, and, if applicable, the device; and

(ii) Sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Such information must include a description of the source or device, a description of radiation safety features, the intended use and associated operating experience, and the results of a recent leak test.

(3) For sealed sources and devices allowed to be distributed without registration of safety information in accordance with 10 CFR 32.210(g)(1), the applicant may supply only the manufacturer, model number, and radionuclide and quantity.

(4) If it is not feasible to identify each sealed source and device individually, the applicant may propose constraints on the number and type of sealed sources and devices to be used and the conditions under which they will be used, in lieu of identifying each sealed source and device.

(g) **Registration of Product Information.** The Agency does not currently administer a sealed source and device registration program. Any manufacturer or initial distributor of a sealed source or device containing a sealed source who is subject to these Regulations shall submit a request for evaluation of radiation safety information about its product and for its registration to the Nuclear Regulatory Commission pursuant to 10 CFR 32.210.

(h) **Inactivation of Certificates of Registration of Sealed Sources and Devices.**

(1) A certificate holder who no longer manufactures or initially transfers any of the sealed source(s) or device(s) covered by a particular certificate issued by the Agency shall request inactivation of the registration certificate. Such a request must be made to the Agency and must normally be made no later than two (2) years after initial distribution of all of the source(s) or device(s) covered by the certificate has ceased. However, if the certificate holder determines that an initial transfer was in fact the last initial transfer more than two (2) years after that transfer, the certificate holder shall request inactivation of the certificate within ninety (90) days of this determination and briefly describe the circumstances of the delay.

(2) If a distribution license is to be terminated in accordance with these Regulations, the licensee shall request inactivation of its registration certificates associated with that distribution license before the Agency will terminate the license. Such a request for inactivation of certificate(s) must indicate that the license is being terminated and include the associated specific license number.

(3) A specific license to manufacture or initially transfer a source or device covered only by an inactivated certificate no longer authorizes the licensee to initially transfer such sources or devices for use. Servicing of devices must be in accordance with any conditions in the certificate, including in the case of an inactive certificate.

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C.5.5 **Special Requirements for a Specific License to Manufacture, Assemble, Repair, or Distribute Commodities, Products, or Devices which Contain Radioactive Material.**

(a) **[DELETED]** ~~**Licensing the Introduction of Radioactive Material into Products in Exempt Concentrations.**~~

~~(1) In addition to the requirements set forth in C.5.2, a specific license authorizing the introduction of radioactive material into a product or material owned by or in the possession of the licensee or another to be transferred to persons exempt under C.2.2(a)(1) will be issued if:~~

~~(i) The applicant submits a description of the product or material into which the radioactive material will be introduced, intended use of the radioactive material and the product or material into which it is introduced, method of introduction, initial concentration of the radioactive material in the product or material, control methods to assure that no more than the specified concentration is introduced into the product or material, estimated time interval between introduction and transfer of the product or material, and estimated concentration of the radioactive material in the product or material at the time of transfer; and~~

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

~~(2) Each person licensed under C.5.5(a) shall file an annual report with the Agency which shall identify the type and quantity of each product or material into which radioactive material has been introduced during the reporting period; name and address of the person who owned or possessed the product or material, into which radioactive material has been introduced, at the time of introduction; the type and quantity of radionuclide introduced into each such product or material; and the initial concentrations of the radionuclide in the product or material at time of transfer of the radioactive material by the licensee. If no transfers of radioactive material have been made pursuant to C.5.5(a) during the reporting period, the report shall so indicate. The report shall cover the year ending June 30, and shall be filed within 30 days thereafter.~~

(b) **[DELETED]** ~~**Licensing the Distribution of Radioactive Material in Exempt Quantities.**~~[14]

~~(1) An application for a specific license to distribute NARM to persons exempted from these regulations pursuant to C.2.2(b) will be approved if:~~

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

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

~~(iii) The applicant submits copies of prototype labels and brochures and the Agency approves~~

~~[14] Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing byproduct material whose subsequent possession, use transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, DC 20555.~~

~~such labels and brochures.~~

~~(2) The license issued under C.5.5(b)(1) is subject to the following conditions:~~

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

~~(ii) Each exempt quantity shall be separately and individually packaged. No more than 10 such packaged exempt quantities shall be contained in any outer package for transfer to persons exempt pursuant to C.2.2(b). The outer package shall be such that the dose rate at the external surface of the package does not exceed 0.5 millirem (5 μSv) per hour.~~

~~(iii) The immediate container of each quantity or separately packaged fractional quantity of radioactive material shall bear a durable, legible label which:~~

~~(a) Identifies the radionuclide and the quantity of radioactivity, and~~

~~(b) Bears the words "**Radioactive Material**".~~

~~(iv) In addition to the labeling information required by C.5.5(b)(2)(iii), the label affixed to the immediate container, or an accompanying brochure, shall:~~

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

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

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

~~(3) Each person licensed under C.5.5(b) shall maintain records identifying, by name and address, each person to whom radioactive material is transferred for use under C.2.2(b) or the equivalent regulations of a Licensing State, and stating the kinds and quantities of radioactive material transferred. An annual summary report stating the total quantity of each radionuclide transferred under the specific license shall be filed with the Agency. Each report shall cover the year ending June 30, and shall be filed within 30 days thereafter. If no transfers of radioactive material have been made pursuant to C.5.5(b) during the reporting period, the report shall so indicate.~~

(c) **[DELETED]** ~~**Licensing the Incorporation of Naturally Occurring and Accelerator- Produced Radioactive Material into Gas and Aerosol Detectors.** An application for a specific license authorizing the incorporation of NARM into gas and aerosol detectors to be distributed to persons exempt under C.2.2(c)(3) will be approved if the application satisfies requirements equivalent to those contained in Section 32.26 of 10 CFR Part 32. The maximum quantity of radium-226 in each device shall not exceed 0.1 microcurie (3.7 kBq).~~

(d) **Licensing the Manufacture ~~and Distribution~~ or Initial Transfer of Devices to Persons Generally Licensed Under C.4.2(b).**

(1) An application for a specific license to manufacture or ~~distribute~~ initially transfer devices containing radioactive material, excluding special nuclear material, to persons generally licensed under C.4.2(b) or equivalent regulations of the U.S. Nuclear Regulatory Commission~~, an~~ or another Agreement State ~~or a Licensing State~~ will be approved if:

(i) The applicant satisfies the general requirements of C.5.2;

(ii) The applicant submits sufficient information relating to the design, manufacture, prototype

testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:

(a) The device can be safely operated by persons not having training in radiological protection;

(b) Under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in any period of one (1) calendar quarter a dose in excess of ten percent (10%) of the limits specified in A.2.3(a); and

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(iii) Each device bears a durable, legible, clearly visible label or labels approved by the Agency, which contain in a clearly identified and separate statement:

***

(c) The information called for in ~~one of~~ the following statement~~s, as appropriate,~~ in the same or substantially similar form:

~~(1)~~ The receipt, possession, use, and transfer of this device, Model _____[15], Serial No. _____[3], are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or a State with which the U.S. Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION-RADIOACTIVE MATERIAL

_____.
(Name of manufacturer or distributor)

~~(2) The receipt, possession, use, and transfer of this device, Model _____[3], Serial No. _____[3], are subject to a general license or the equivalent, and the regulations of a Licensing State. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.~~

~~**CAUTION-RADIOACTIVE MATERIAL**~~

~~_____.~~
~~(Name of manufacturer or distributor)~~

***

(vi) The device has been registered in the Sealed Source and Device Registry.

***

(2) In the event the applicant desires that the device be required to be tested at intervals longer than six (6) months, either for proper operation of the on-off mechanism and indicator, if any, or for leakage of radioactive material or for both, he shall include in his application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices and by design features which have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the on-off mechanism

[15] The model, serial number, and name of the manufacturer or distributor may be omitted from this label provided the information is elsewhere specified in labeling affixed to the device.

and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the Agency will consider information which includes, but is not limited to:

(i) Primary containment or ~~(~~source capsule~~)~~;

***

(3) In the event the applicant desires that the general licensee under C.4.2(b), or under equivalent regulations of the U.S. Nuclear Regulatory Commission~~, an~~ or another Agreement State ~~or a Licensing State~~ be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the on-off mechanism and indicator, or remove the device from installation, ~~he~~ the applicant shall include in ~~his~~ the application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and bases for such estimates. The submitted information shall demonstrate that performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a calendar quarter dose in excess of ten percent (10%) of the limits specified in A.2.3(a).

***

(5) If a device containing radioactive material is to be transferred ~~in a device~~ for use under an equivalent general license of the U.S. Nuclear Regulatory Commission~~,~~ or another Agreement State ~~or a Licensing State~~, each person that is licensed under C.5.5(d)(1) shall provide the information specified in this paragraph to each person to whom a device is to be transferred. This information shall be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information shall also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

(i) A copy of the U.S. Nuclear Regulatory Commission~~,~~ or Agreement State ~~or Licensing State~~ regulations (as appropriate) equivalent to C.4.2(b), C.4.2 (title paragraph), C.5.15, A.1.3, A.5.12 and A.5.13,or a copy of C.4.2(b), C.4.2 (title paragraph), C.5.15, A.1.3, A.5.12 and A.5.13. If a copy of the Agency regulations is provided to a prospective general licensee in lieu of the appropriate regulatory authority's regulations, it shall be accompanied by a note explaining that use of the device is regulated by that appropriate regulatory authority. If certain paragraphs of the regulations do not apply to the particular device, those paragraphs may be omitted.

***

(8) If a notification of bankruptcy has been made under C.5.7(f)(1) or the license is to be terminated, each person licensed under C.5.5(d)(1) shall provide, upon request, to the Agency and to the U.S. Nuclear regulatory Commission or any appropriate Agreement State ~~or Licensing State~~, records of final disposition required under C.5.5(d)(12).

(9) **Reports to the Agency.** Each person licensed under C.5.5(d)(1) to initially transfer devices to generally licensed persons shall report to the Agency all transfers of such devices to persons for use under the general license in C.4.2(b) and all receipts of devices from persons licensed under C.4.2(b). The report shall be submitted on a quarterly basis on the NRC Form 653 "Transfers of Industrial Devices Report" or in a clear and legible report containing all of the data required by the form.

***

(11) **Reports - General**. The following requirements are applicable to all reports required by C.5.10 of these Regulations:

(i) If one or more intermediate persons will temporarily possess the device at the intended place

of use before its possession by the user, the report shall include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).

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

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

(iv) The report shall cover each calendar quarter, shall be filed within thirty (30) days of the end of the calendar quarter, and shall clearly indicate the period covered by the report.

(v) The report shall clearly identify the specific licensee submitting the report and shall include the license number of the specific licensee.

(12) **Recordkeeping.** Each person licensed under C.5.5(d)(1) to initially transfer devices to generally licensed persons shall maintain all information concerning transfers and receipts of devices that supports the reports required by this section. Records required by this section shall be maintained for a period of three (3) years following the date of the recorded event.

(e) **Special Requirements for the Manufacture, Assembly, or Repair of Luminous Safety Devices for Use in Aircraft.** An application for a specific license to manufacture, assemble, or repair luminous safety devices containing tritium or promethium-147 for uses in aircraft, for distribution to persons generally licensed under C.4.2(c) will be approved subject to the following conditions:

(1) The applicant satisfies the general requirements specified in C.5.2 and

(2) The applicant satisfies the requirements of Sections 32.53, 32.54, 32.55, 32.56~~, 32.101~~ of 10 CFR Part 32 or their equivalent.

(f) **Special Requirements for License to Manufacture or Initially Transfer Calibration Sources Containing Americium-241, Plutonium or Radium-226 for Distribution to Persons Generally Licensed Under C.4.2(e).** An application for a specific license to manufacture or initially transfer calibration and reference sources containing americium-241, plutonium or radium-226 to persons generally licensed under C.4.2(e) will be approved subject to the following conditions:

(1) The applicant satisfies the general requirement of C.5.2, and

(2) The applicant satisfies the requirements of Sections 32.57, 32.58, 32.59, 32.60~~, 32.102~~ of 10 CFR Part 32 and Section 70.39 of 10 CFR Part 70 or their equivalent.

(g) **[DELETED]** ~~**Manufacture and Distribution of Radioactive Material for Medical Use Under General License.** In addition to requirements set forth in C.5.2, a specific license authorizing the distribution of radioactive material for use by physicians under the general license in C.5.2(f) will be issued if:~~

~~(1) The applicant submits evidence that the radioactive material is to be manufactured, labeled, and packaged in accordance with a new drug application which the Commissioner of Food and Drugs, Food and Drug Administration, has approved, or in accordance with a license for a biologic product issued by the Secretary, Department of Health, Education and Welfare; and~~

~~(2) One of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, appears on the label affixed to the container or appears in the leaflet or brochure which accompanies the package:~~

~~(i) This radioactive drug may be received, possessed, and used only by physicians licensed (to dispense drugs) in the practice of medicine. Its receipt, possession, use and transfer are subject to the regulations and a general license or its equivalent of the U.S. Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority.~~

~~_____.~~
~~(Name of manufacturer)~~

~~(ii) This radioactive drug may be received, possessed, and used only by physicians licensed (to dispense drugs) in the practice of medicine. Its receipt, possession, use and transfer are subject to the regulations and a general license or its equivalent of a Licensing State.~~

~~_____.~~
~~(Name of manufacturer)~~

(h) **Manufacture and Distribution of Radioactive Material for Certain In-vitro Clinical or Laboratory Testing Under General License.** An application for a specific license to manufacture or distribute radioactive material for use under the general license of C.4.2(g) will be approved if:

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(4) ~~One of~~ The following statement~~s, as appropriate,~~ or a substantially similar statement which contains the information called for in ~~one of~~ the following statement~~s~~, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

~~(i)~~ This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians in the practice of veterinary medicine, clinical laboratories or hospitals and only for in-vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority.

_____.
(Name of manufacturer)

~~(ii) This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians in the practice of veterinary medicine, clinical laboratories or hospitals and only for in-vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human being or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of a Licensing State.~~

~~_____.~~
~~(Name of manufacturer)~~

(5) The label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such radioactive material. In the case of the mock iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements set out in A.4.1 of these regulations.

(i) **Licensing the Manufacture and Distribution of Ice Detection Devices Containing Strontium-90.**

An application for a specific license to manufacture ~~and distribute~~ or initially transfer ice detection devices to persons generally licensed under C.4.2(h) will be approved subject to the following conditions:

(1) The applicant satisfies the general requirements of C.5.2, and

(2) The criteria of Sections 32.61, 32.62, 32.63~~, 32.103~~ of 10 CFR Part 32 are met.

(j) **Manufacture~~, Preparation, or Transfer for Commercial~~ and Distribution of Radioactive Drugs Containing Radioactive Material for Medical Use Under Subpart C.8.**

(1) An application for a specific license to manufacture, prepare, or transfer for commercial distribution radioactive drugs containing radioactive material for use by persons licensed pursuant to C.5.3(a) will be approved if:

(i) The applicant satisfies the general requirements specified in C.5.2 of this part;

(ii) The applicant submits evidence that the applicant is at least one of the following:

(a) Registered ~~or licensed~~ with the U.S. Food and Drug Administration (FDA) as ~~a drug manufacturer~~ the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR 207.20(a);

(b) Licensed as a drug manufacturer in accordance with the *Rules and Regulations Pertaining to Pharmacists, Pharmacies and Manufacturers, Wholesalers and Distributors* [*R5-19-PHAR*] of the Rhode Island Department of Health; ~~or~~

(c) Licensed as a pharmacy in accordance with the *Rules and Regulations Pertaining to Pharmacists, Pharmacies and Manufacturers, Wholesalers and Distributors* [*R5-19-PHAR*] of the Rhode Island Department of Health; or

(d) A positron emission tomography (PET) drug production facility licensed pursuant to C.5.5(j)(1)(ii)(b) or C.5.5(j)(1)(ii)(b) (as applicable.

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

(iv) The applicant satisfies the following labeling requirements:

(a) A label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words **"CAUTION, RADIOACTIVE MATERIAL"** or **"DANGER, RADIO-ACTIVE MATERIAL"**, the name of the radioactive drug or its abbreviation, and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half-life greater than one hundred (100) days, the time may be omitted.

(b) A label is affixed to each syringe, vial or other container used to hold a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words **"CAUTION, RADIOACTIVE MATERIAL"** or **"DANGER, RADIOACTIVE MATERIAL"**, and an identifier that ensures that the syringe, vial or other container can be correlated with the information on the transport radiation shield label.

(2) A licensee described by ~~Subparagraph (1)(ii)(c) of this Section~~ C.5.5(j)(1) of these Regulations:

(i) May prepare radioactive drugs for medical use, as defined by these Regulations, provided that the radioactive drug is prepared by either an authorized nuclear pharmacist as specified in ~~Sub-paragraph (2)(ii) of this Section~~ C.5.5(j)(2)(ii) of these Regulations, or an individual under the supervision of an authorized nuclear pharmacist as specified in Section C.8.8 of these regulations.

(ii) May allow a pharmacist to work as an authorized nuclear pharmacist if:

(a) This individual qualifies as an authorized nuclear pharmacist as defined in these Regulations; and

(b) This individual meets the requirements specified in ~~Paragraph~~ C.8.76(b) and ~~Section~~ C.8.74 of these Regulations and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist.

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(l) **Manufacture and Distribution of Sources or Devices Containing Radioactive Material for Medical Use.** An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to C.5.3(a) or C.5.3(b) for use as a calibration or reference source or for the uses listed in C.8.38, C.8.40, ~~and~~ C.8.46 and C.8.79 will be approved if:

(1) The applicant satisfies the general requirements in C.5.2 ~~of this part~~ of these Regulations.

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(3) The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity, and date of assay, and a statement that the Agency has approved distribution of the (name of source or device) to persons licensed to use radioactive material identified in C.8.17, C.8.38, C.8.40 and C.8.46, as appropriate, and to persons who hold an equivalent licenses of the U.S. Nuclear Regulatory Commission~~,~~ or an Agreement State ~~or a Licensing State~~.

(4) In the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than six (6) months, ~~he~~ the applicant shall include in ~~his~~ the application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source; and

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(6) The source or device has been registered in the Sealed Source and Device Registry.

(m) **Requirements for License to Manufacture and Distribute Industrial Products Containing Depleted Uranium for Mass-Volume Applications.**

(1) An application for a specific license to manufacture industrial products and devices containing depleted uranium for use pursuant to C.4.1(d) or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State will be approved if:

(i) The applicant satisfies the general requirements specified in C.5.2;

(ii) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling and marking, proposed uses, and potential hazards of the industrial product or device to provide reasonable assurance that possession, use, and transfer of the depleted uranium in the product or device is not likely to cause any

individual to receive in any period of one calendar quarter a radiation dose in excess of ~~10~~ ten percent (10%) of the limits specified in A.2.3(a); and

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(4) Each person licensed pursuant to C.5.5(m)(1) shall:

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(iv) (a) Furnish a copy of the general license contained in C.4.1(d) and a copy of Agency Form GEN-1 to each person to whom ~~he~~ the licensee transfers depleted uranium in a product or device for use pursuant to the general license contained in C.4.1(d), or

(b) Furnish a copy of the general license contained in the U.S. Nuclear Regulatory Commission's or Agreement State's regulation equivalent to C.4.1(d) and a copy of the U.S. Nuclear Regulatory Commission's or Agreement State's certificate, or alternatively, furnish a copy of the general license contained in C.4.1(d) and a copy of Agency Form GEN-1 to each person to whom he transfers depleted uranium in a product or device for use pursuant to the general license of the U.S. Nuclear Regulatory Commission or an Agreement State, with a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or an Agreement State under requirements substantially the same as those in C.4.1(d);

(v) Report to the Agency all transfers of industrial products or devices to persons for use under the general license in C.4.1(d). Such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the Agency and the general licensee, the type and model number of device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within thirty (30) days after the end of each calendar quarter in which such a product or device is transferred to the generally licensed person. If no transfers have been made to persons generally licensed under C.4.1(d) during the reporting period, the report shall so indicate;

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

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(c) Such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the agency and the general licensee, the type and model number of the device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within thirty (30) days after the end of each calendar quarter in which such product or device is transferred to the generally licensed person,

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(vii) Keep records showing the name, address, and point of contact for each general licensee to whom ~~he~~ the licensee transfers depleted uranium in industrial products or devices for use pursuant to the general license provided in C.4.4(d) or equivalent regulations of the U.S. Nuclear Regulatory Commission or of an Agreement State. The records shall be maintained for a period of two (2) years and shall show the date of each transfer, the quantity of depleted uranium in each product or device transferred, and compliance with the report requirements of this section.

(n) **Serialization of Nationally Tracked Sources.** Each licensee who manufactures a nationally tracked

source[16] shall assign a unique serial number to each nationally tracked source. Serial numbers shall be composed only of alpha-numeric characters.

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C.5.7 **Specific Terms and Conditions of License.**

(a) Each licensee issued pursuant to this part shall be subject to all the provisions of the Act, now or thereafter in effect, and to all rules, regulations and orders of the Agency.

(b) (1) No license issued or granted under this part and no right to possess or utilize radioactive material granted by any license issued pursuant to this part shall be transferred, assigned, or in any manner disposed of either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the Agency shall, after securing full information find that the transfer is in accordance with the provisions of the Act, and shall give its consent in writing.

(2) An application for transfer of license must include:

(i) The identity, technical and financial qualifications of the proposed transferee; and

(ii) Financial assurance for decommissioning information required by C.5.16.

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(d) Each licensee preparing Technetium-99m radiopharmaceuticals from Molybdenum-99/ Technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for Molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with Section C.8.31. The licensee shall record the results of each test and retain each record for three (3) years after the record is made.

(e) Each licensee shall notify the Agency in writing when he decides to permanently discontinue all activities involving materials authorized under the license. This notification requirement applies to all specific licenses issued under this part.

(f) (1) Each general licensee that is required to register by C.4.2(b)(6) and each specific licensee shall notify the Agency, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against:

(i) the licensee;

(ii) an entity (as that term is defined in ~~11 USC 101(14)~~ 11 U.S.C. 101(15)) controlling the licensee or listing the license or licensee as property of the estate; or

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(h) **Production of PET Radioactive Drugs for Noncommercial Transfer.**

(1) Authorization under C.5.3(e) to produce Positron Emission Tomography (PET) radioactive drugs for non-commercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other Federal and State requirements governing radioactive drugs.

(2) Each licensee authorized under C.5.3(e) to produce PET radioactive drugs for noncommercial

[16] The requirement is only applicable to sources manufactured after 6 February 2007.

transfer to medical use licensees in its consortium shall:

(i) Satisfy the labeling requirements in C.5.5(j)(1)(iv) for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium.

(ii) Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in C.5.5(j)(3.

(3) A licensee that is a pharmacy authorized under C.5.3(e) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radioactive drugs shall be:

(i) an authorized nuclear pharmacist that meets the requirements in C.5.5(j)(2)(ii), or

(ii) an individual under the supervision of an authorized nuclear pharmacist as specified in C.8.8.

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C.5.14 **Transfer of Material.**

(a) No licensee shall transfer radioactive material except as authorized pursuant to this section.

(b) Except as otherwise provided in his license and subject to the provisions of C.5.14(c) and (d), any licensee may transfer radioactive material:

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(4) to any person authorized to receive such material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the Agency, the U.S. Nuclear Regulatory Commission~~,~~ or any Agreement State ~~or any Licensing State~~, or to any person otherwise authorized to receive such material by the Federal Government or any agency thereof, the Agency~~,~~ or any Agreement State ~~or any Licensing State~~; or

(5) as otherwise authorized by the Agency in writing.

(c) Before transferring radioactive material to a specific licensee of the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State, or to a general licensee who is required to register with the Agency, the U.S. Nuclear Regulatory Commission~~,~~ or an Agreement State ~~or a Licensing State~~ prior to receipt of the radioactive material, the licensee transferring the material shall verify that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred.

(d) The following methods for the verification required by C.5.14(c) are acceptable:

(1) The transferor may have in his possession, and read, a current copy of the transferee's specific license or registration certificate;

(2) the transferor may have in his possession a written certification by the transferee that he is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date;

(3) for emergency shipments the transferor may accept oral certification by the transferee that he is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the licensee or registration certificate number, issuing agency,

and expiration date; provided, that the oral certification is confirmed in writing within 10 days;

(4) the transferor may obtain other sources of information compiled by a reporting service from official records of the Agency, the U.S. Nuclear Regulatory Commission~~,~~ or the licensing agency of another Agreement State ~~or a Licensing State~~ as to the identity of licensees and the scope and expiration dates of licenses and registration; or

(5) when none of the methods of verification described in C.5.14(d)(1) to (4) are readily available or when a transferor desires to verify that information received by one of such methods is correct or up-to-date, the transferor may obtain and record confirmation from the Agency, the U.S. Nuclear Regulatory Commission~~,~~ or the licensing agency of another Agreement State ~~or a Licensing State~~ that the transferee is licensed to receive the radioactive material.

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C.5.16 **Financial Assurance and Recordkeeping for Decommissioning.**

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(e) (1) Each decommissioning funding plan must contain:

(i) A detailed cost estimate for decommissioning, in an amount reflecting:

(a) The cost of an independent contractor to perform all decommissioning activities;

(b) The cost of meeting the A.2.14 criteria for unrestricted use, provided that, if the applicant or licensee can demonstrate its ability to meet the provisions of A.2.15, the cost estimate may be based on meeting the A.2.15 criteria;

(c) The volume of onsite subsurface material containing residual radioactivity that will require remediation to meet the criteria for license termination; and

(d) An adequate contingency factor.

(ii) Identification of and justification for using the key assumptions contained in the DCE;

(iii) A description of the method of assuring funds for decommissioning from C.5.16(f), including means for adjusting cost estimates and associated funding levels periodically over the life of the facility. ~~Cost estimates must be adjusted at intervals not to exceed 3 years. The decommissioning funding plan must also contain~~

(iv) A certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning and

(v) A signed original of the financial instrument obtained to satisfy the requirements of C.5.16(f) (unless a previously submitted and accepted financial instrument continues to cover the cost estimate for decommissioning).

(2) At the time of license renewal and at intervals not to exceed three (3) years, the decommissioning funding plan must be resubmitted with adjustments as necessary to account for changes in costs and the extent of contamination. If the amount of financial assurance will be adjusted downward, this can not be done until the updated decommissioning funding plan is approved. The decommissioning funding plan must update the information submitted with the original or prior approved plan, and must specifically consider the effect of the following events on decommissioning costs:

(i) Spills of radioactive material producing additional residual radioactivity in onsite subsurface material;

(ii) Waste inventory increasing above the amount previously estimated;

(iii) Waste disposal costs increasing above the amount previously estimated;

(iv) Facility modifications;

(v) Changes in authorized possession limits;

(vi) Actual remediation costs that exceed the previous cost estimate;

(vii) Onsite disposal; and

(viii) Use of a settling pond.

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C.6 RECIPROCITY

C.6.1 **Reciprocal Recognition of Licenses.**

(a) **Licenses of Radioactive Material.**

(1) Subject to these regulations, and the limitations contained in C.6.1(a)(4), any person who holds a specific license from the U.S. Nuclear Regulatory Commission or any Agreement State, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this State, except for areas under exclusive federal jurisdiction, for a period not in excess of 180 days in any calendar year provided that:

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(v) the out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in C.6.1(a)(1) except by transfer to a person:

(a) specifically licensed by the Agency, another Agreement State or by the U.S. Nuclear Regulatory Commission to receive such material~~, or~~

~~(b) exempt from the requirements for a license for such material under C.2.2(a)~~.

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(b) **[DELETED]** ~~**Licenses of Naturally-Occurring and Accelerator-Produced Radioactive Material.**~~

~~(1) Subject to these regulations, and the limitations contained in C.6.1(b)(4), any person who holds a specific license from any Licensing State, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this State, except for areas under exclusive federal jurisdiction, for a period not in excess of 180 days in any calendar year provided that:~~

~~(i) the licensing document does not limit the activity authorized by such document to specified installations or locations;~~

~~(ii) the out-of-state licensee submits Agency Form MAT-9, a copy of the pertinent licensing document, and the appropriate fee as prescribed in I.3.4 to the Agency at least three (3) days prior to engaging in such activity for the first time in a calendar year. If a submittal cannot be filed three (3) days before engaging in activities under reciprocity, because of an emergency or other reason, the Agency may waive the 3-day time requirement provided the licensee:~~

~~(a) Informs the Agency by telephone, facsimile, an Agency Form MAT-9, or a letter of~~

~~initial activities or revisions to the information submitted on the initial Agency Form MAT-9;~~

~~(b) Receives oral or written authorization for the activity from the Agency; and~~

~~(c) Within three (3) days after the notification, files an Agency Form MAT-9, a copy of the pertinent licensing document, and the appropriate fee as prescribed in I.3.4.~~

~~(iii) The out-of-state licensee complies with all applicable regulations of the Agency and with all the terms and conditions of his licensing document, except any such terms and conditions which may be inconsistent with applicable regulations of the Agency;~~

~~(iv) the out-of-state licensee supplies such other information as the Agency may request; and~~

~~(v) the out-of-state license shall not transfer or dispose of radioactive material possessed or used under the general license provided in C.6.1(b)(1) except by transfer to a person;~~

~~(a) specifically licensed by the Agency or by another Licensing State to receive such material, or~~

~~(b) exempt from the requirements for a license for such material under C.2.2.~~

~~(2) Notwithstanding the provisions of C.6.1(b)(1), any person who holds a specific license issued by a Licensing State authorizing the holder to manufacture, transfer, install, or service a device described in C.4.2(b)(1) within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate or service such a device in this State, except for areas under exclusive federal jurisdiction, provided that:~~

~~(i) such person shall file a report with the Agency within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this State. Each such report shall identify each general licensee to whom such device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;~~

~~(ii) the device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by a Licensing State;~~

~~(iii) such person shall assure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that "Removal of this label is prohibited;" and~~

~~(iv) the holder of the specific license shall furnish to each general licensee to whom he transfers such device or on whose premises he installs such device a copy of the general license contained in C.4.2(b).~~

~~(3) The Agency may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by a Licensing State, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.~~

~~(4) The Agency will not accept any applications for reciprocity under this subpart with respect to activities authorized pursuant to regulations that are equivalent to Subpart C.8 ["Use of Radionuclides in the Healing Arts"]. These activities will only be authorized under the provision of a specific license issued by the Agency.~~

(c) **Generally Licensed Devices .**

(1) Reciprocity requests involving generally licensed devices registered pursuant to C.4.2(b)(6) or the

equivalent regulations of the U.S. Nuclear Regulatory Commission~~,~~ or another Agreement State ~~or a Licensing State~~ shall be handled in accordance with the procedures contained in C.6.1(a) or (b), as appropriate. Applicants for reciprocity shall submit evidence of current registration pursuant to C.4.2(b)(6) (or the equivalent regulations of the U.S. Nuclear Regulatory Commission~~,~~ or another Agreement State ~~or a Licensing State~~) in lieu of a specific radioactive materials license.

(2) Reciprocity requests involving other generally licensed devices shall also be handled in accordance with the procedures contained in C.6.1(a) or (b), as appropriate. In lieu of a specific radioactive materials license, applicants for reciprocity shall submit a copy of the general license authorization for the device and documentation that they are authorized to possess the device under a general license pursuant to the regulations of the U.S. Nuclear Regulatory Commission~~,~~ or another Agreement State ~~or a Licensing State~~ that are applicable to the jurisdiction where the reciprocity request originated.

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C.7 TRANSPORTATION OF RADIOACTIVE MATERIAL

C.7.1 Purpose and Scope.

(a) The regulations in this Subpart establish requirements for packaging, preparation for shipment, and transportation of ~~radioactive~~ licensed material ~~and apply to any person who transports radioactive material or delivers radioactive material to a carrier for transport~~.

(b) The packaging and transportation of licensed material are also subject to the requirements of other agencies (e.g., the U.S. Department of Transportation, the U.S. Nuclear Regulatory Commission and the U.S. Postal Service[17]) having jurisdiction over means of transport. The requirements of this Subpart are in addition to, and not in substitution for, other requirements.

(c) The Regulations in this Subpart apply to any licensee authorized by specific or general license issued by the Agency to receive, possess, use or transfer licensed material, if the licensee delivers that material to a carrier for transport, transports the material outside the site of usage as specified in the Agency license, or transports that material on public highways. No provision of this Subpart authorizes possession of licensed material.

(d) Definition of terms used in this Subpart are those listed in Subpart A.0 of these Regulations, 49 CFR and 10 CFR 71.4, except that whenever a definition refers to evaluation or approval by the U.S. Department of Transportation or NRC, and such evaluation or approval is within the jurisdiction of the State of Rhode Island as an Agreement State, the Agency shall perform the evaluation or approval.

C.7.2 Requirement for License and Opening Instructions.

(a) **Requirement for License.** No person shall transport radioactive material or deliver radioactive material to a carrier for transport except as authorized in a general or specific license issued by the Agency or as exempted in C.7.3.

(b) **Opening Instructions.** Before delivery of a package to a carrier for transport, the licensee shall ensure that any special instructions needed to safely open the package have been sent to, or otherwise made available to, the consignee for the consignee's use in accordance with A.3.17(e) of these Regulations.

C.7.3 Exemptions.

~~(a) Common and contract carriers, freight forwarders, and warehouse workers which are subject to the~~

[17] Postal Service Manual (Domestic Mail Manual), section 124, which is incorporated by reference at 39 CFR 111.1.

~~requirements of the U.S. Department of Transportation in 49 CFR 170 through 189 or the U.S. Postal Service in the U.S. Postal Service (Domestic Mail Manual), Section C-023.9.0, and the U.S. Postal Service, are exempt from the requirements of this Subpart to the extent that they transport or store radioactive material in the regular course of their carriage for others or storage incident thereto. Common and contract carriers who are not subject to the requirements of the U.S. Department of Transportation or U.S. Postal Service are subject to C.7.2 and other applicable requirements of these Regulations.~~

(a) Any physician licensed by a State to dispense drugs in the practice of medicine is exempt from C.7.4 with respect to transport by the physician of licensed material for use in the practice of medicine. However, any physician operating under this exemption must be licensed under Subpart C.8 of these Regulations, 10 CFR 35 or the equivalent regulations of another Agreement State.

~~(b) Any licensee is exempt from the requirements of this Subpart to the extent that the licensee delivers to a carrier for transport a package containing radioactive material having a specific activity not greater than 70 becquerel per gram (0.002 μCi/g)~~

(b) A licensee is exempt from all the requirements of this Subpart with respect to shipment or carriage of the following low-level materials:

(1) Natural material and ores containing naturally occurring radionuclides that are not intended to be processed for use of these radionuclides, provided the activity concentration of the material does not exceed ten (10) times the values specified in Table IV of Appendix G to Part C.

(2) Materials for which the activity concentration is not greater than the activity concentration values specified in Table IV of Appendix G to Part C, or for which the consignment activity is not greater than the limit for an exempt consignment found in Table IV of Appendix G to Part C.

(e) Fissile material meeting all the requirements of at least one paragraph in C.7.3(e)(1) through (e)(6) are exempt from classification as fissile material and from the fissile material package standards of 10 CFR 71.55 and 71.59, but are subject to all other requirements of C.7, except as noted.

(1) Individual package containing two (2) grams or less fissile material.

(2) Individual or bulk packaging containing fifteen (15) grams or less of fissile material provided the package has at least two hundred (200) grams of solid nonfissile material for every gram of fissile material. lead, beryllium, graphite, and hydrogenous material enriched in deuterium may be present in the package but must not be included in determining the required mass for solid nonfissile material.

(3) (i) Low concentrations of solid fissile material commingled with solid nonfissile material, provided that:

(a) There is at least two thousand (2000) grams of solid nonfissile material for every gram of fissile material, and

(b) There is no more than one hundred eighty (180) grams of fissile material distributed within three hundred sixty (360) kg of contiguous nonfissile material.

(ii) Lead, beryllium, graphite, and hydrogenous material enriched in deuterium may be present in the package but must not be included in determining the required mass of solid nonfissile material.

(4) Uranium enriched in uranium-235 to a maximum of one percent (1%) by weight, and with total plutonium and uranium-233 content of up to one percent (1%) of the mass of uranium-235, provided that the mass of any beryllium, graphite, and hydrogenous material enriched in deuterium constitutes less than five percent (5%) of the uranium mass.

(5) Liquid solutions of uranyl nitrate enriched in uranium-235 to a maximum of two percent (2%) by mass, with a total plutonium and uranium-233 content not exceeding two one-thousandth of a percent

(0.002%) of the mass of uranium, and with a minimum nitrogen to uranium atomic ratio (N/U) of 2. The material must be contained in at least a DOT Type A package.

(6) Packages containing, individually, a total plutonium mass of not more than one-thousand (1000) grams, of which not more than twenty percent (20%) by mass may consist of plutonium-239, plutonium-241, or any combination of these radionuclides.

C.7.4 Transportation of Licensed Material.

(a) Each licensee who transports licensed material outside of the site of usage, as specified in the Agency license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, shall:

(1) Comply with the applicable requirements, appropriate to the mode of transport, of 49 CFR Parts 107, 171-180, 390-397 , appropriate to the mode of transport. ~~the regulations of the U.S. Department of Transportation;~~ The licensee shall particularly note the regulations of the U.S. Department of Transportation in the following areas:

(i) Packaging - 49 CFR Part 173: Subparts A and B and I.

(ii) Marking and labeling - 49 CFR Part 172: Subpart D, §§172.400 through 172.407, §§172.436 through 172.440, and 172.441 of Subpart E.

(iii) Placarding - 49 CFR Part 172: Subpart F, especially §§172.500 through 172.519 and 172.556 and Appendices B and C.

(iv) Accident reporting - 49 CFR Part 171: §§171.15 and 171.16.

(v) Shipping papers and emergency information - 49 CFR Part 172: Subpart C and Subpart G.

(vi) Hazardous material employee training - 49 CFR Part 172: Subpart H.

(vii) Hazardous material shipper/carrier registration - 49 CFR Part 107: Subpart G.

(viii) Security plans, 49 CFR part 172, subpart I;

(2) The licensee shall also comply with applicable U.S. Department of Transportation regulations pertaining to the following modes of transportation:

(i) Rail - 49 CFR Part 174: Subparts A through D and K.

(ii) Air - 49 CFR Part 175.

(iii) Vessel - 49 CFR Part 176: Subparts A through F and M.

(iv) Public Highway - 49 CFR Part 177 and Parts 390 through 397.

~~(3) Assure that any special instructions needed to safely open the package are sent to or have been made available to the consignee in accordance with A.3.17(e).~~

(b) If~~, for any reason, the regulations of the~~ U.S. Department of Transportation regulations are not applicable to a shipment of licensed material, the licensee shall conform to the standards and requirements of ~~49 CFR Parts 170 through 189 appropriate to the mode of transport~~ the U.S. Department of Transportation specified in C.7.4(a) to the same extent as if the shipment was subject to the regulations. A request for modification, waiver, or exemption from those requirements, and any notification referred to in those requirements, must be filed with, or made to, the Agency.

C.7.5 General Licenses for Carriers.

(a) A general license is hereby issued to any common or contract carrier not exempt under C.7.3 to receive, possess, transport, and store radioactive material in the regular course of their carriage for others or storage incident thereto, provided the transportation and storage is in accordance with the applicable

requirements, appropriate to the mode of transport, of the U.S. Department of Transportation insofar as such requirements relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting.[18]

(b) A general license is hereby issued to any private carrier to transport radioactive material, provided the transportation is in accordance with the applicable requirements, appropriate to the mode of transport, of the U.S. Department of Transportation insofar as such requirements relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting.[18]

(c) Persons who transport radioactive material pursuant to the general licenses in C.7.5(a) or C.7.5(b) are exempt from the requirements of Part A of these regulations to the extent that they transport radioactive material.

C.7.6 General License: Nuclear Regulatory Commission-Approved Packages.

(a) A general license is hereby issued to any licensee of the Agency to transport, or to deliver to a carrier for transport, licensed material in a package for which a license, certificate of compliance (CoC), or other approval has been issued by the Nuclear Regulatory Commission.

(b) This general license applies only to a licensee who:

(1) Has a copy of the ~~specific license,~~ certificate of compliance (CoC), or other approval ~~by the Nuclear Regulatory Commission~~ of the package and has the drawings and other documents referenced in the approval relating to the use and maintenance of the packaging and to the actions to be taken prior to shipment;

(2) Complies with the terms and conditions of the license, certificate, or other approval by the Nuclear Regulatory Commission, as applicable, and the applicable requirements of ~~this~~ 10 CFR 71, Subparts A, G and H;

(3) Prior to the licensee's first use of the package, has ~~registered with~~ submitted to the Nuclear Regulatory Commission, in writing, the licensee's name and license number and the package identification number specified in the package approval; and

(4) Has a quality assurance program approved by the Nuclear Regulatory Commission as satisfying the provisions of 10 CFR 71, Subpart H ~~required by C.7.19~~.

(c) The general license in C.7.6(a) applies only when the package approval authorizes use of the package under this general license.

(d) For a Type B or fissile material package, the design of which was approved by the Nuclear Regulatory Commission before 1 April 1996, the general license is subject to the additional restrictions of C.7.7.

C.7.7 General License: Previously Approved Package.

(a) **[RESERVED]** ~~A Type B package previously approved by the Nuclear Regulatory Commission, but not designated as B(U) or B(M) in the identification number of the Nuclear Regulatory Commission certificate of compliance, may be used under the general license of C.7.6 with the following additional conditions:~~

~~(1) Fabrication of the packaging was satisfactorily completed before August 31, 1986, as demonstrated by application of its model number in accordance with Nuclear Regulatory Commission regulations at 10 CFR 71.85(c);~~

~~(2) A package used for a shipment to a location outside the United States is subject to multilateral~~

[18] Notification of an incident shall be filed with, or made to, the Agency as prescribed in 49 CFR, regardless of and in addition to notification made to the U.S. Department of Transportation or other agencies

~~approval, as defined in U.S. Department of Transportation regulations at 49 CFR 173.403; and~~

~~(3) A serial number that uniquely identifies each packaging which conforms to the approved design is assigned to, and legibly and durably marked on, the outside of each packaging.~~

(b) A Type B(U) package, a Type B(M) package~~, a low specific activity (LSA) material package~~ or a fissile material package, previously approved by the Nuclear Regulatory Commission but without the designation "-85" in the identification number of the Nuclear Regulatory Commission certificate of compliance, may be used under the general license of C.7.6 with the following additional conditions:

(1) Fabrication of the package was satisfactorily completed by 1 April 1999, as demonstrated by application of its model number in accordance with Nuclear Regulatory Commission regulations at 10 CFR 71.85(c);

(2) A package used for a shipment to a location outside the United States is subject to multilateral approval as defined in U.S. Department of Transportation regulations at 49 CFR 173.403; and

(3) A serial number which uniquely identifies each packaging which conforms to the approved design is assigned to and legibly and durably marked on the outside of each packaging.

(c) A Type B(U) package, a Type B(M) package, or a fissile material package previously approved by the Nuclear Regulatory Commission with the designation "-85" in the identification number of the Nuclear Regulatory Commission certificate of compliance, may be used under the general license of C.7.6 with the following additional conditions:

(1) Fabrication of the package was satisfactorily completed by 31 December 2006, as demonstrated by application of its model number in accordance with Nuclear Regulatory Commission regulations at 10 CFR 71.85(c); and

(2) A package used for a shipment to a location outside the United States is subject to multilateral approval as defined in DOT regulations at 49 CFR 173.403.

~~C.7.8 General License: U.S. Department of Transportation Specification Container.~~

~~(a) A general license is issued to any licensee to transport, or to deliver to a carrier for transport, licensed material in a specification container for fissile material or for a Type B quantity of radioactive material as specified in 49 CFR Parts 173 and 178.~~

~~(b) This general license applies only to a licensee who:~~

~~(1) Has a copy of the specification;~~

~~(2) Complies with the terms and conditions of the specification and the applicable requirements of this Subpart; and~~

~~(3) Has a quality assurance program required by C.7.19.~~

~~(c) The general license in C.7.8(a) is subject to the limitation that the specification container may not be used for a shipment to a location outside the United States except by multilateral approval as defined in 49 CFR 173.403.~~

C.7.8 General License: Plutonium-Beryllium Special Form Material.

(a) A general license is hereby issued to any licensee of the Agency to transport fissile material in the form of plutonium-beryllium (Pu-Be) special form sealed sources, or to deliver Pu-Be sealed sources to a carrier for transport, if the material is shipped in accordance with C.7.8. This material need not be contained in a package which meets the standards of 10 CFR 71 Subparts E and F. However, the material must be contained in a Type A package. The Type A package must also meet the DOT requirements of 49 CFR 173.417(a).

(b) The general license applies only to a licensee who has a quality assurance program approved by the Nuclear Regulatory Commission as satisfying the provisions of 10 CFR 71 Subpart H.

(c) The general license applies only when a package's contents:

(1) Contain less than a Type A quantity of material; and

(2) Contain less than one-thousand grams (1000 g) of plutonium, provided that: plutonium-239, plutonium-241, or any combination of these radionuclides, constitutes less than two hundred forty grams (240 g) of the total quantity of plutonium in the package.

(d) The general license applies only to packages labeled with a CSI which:

(1) Has been determined in accordance with C.7.8(e);

(2) Has a value less than or equal to one-hundred (100); and

(3) For a shipment of multiple packages containing Pu-Be sealed sources, the sum of the CSIs must be less than or equal to fifty (50) for shipment on a nonexclusive use conveyance and less than or equal to one-hundred (100) for shipment on an exclusive use conveyance.

(e) (1) The value for the CSI must be greater than or equal to the number calculated by the following equation:

$$\mathbf{CSI = 10 \left[\frac{Grams\ ^{239}Pu + Grams\ ^{241}Pu}{24} \right]}$$

and

(2) The calculated CSI must be rounded up to the first decimal place.

C.7.9 General License: Use of Foreign Approved Package.

(a) A general license is issued to any licensee of the Agency to transport, or to deliver to a carrier for transport, licensed material in a package the design of which has been approved in a foreign national competent authority certificate which has been revalidated by the U.S. Department of Transportation as meeting the applicable requirements of 49 CFR 171.12.

(b) This general license applies only to ~~international~~ shipments made to or from locations outside the United States.

(c) This general license applies only to a licensee who:

(1) Has a copy of the applicable certificate, the revalidation, and the drawings and other documents referenced in the certificate relating to the use and maintenance of the packaging and to the actions to be taken ~~prior to~~ before shipment;

(2) Complies with the terms and conditions of the certificate and revalidation, and with the applicable requirements of ~~this~~ 10 CFR 71, Subparts A, G and H. With respect to the quality assurance provisions of 10 CFR 71, Subpart H, the licensee is exempt from design, construction, and fabrication considerations; and

(3) Except as otherwise provided in C.7.9, the licensee has a quality assurance program approved by the Nuclear Regulatory Commission as satisfying the provisions of 10 CFR 71, Subpart H.

C.7.10 General License: Fissile Material, Limited Quantity Per Package.

(a) A general license is hereby issued to any licensee of the Agency to transport fissile material, or to deliver fissile material to a carrier for transport, if the material is shipped in accordance with ~~this Section~~ C.7.10. The fissile material need not be contained in a package which meets the standards of 10 CFR 71,

Subparts E and F; However, the material must be contained in a Type A package. The Type A package must also meet the DOT requirements of 49 CFR 173.417(a).

(b) This general license applies only when a package's contents: ~~contains no more than a Type A quantity of radioactive material, including only one of the following:~~

(1) ~~Up to 40 grams of uranium-235;~~ Contain less than a Type A quantity of fissile material; and

(2) ~~Up to 30 grams of uranium-233;~~ Contain less than five hundred (500) total grams of beryllium, graphite, or hydrogenous material enriched in deuterium.

~~(3) Up to 25 grams of the fissile radionuclides of plutonium, except that for encapsulated plutonium-beryllium neutron sources in special form, an A_1 quantity of plutonium may be present; or~~

~~(4) A combination of fissile radionuclides in which the sum of the ratios of the amount of each radionuclide to the corresponding maximum amounts in C.7.10(b)(1), (2), and (3) does not exceed unity.~~

(c) The general license applies only to a licensee who has a quality assurance program approved by the Nuclear Regulatory Commission as satisfying the provisions of 10 CFR 71, Subpart H.

~~(c) Except as specified in C.7.10(c)(2), this general license applies only when all of the following requirements are met:~~

~~(1) A package containing more than 15 grams of fissile radionuclides is labeled with a transport index not less than the number given by the following equation:~~

~~Minimum Transport Index = (0.40x + 0.67y + z) (1 – 15/(x+y+z))~~

~~where the package contains x grams of uranium-235, y grams of uranium-233, and z grams of the fissile radionuclides of plutonium;~~

~~(2) For a package in which the only fissile material is in the form of encapsulated plutonium-beryllium neutron sources in special form, the transport index based on criticality considerations may be taken as 0.026 times the number of grams of the fissile radionuclides of plutonium in excess of 15 grams.~~

~~(3) In all cases, the transport index shall be rounded up to one decimal place and shall not exceed 10.0.~~

~~(4) The licensee has a quality assurance program as required by C.7.19.~~

(d) The general license applies only to packages containing fissile material that are labeled with a CSI which:

(1) Has been determined in accordance with C.7.10(e);

(2) Has a value less than or equal to ten (10); and

(3) For a shipment of multiple packages containing fissile material, the sum of the CSIs must be less than or equal to fifty (50) [for shipment on a nonexclusive use conveyance] and less than or equal to one hundred (100) [for shipment on an exclusive use conveyance].

(e) (1) The value for the CSI must be greater than or equal to the number calculated by the following equation:

$$\mathbf{CSI = 10 \left[\frac{Grams\ ^{235}U}{X} + \frac{Grams\ ^{233}U}{Y} + \frac{Grams\ Pu}{Z} \right]}$$

(2) The calculated CSI must be rounded up to the first decimal place;

(3) The values of X, Y, and Z used in the CSI equation must be taken from Tables 1 or 2, as appropriate;

(4) If Table 1 is used to obtain the value of X, then the values for the terms in the equation for uranium-233 and plutonium must be assumed to be zero; and

(5) Table 1 values for X, Y, and Z must be used to determine the CSI if:

(i) Uranium-233 is present in the package;

(ii) The mass of plutonium exceeds 1 percent of the mass of uranium-235;

(iii) The uranium is of unknown uranium-235 enrichment or greater than 24 weight percent enrichment; or

(iv) Substances having a moderating effectiveness (i.e., an average hydrogen density greater than H_2O) (e.g., certain hydrocarbon oils or plastics) are present in any form, except as polyethylene used for packing or wrapping.

Table 1 - Mass Limits for General License Packages Containing Mixed Quantities of Fissile Material or Uranium-235 of Unknown Enrichment per §C.7.10(e)

Fissile material	Fissile material mass mixed with moderating substances having an average hydrogen density less than or equal to H_2O (grams)	Fissile material mass mixed with moderating substances having an average hydrogen density greater than H_2O[19] (grams)
^{235}U (X)	60	38
^{233}U (Y)	43	27
^{239}Pu or ^{241}Pu (Z)	37	24

Table 2 - Mass Limits for General License Packages Containing Uranium-235 of Known Enrichment per §§C.7.10(e)

Uranium enrichment in weight percent of ^{235}U not exceeding	Fissile material mass of ^{235}U (X) (grams)
24	60
20	63
15	67
11	72
10	76
9.5	78
9	81
8.5	82

[19] When mixtures of moderating substances are present, the lower mass limits shall be used if more than 15 percent of the moderating substance has an average hydrogen density greater than H_2O.

8	85
7.5	88
7	90
6.5	93
6	97
5.5	102
5	108
4.5	114
4	120
3.5	132
3	150
Uranium enrichment in weight percent of ^{235}U not exceeding	**Fissile material mass of ^{235}U (X) (grams)**
2.5	180
2	246
1.5	408
1.35	480
1	1,020
0.92	1,800

~~**C.7.11 General License: Fissile Material, Limited Moderator Per Package.**~~

~~(a) A general license is hereby issued to any licensee to transport fissile material, or to deliver fissile material to a carrier for transport, if the material is shipped in accordance with this Section.~~

~~(b) This general license applies only when all of the following requirements are met:~~

~~(1) The package contains no more than a Type A quantity of radioactive material;~~

~~(2) Neither beryllium nor hydrogenous material enriched in deuterium is present;~~

~~(3) The total mass of graphite present does not exceed 7.7 times the total mass of uranium-235 plus plutonium;~~

~~(4) Substances having a higher hydrogen density than water, for example certain hydrocarbon oils, are not present, except that polyethylene may be used for packing or wrapping;~~

~~(5) Uranium-233 is not present, and the amount of plutonium does not exceed 1 percent of the amount of uranium-235;~~

~~(6) The amount of uranium-235 is limited as follows:~~

~~(i) If the fissile radionuclides are not uniformly distributed, the maximum amount of uranium-235 per package may not exceed the value given in TABLE I; or~~

~~(ii) If the fissile radionuclides are distributed uniformly, for example, cannot form a lattice arrangement within the packaging, the maximum amount of uranium-235 per package may~~

~~not exceed the value given in TABLE II; and~~

~~(7) The transport index of each package based on criticality considerations is taken as 10 times the number of grams of uranium-235 in the package divided by the maximum allowable number of grams per package in accordance with TABLE I or TABLE II, as applicable.~~

~~(d) The licensee has a quality assurance program as required by C.7.19.~~

C.7.11 External Radiation Standards for All Packages.

(a) Except as provided in C.7.11(b), each package of radioactive materials offered for transportation must be designed and prepared for shipment so that under conditions normally incident to transportation the radiation level does not exceed 2 mSv/h (200 mrem/h) at any point on the external surface of the package, and the transport index does not exceed 10.

(b) A package that exceeds the radiation level limits specified in C.7.11(a) must be transported by exclusive use shipment only, and the radiation levels for such shipment must not exceed the following during transportation:

(1) 2 mSv/h (200 mrem/h) on the external surface of the package, unless the following conditions are met, in which case the limit is 10 mSv/h (1000 mrem/h):

(i) The shipment is made in a closed transport vehicle;

(ii) The package is secured within the vehicle so that its position remains fixed during transportation; and

(iii) There are no loading or unloading operations between the beginning and end of the transportation;

(2) 2 mSv/h (200 mrem/h) at any point on the outer surface of the vehicle, including the top and underside of the vehicle; or in the case of a flat-bed style vehicle, at any point on the vertical planes projected from the outer edges of the vehicle, on the upper surface of the load or enclosure, if used, and on the lower external surface of the vehicle; and

(3) 0.1 mSv/h (10 mrem/h) at any point 2 meters (80 in) from the outer lateral surfaces of the vehicle (excluding the top and underside of the vehicle); or in the case of a flat-bed style vehicle, at any point 2 meters (6.6 feet) from the vertical planes projected by the outer edges of the vehicle (excluding the top and underside of the vehicle); and

(4) 0.02 mSv/h (2 mrem/h) in any normally occupied space, except that this provision does not apply to private carriers, if exposed personnel under their control wear radiation dosimetry devices in conformance with A.3.3 of these Regulations.

(c) For shipments made under the provisions of C.7.11(b), the shipper shall provide specific written instructions to the carrier for maintenance of the exclusive use shipment controls. The instructions must be included with the shipping paper information.

(d) The written instructions required for exclusive use shipments must be sufficient so that, when followed, they will cause the carrier to avoid actions that will unnecessarily delay delivery or unnecessarily result in increased radiation levels or radiation exposures to transport workers or members of the general public.

C.7.12 Assumptions as to Unknown Properties ~~of Fissile Material~~. When the isotopic abundance, mass, concentration, degree of irradiation, degree of moderation, or other pertinent property of fissile material in any package is not known, the licensee shall package the fissile material as if the unknown properties have credible values that will cause the maximum neutron multiplication.

C.7.13 Preliminary Determinations. Prior to the first use of any packaging for the shipment of radioactive material:

(a) The licensee shall ascertain that there are no cracks, pinholes, uncontrolled voids, or other defects which could significantly reduce the effectiveness of the packaging;

(b) Where the maximum normal operating pressure will exceed 35 kilopascal (5 lbf/in^2) gauge, the licensee shall test the containment system at an internal pressure at least ~~50 percent~~ fifty percent (50 %) higher than the maximum normal operating pressure to verify the capability of that system to maintain its structural integrity at that pressure;

(c) Before applying the model number, the licensee shall determine that the packaging has been fabricated in accordance with the design approved by the Nuclear Regulatory Commission.; and

(d) The licensee shall conspicuously and durably mark the packaging with its model number, serial number, gross weight, and a package identification number ~~as~~ assigned by the Nuclear Regulatory Commission.

C.7.14 Routine Determinations. Prior to each shipment of licensed material, the licensee shall ensure that the package with its contents satisfies the applicable requirements of Subpart C.7 and of the license. The licensee shall determine that:

(a) The package is proper for the contents to be shipped;

(b) The package is in unimpaired physical condition except for superficial defects such as marks or dents;

(c) Each closure device of the packaging, including any required gasket, is properly installed and secured and free of defects;

(d) Any system for containing liquid is adequately sealed and has adequate space or other specified provision for expansion of the liquid;

(e) Any pressure relief device is operable and set in accordance with written procedures;

(f) The package has been loaded and closed in accordance with written procedures;

(g) Any structural part of the package which could be used to lift or tie down the package during transport is rendered inoperable for that purpose unless it satisfies design requirements specified in 10 CFR 71.45;

(h) The level of non-fixed (removable) radioactive contamination on the external surfaces of each package offered for shipment is as low as reasonably achievable and within the limits specified in U.S. Department of Transportation regulations at, 49 CFR 173.443;

~~(1) The level of non-fixed radioactive contamination may be determined by wiping an area of 300 square centimeters of the surface concerned with an absorbent material, using moderate pressure, and measuring the activity on the wiping material. Sufficient measurements shall be taken in the most appropriate locations to yield a representative assessment of the removable contamination levels. Except as provided in C.7.14(h)(2), the amount of radioactivity measured on any single wiping material, when averaged over the surface wiped, shall not exceed the limits given in TABLE III at any time during transport. Other methods of assessment of equal or greater efficiency may be used. When other methods are used, the detection efficiency of the method used shall be taken into account and in no case may the removable contamination on the external surfaces of the package exceed 10 times the limits listed in TABLE III.~~

~~(2) In the case of packages transported as exclusive use shipments by rail or highway only, the non-fixed radioactive contamination at any time during transport shall not exceed 10 times the levels prescribed in C.7.14(h)(1). The levels at the beginning of transport shall not exceed the levels in~~

~~C.7.14(h)(1);~~

(i) External radiation levels around the package and around the vehicle, if applicable, will not exceed the limits specified in C.7.11 at any time during transportation. ~~2 mSv per hour (200 mrem/hr) at any point on the external surface of the package at any time during transportation. The transport index shall not exceed 10.0;~~

(j) For fissile material, any moderator or neutron absorber, if required, is present and in proper condition; and

(k) Accessible package surface temperatures will not exceed the limits specified in 10 CFR 71.43(g) at any time during transportation.

~~**TABLE I**~~
~~**PERMISSIBLE MASS OF URANIUM-235 PER FISSILE MATERIAL PACKAGE [NONUNIFORM DISTRIBUTION]**~~

~~Uranium Enrichment in Weight Percent of Uranium-235 Not Exceeding~~	~~Permissible Maximum Grams of Uranium-235 Per Package~~
~~24~~	~~40~~
~~20~~	~~42~~
~~15~~	~~45~~
~~11~~	~~48~~
~~10~~	~~51~~
~~9.5~~	~~52~~
~~9~~	~~54~~
~~8.5~~	~~55~~
~~8~~	~~57~~
~~7.5~~	~~59~~
~~7~~	~~60~~
~~6.5~~	~~62~~
~~6~~	~~65~~
~~5.5~~	~~68~~
~~5~~	~~72~~
~~4.5~~	~~76~~
~~4~~	~~80~~
~~3.5~~	~~88~~
~~3~~	~~100~~
~~2.5~~	~~120~~
~~2~~	~~164~~
~~1.5~~	~~272~~
~~1.35~~	~~320~~
~~1~~	~~680*~~
~~0.92~~	~~1,200*~~

~~**Pursuant to the Agency's agreement with the Nuclear Regulatory Commission, jurisdiction extends only to 350 grams of uranium-235.*~~

TABLE II
PERMISSIBLE MASS OF URANIUM-235 PER FISSILE MATERIAL PACKAGE [UNIFORM DISTRIBUTION]

Uranium Enrichment in Weight Percent of Uranium-235 Not Exceeding	Permissible Maximum Grams of Uranium-235 Per Package
4	84
3.5	92
3	112
2.5	148
2	240
1.5	560*
1.35	800*

**Pursuant to the Agency's agreement with the Nuclear Regulatory Commission, jurisdiction extends only to 350 grams of uranium-235*

TABLE III
NON-FIXED (REMOVABLE) EXTERNAL RADIOACTIVE CONTAMINATION - WIPE LIMITS

Contaminant	Maximum Permissible Limit Bq/cm^2	Ci/cm^2	dpm/cm^2
Beta and gamma emitters and low toxicity alpha emitters	0.4	10^{-5}	22
All other alpha-emitting radionuclides	0.04	10^{-6}	2.2

(j) For a package transported in exclusive use by rail, highway or water, radiation levels external to the package may exceed the limits specified in C.7.14(i) but shall not exceed any of the following:

(1) 2 mSv per hour (200 mrem/hr) on the accessible external surface of the package unless the following conditions are met, in which case the limit is 10 mSv per hour (1000 mrem/hr);

(i) The shipment is made in a closed transport vehicle;

(ii) Provisions are made to secure the package so that its position within the vehicle remains fixed during transportation; and

(iii) There are no loading or unloading operations between the beginning and end of the transportation.

(2) 2 mSv per hour (200 mrem/hr) at any point on the outer surface of the vehicle, including the top and underside of the vehicle, or, in the case of a flat-bed style vehicle, with a personnel barrier[20], at any point on the vertical planes projected from the outer edges of the vehicle, on the upper surface of the load (or enclosure, if used), and on the lower external surface of the vehicle;

[20] A flat-bed style vehicle with a personnel barrier shall have radiation levels determined at vertical planes. If no personnel barrier is in place, the package cannot exceed 2 mSv per hour (200 mrem/hr) at any accessible surface.

~~(3) 0.1 mSv per hour (10 mrem/hr) at any point 2 meters from the vertical planes represented by the outer lateral surfaces of the vehicle, or, in the case of a flat-bed style vehicle, at any point 2 meters from the vertical planes projected from the outer edges of the vehicle; and~~

~~(4) 0.02 mSv per hour (2 mrem/hr) in any normally occupied positions of the vehicle, except that this provision does not apply to private motor carriers when persons occupying these positions are provided with special health supervision, personnel radiation exposure monitoring devices, and training in accordance with A.6.3 of these regulations; and~~

~~(k) A package shall be prepared for transport so that in still air at 38° Celsius (100°F) and in the shade, no accessible surface of a package would have a temperature exceeding 50° Celsius (122°F) in a nonexclusive use shipment or 85° Celsius (185°F) in an exclusive use shipment. Accessible package surface temperatures shall not exceed these limits at any time during transportation.~~

~~(l) A package may not incorporate a feature intended to allow continuous venting during transport.~~

C.7.15 Air Transport of Plutonium.

(a) Notwithstanding the provisions of any general licenses and notwithstanding any exemptions stated directly in Subpart C.7 or included indirectly by citation of the U.S. Department of Transportation regulations at 49 CFR Chapter I, as may be applicable, the licensee shall assure that plutonium in any form, whether for import, export, or domestic shipment, is not transported by air, or delivered to a carrier for air transport, unless:

(1) The plutonium is contained in a medical device designed for individual human application; or

(2) The plutonium is contained in a material in which the specific activity is ~~not greater than 70 becquerel per gram (0.002 μCi/g) of material~~ is less than or equal to the activity concentration values for plutonium specified in Table IV of Appendix G to Part C, and in which the radioactivity is essentially uniformly distributed; or

(3) The plutonium is shipped in a single package containing no more than an A_2 quantity of plutonium in any isotope or form and is shipped in accordance with C.7.4; or

(4) The plutonium is shipped in a package specifically authorized, in the certificate of compliance, issued by the Nuclear Regulatory Commission~~, for the shipment of plutonium by air and the licensee requires, through special arrangement with the carrier, compliance with 49 CFR 175.704, the U.S. Department of Transportation regulations applicable to the air transport of plutonium~~.

(b) Nothing in C.7.15(a) is to be interpreted as removing or diminishing the requirements of 10 CFR 73.24.

(c) For a shipment of plutonium by air which is subject to C.7.15(a)(4), the licensee shall, through special arrangement with the carrier, require compliance with 49 CFR 175.704, U.S. Department of Transportation regulations applicable to the air transport of plutonium.

C.7.16 Shipment Records. Each licensee shall maintain for a period of three (3) years after shipment a record of each shipment of licensed material not exempt under C.7.3, showing, where applicable:

(a) Identification of the packaging by model number and serial number;

(b) Verification that the packaging, as shipped, had no significant defect;

(e) Volume and identification of coolant;

(f) Type and quantity of licensed material in each package, and the total quantity of each shipment;

(e) Date of the shipment;

(f) Name and address of the transferee;

(g) Address to which the shipment was made; ~~and~~

(h) Results of the determinations required by C.7.14 and by the conditions of the package approval;

(i) For each item of irradiated fissile material:

(1) Identification by model number and serial number;

(2) Irradiation and decay history to the extent appropriate to demonstrate that its nuclear and thermal characteristics comply with license conditions; and

(3) Any abnormal or unusual condition relevant to radiation safety; and

(j) For fissile packages and for Type B packages, any special controls exercised.

C.7.17 Reports.

(a) The licensee, after requesting the certificate holder's input, shall submit a written report to the Agency of ~~within 30 days~~:

(1) Instances in which there is significant reduction in the effectiveness of any NRC-approved Type B or Type AF packaging during use;

(2) Details of any defects with safety significance in ~~the~~ any NRC-approved Type B or fissile material packaging, after first use.~~, with the means employed to repair the defects and prevent their recurrence; or~~

(3) Instances in which the conditions of approval in the certificate of compliance were not observed in making a shipment.

(b) The licensee shall submit a written report to the Agency of instances in which the conditions in the certificate of compliance were not followed during a shipment.

(c) Each licensee shall submit a written report required by C.7.17(a) or (b) within sixty (60) days of the event or discovery of the event. The licensee shall also provide a copy of each report submitted to the Agency to the applicable certificate holder. Written reports prepared under other regulations may be submitted to fulfill this requirement if the reports contain all the necessary information, and the appropriate distribution is made. These written reports must include the following:

(1) A brief abstract describing the major occurrences during the event, including all component or system failures that contributed to the event and significant corrective action taken or planned to prevent recurrence.

(2) A clear, specific, narrative description of the event that occurred so that knowledgeable readers conversant with the requirements of 10 CFR 71, but not familiar with the design of the packaging, can understand the complete event. The narrative description must include the following specific information as appropriate for the particular event.

(i) Status of components or systems that were inoperable at the start of the event and that contributed to the event;

(ii) Dates and approximate times of occurrences;

(iii) The cause of each component or system failure or personnel error, if known;

(iv) The failure mode, mechanism, and effect of each failed component, if known;

(v) A list of systems or secondary functions that were also affected for failures of components with multiple functions;

(vi) The method of discovery of each component or system failure or procedural error;

(vii) For each human performance-related root cause, a discussion of the cause(s) and circumstances;

(viii) The manufacturer and model number (or other identification) of each component that failed during the event; and

(ix) For events occurring during use of a packaging, the quantities and chemical and physical form(s) of the package contents.

(3) An assessment of the safety consequences and implications of the event. This assessment must include the availability of other systems or components that could have performed the same function as the components and systems that failed during the event.

(4) A description of any corrective actions planned as a result of the event, including the means employed to repair any defects, and actions taken to reduce the probability of similar events occurring in the future.

(5) Reference to any previous similar events involving the same packaging that are known to the licensee or certificate holder.

(6) The name and telephone number of a person within the licensee's organization who is knowledgeable about the event and can provide additional information.

(7) The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

(d) **Report Legibility.** The reports submitted by licensees and/or certificate holders under C.7.17 must be of sufficient quality to permit reproduction and micrographic processing.

C.7.18 Advance Notification of ~~Transport~~ Shipment of Nuclear Waste.

(a) ~~Prior to the transport of any nuclear waste outside of the confines of the licensee's facility or other place of use or storage, or prior to the delivery of any nuclear waste to a carrier for transport~~

(1) As specified in C.7.18(b), (d) and (e), each licensee shall provide advance notification ~~of such transport~~ to the governor of a State, or governor's designee[21], of the shipment of licensed material, within, or across the boundary of the State, before the transport, or delivery to a carrier, for transport, of licensed material outside the confines of the licensee's plant or other place of use or storage. ~~of each state within or through which the waste will be transported.~~

(2) As specified in C.7.18(b), (d) and (e), after 11 June 2013, each licensee shall provide advance notification to the Tribal official of participating Tribes[*], or the official's designee, of the shipment of licensed material, within or across the boundary of the Tribe's reservation, before the transport, or delivery to a carrier, for transport, of licensed material outside the confines of the licensee's plant or other place of use or storage.

(b) Advance notification is required ~~only when~~ under C.7.18 for shipment of licensed material, other than irradiated fuel, meeting the following three (3) conditions:

[21] A list of the names and mailing addresses of the ~~governors and~~ governors' designees and Tribal official's designees of participating Tribes is available upon request from the Director, ~~Office of State Programs,~~ Division of Intergovernmental Liaison and Rulemaking, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. The list of governor's designees and Tribal official's designees of participating Tribes will be published annually in the Federal Register on or about June 30 to reflect any changes in information.

(1) The ~~nuclear waste~~ licensed material is required by C.7 to be in Type B packaging for transportation;

(2) The ~~nuclear waste~~ licensed material is being transported ~~into, within, or through a state~~ to or across a state boundary en route to a disposal facility or to a collection point for transport to a disposal facility; and

(3) The quantity of licensed material in a single package exceeds the least of the following:

(i) Three thousand (3000) times the A_1 value of the radionuclides as specified in Table I of Appendix G to ~~this~~ Part C for special form radioactive material; or

(ii) Three thousand (3000) times the A_2 value of the radionuclides as specified in Table I of Appendix G to ~~this~~ Part C for normal form radioactive material;

(iii) One thousand (1000) terabecquerel (27,000 Ci).

(c) **Information to be Furnished in Advance Notification of Shipment.** Each advance notification required by C.7.18(a) shall contain the following information:

(1) The name, address, and telephone number of the shipper, carrier, and receiver of the nuclear waste shipment;

(2) A description of the nuclear waste contained in the shipment as ~~required~~ specified by the regulations of the U.S. Department of Transportation in 49 CFR 172.202 and 172.203(d);

(3) The point of origin of the shipment and the seven (7)-day period during which departure of the shipment is estimated to occur;

(4) The seven (7)-day period during which arrival of the shipment at State boundaries or Tribal reservation boundaries is estimated to occur;

(5) The destination of the shipment, and the seven (7)-day period during which arrival of the shipment is estimated to occur; and

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

(d) **Procedures for Submitting Advance Notification.** The notification required by C.7.18(a) shall be made in writing to the office of each appropriate governor, or governor's designee, the office of each appropriate Tribal official or Tribal official's designee, ~~and~~ to the Agency and to the Director, NRC Division of Security Policy, Office of Nuclear Security and Incident Response.

(1) A notification delivered by mail shall be postmarked at least seven (7) days before the beginning of the seven (7)-day period during which departure of the shipment is estimated to occur.

(2) A notification delivered by ~~messenger~~ any other means than mail shall reach the office of the governor, or governor's designee or the Tribal official or Tribal official's designee at least four (4) days before the beginning of the seven (7)-day period during which departure of the shipment is estimated to occur.

(3) The licensee shall retain a copy of the notification ~~shall be retained by the licensee~~ as a record for three (3) years.

(e) **Revision Notice.** ~~The~~ A licensee ~~shall notify each appropriate~~ who finds that schedule information previously furnished to a governor, or governor's designee or a Tribal official or Tribal official's designee, ~~and the Agency of any changes to schedule information provided~~ pursuant to C.7.18(a) will not be met, shall ~~Such notification~~ shall ~~be by~~ telephone ~~to~~ a responsible individual in the office of the governor of the State or of the governor's designee or the Tribal official or the Tribal official's designee ~~of the appropriate state or states~~ and inform that individual of the extent of the delay beyond the schedule originally reported. The licensee shall

maintain for three (3) years a record of the name of the individual contacted.

(f) **Cancellation Notice.** Each licensee who cancels a nuclear waste shipment, for which advance notification has been sent, shall send a cancellation notice, identifying the advance notification that is being canceled, to the governor, or governor's designee previously notified, each Tribal official or to the Tribal official's designee previously notified, ~~of each appropriate state and~~ to the Agency and to the Director, NRC Division of Security Policy, Office of Nuclear Security and Incident Response. A copy of the notice shall be retained by the licensee as a record for three (3) years .

C.7.19 Quality Assurance Requirements.

(a) **Purpose**. C.7.19 describes quality assurance requirements applying to purchase, handling, shipping, storing, cleaning, assembly, inspection, operation, maintenance, and repair of components of packaging that are important to safety. As used in C.7.19, *quality assurance* comprises all those planned and systematic actions necessary to provide adequate confidence that a system or component will perform satisfactorily in service. Quality assurance includes *quality control*, which comprises those quality assurance actions related to control of the physical characteristics and quality of the material or component to predetermined requirements. Each licensee is responsible for the quality assurance provision which applies to its use of a packaging for the shipment of licensed material subject to C.7. ~~Unless otherwise authorized by the Agency, each licensee shall establish, maintain, and execute a quality assurance program to verify by procedures such as checking, auditing, and inspection that deficiencies, deviations, and defective material and equipment relating to the shipment of packages containing radioactive material are promptly identified and corrected.~~

(b) **Establishment of Program.** Each licensee shall establish, maintain, and execute a quality assurance program satisfying each of the applicable criteria of C.7.19 and 10 CFR 71.101 through 71.137 and satisfying any specific provisions that are applicable to the licensee's activities including procurement of packaging. The licensee shall execute the applicable criteria in a graded approach to an extent that is commensurate with the quality assurance requirements importance to safety. ~~The licensee shall identify the material and components to be covered by the quality assurance program.~~

(c) **Approval of Program.** Before the use of any package for the shipment of licensed material subject to this C.7.19, each licensee shall obtain Agency approval of its quality assurance program by submitting a description of its quality assurance program, including a discussion of which requirements of C.7.19 are applicable and how they will be satisfied. ~~Each licensee shall document the quality assurance program by written procedures or instructions and shall carry out the program in accordance with those procedures throughout the period during which packaging is used.~~

(d) **Previously Approved Programs**. A NRC-approved quality assurance program that satisfies the applicable criteria of 10 CFR 71 Subpart H, 10 CFR 50 Appendix B or 10 CFR 72 Subpart G, and that is established, maintained, and executed regarding transport packages, will be accepted as satisfying the requirements of C.7.19(b). Before first use, the licensee shall notify the Agency of its intent to apply its previously approved 10 CFR 71 Subpart H, 10 CFR 50 Appendix B or 10 CFR 72 Subpart G quality assurance program to transportation activities. The licensee shall identify the program by date of submittal to the NRC, Docket Number, and date of NRC approval. ~~Prior to the use of any package for the shipment of radioactive material, each licensee shall obtain approval by the Agency of its quality assurance program.~~

(e) **Radiography Containers.** A program for transport container inspection and maintenance limited to radiographic exposure devices, source changers, or packages transporting these devices and meeting the requirements of E.2.9(b) of these Regulations, 10 CFR 34.31(b) or equivalent requirement of another Agreement State, is deemed to satisfy the requirements of C.7.6(b) and C.7.19(b). ~~The licensee shall maintain sufficient written records to demonstrate compliance with the quality assurance program. Records of quality assurance pertaining to the use of a package for shipment of radioactive material shall be maintained for a period of 3 years after shipment.~~

(f) **Quality Assurance Organization.** Each licensee shall establish a quality assurance organization in accordance with 10 CFR 71.103.

(g) **Quality Assurance Program.** Each licensee shall establish a quality assurance program in accordance with 10 CFR 71.105(a) through (d).

(h) **Handling, Storage and Shipping Control.** Each licensee shall establish measures to control, in accordance with instructions, the handling, storage, shipping, cleaning, and preservation of materials and equipment to be used in packaging to prevent damage or deterioration. When necessary for particular products, special protective environments, such as inert gas atmosphere, and specific moisture content and temperature levels must be specified and provided.

(i) **Inspection, Test and Operating Status.**

(1) Each licensee shall establish measures to indicate, by the use of markings such as stamps, tags, labels, routing cards, or other suitable means, the status of inspections and tests performed upon individual items of the packaging. These measures must provide for the identification of items that have satisfactorily passed required inspections and tests, where necessary to preclude inadvertent bypassing of the inspections and tests.

(2) Each licensee shall establish measures to identify the operating status of components of the packaging, such as tagging valves and switches, to prevent inadvertent operation.

(j) **Nonconforming Materials, Parts or components.** Each licensee, shall establish measures to control materials, parts, or components that do not conform to the licensee's requirements to prevent their inadvertent use or installation. These measures must include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations. Nonconforming items must be reviewed and accepted, rejected, repaired or reworked in accordance with documented procedures.

(k) **Corrective Action.** Each licensee shall establish measures to assure that conditions adverse to quality, such as deficiencies, deviations, defective material and equipment, and nonconformances, are promptly identified and corrected. In the case of a significant condition adverse to quality, the measures must assure that the cause of the condition is determined and corrective action taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken must be documented and reported to appropriate levels of management.

(l) **Quality Assurance Records.** The licensee shall maintain sufficient written records to describe the activities affecting quality.

(1) The records must include the instructions, procedures, and drawings required by 10 CFR 71.111 to prescribe quality assurance activities and must include closely related specifications such as required qualifications of personnel, procedures, and equipment.

(2) The records must include the instructions or procedures which establish a records retention program that is consistent with applicable regulations and designates factors such as duration, location, and assigned responsibility.

(3) The licensee shall retain these records for three (3) years beyond the date when the licensee last engaged in the activity for which the quality assurance program was developed. If any portion of the written procedures or instructions is superseded, the licensee shall retain the superseded material for three (3) years after it is superseded.

(m) **Audits.** The licensee shall carry out a comprehensive system of planned and periodic audits to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program.

(1) The audits must be performed in accordance with written procedures or checklists by appropriately trained personnel not having direct responsibilities in the areas being audited;

(2) Audited results must be documented and reviewed by management having responsibility in the area audited; and

(3) Follow up action, including re-audit of deficient areas, must be taken where indicated.

C.8 USE OF RADIONUCLIDES IN THE HEALING ARTS

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C.8.1 **Scope, Provisions for Research Involving Human Subjects and FDA, Other Federal and State Requirements.**

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(d) **License Required.** A person shall manufacture, produce, acquire, receive, possess, use or transfer radioactive material for medical use only in accordance with a specific license issued by the Agency, the U.S. Nuclear Regulatory Commission~~,~~ or another Agreement State ~~or Licensing State~~, or as allowed by C.8.8(a) and C.8.8(b) of these regulations. A specific license is not needed for an individual who:

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C.8.9 **Visiting Authorized User, Visiting Authorized Medical Physicist and Visiting Authorized Nuclear Pharmacist.**

(a) A licensee may permit any Visiting Authorized User to use licensed material for medical use under the terms of the licensee's license for 60 days each year if:

(1) The Visiting Authorized User has the prior written permission of the licensee's management and Radiation Safety Committee if one is required;

(2) The licensee has a copy of an Agency, Agreement State~~, Licensing State~~ or U.S. Nuclear Regulatory Commission license that identifies the Visiting Authorized User by name as an Authorized User for medical use; and

(3) Only those procedures for which the Visiting Authorized User is specifically authorized by an Agency, Agreement State~~, Licensing State~~ or U.S. Nuclear Regulatory Commission license are performed by that individual.

(b) A licensee may permit a medical physicist to act as a visiting authorized medical physicist, and perform the duties of a medical physicist under the terms of the licensee's license for 60 days each calendar year if:

(1) The medical physicist is registered with the Agency, under the provisions of Subpart B.4 of these regulations, as a provider of Radiation Physics Services in the area of calibration and compliance surveys of therapeutic medical units; and

(2) The visiting authorized medical physicist has the prior written permission of the licensee's management and Radiation Safety Committee, if one is required; and

(3) The licensee has a copy of:

(i) An Agency, NRC~~,~~ or Agreement State ~~or Licensing State~~ license that identifies the individual as an authorized medical physicist; or

(ii) A permit issued by an Agency, NRC~~,~~ or Agreement State ~~or Licensing State~~ specific license of broad scope that identifies the medical physicist by name as an authorized medical physicist.

(c) A licensee may permit a nuclear pharmacist to act as a visiting authorized nuclear pharmacist, and to perform the duties of a nuclear pharmacist under the terms of the licensee's license for 60 days each calendar year if:

(1) The nuclear pharmacist possesses a current license as a pharmacist in accordance with the Rules

and Regulations Pertaining to Pharmacists, Pharmacies and Manufacturers, Wholesalers and Distributors [R5-19-PHAR] of the Rhode Island Department of Health; and

(2) The visiting authorized nuclear pharmacist has the prior written permission of the licensee's management and Radiation Safety Committee, if one is required; and

(3) The licensee has a copy of:

(i) An Agency, NRC~~,~~ or Agreement State ~~or Licensing State~~ license that identifies the individual as an authorized nuclear pharmacist; or

(ii) A permit issued by an Agency, NRC~~,~~ or Agreement State ~~or Licensing State~~ specific license of broad scope that identifies the nuclear pharmacist by name as an authorized nuclear pharmacist.

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C.8.12 **Suppliers for Sealed Sources or Devices for Medical Use.** A licensee shall use for medical use only:

(a) Sealed sources or devices manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to C.5.5(l) of these regulations or the equivalent regulations of another Agreement State~~, a Licensing State~~ or the U.S. Nuclear Regulatory Commission; or

(b) Sealed sources or devices non-commercially transferred from a license issued pursuant to C.8 of these regulations or the equivalent regulations of another Agreement State or the U.S. Nuclear Regulatory Commission; or

(c) Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to C.5.5(l) of these regulations or the equivalent regulations of another Agreement State~~, a Licensing State~~ or the U.S. Nuclear Regulatory Commission.

C.8.13 **Quality Control of Diagnostic Equipment.** Each licensee shall establish written quality control procedures for all diagnostic equipment used for radionuclide studies. The licensee shall conduct quality control procedures in accordance with written procedures.

C.8.14 **Possession, Use, Calibration and Check of Dose Calibrators (Photon-Emitting Radio-nuclides) and Instruments to Measure Dosages (Alpha- and Beta- Emitting Radionuclides) .**

(a) **Possession and Use.** For direct measurements performed in accordance with C.8.16:

(1) A licensee shall possess a dose calibrator and use it to measure the activity of photon-emitting unsealed radioactive material before it is administered to each patient or human research subject.

(2) For other than unit dosages of alpha- and beta- emitting unsealed radioactive material that has been obtained from a manufacturer or preparer licensed pursuant to C.5.5(j) of these regulations or the equivalent regulations of another Agreement State~~, a Licensing State~~ or the U.S. Nuclear Regulatory Commission, a licensee shall possess and use instrumentation to measure the activity of alpha- or beta-emitting unsealed radioactive material before it is administered to each patient or human research subject. The licensee shall have procedures for use of the instrumentation.

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C.8.15 **Calibration of Survey Instruments.**

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(f) To meet the requirements of C.8.15(a), (b) and (c), the licensee may obtain the services of individuals

licensed by the Agency, the U.S. Nuclear Regulatory Commission~~,~~ or an Agreement State ~~or a Licensing State~~ to perform calibrations of survey instruments.

C.8.16 **Determination of Dosages of Unsealed Radioactive Materials for Medical Use.** A licensee shall determine and record the activity of each dosage prior to medical use.

(a) ~~Measure the activity of each dosage of a photon-emitting radionuclide before medical use;~~ For a unit dosage, this determination shall be made by:

(1) Direct measurement of radioactivity; or

(2) A decay correction, based on the activity or activity concentration determined by:

(i) A manufacturer or preparer licensed pursuant to C.5.5(j) or the equivalent regulations of the U.S. Nuclear Regulatory Commission or another Agreement State; or

(ii) An Agency, U.S. Nuclear Regulatory Commission or another Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

(iii) A PET radioactive drug producer licensed under C.5.3(e) or the equivalent regulations of the U.S. Nuclear Regulatory Commission or another Agreement State.

(b) ~~Measure, by direct measurement or by combination of measurements and calculations, the activity of each dosage of an alpha- or beta- emitting radionuclide prior to medical use, except for unit dosages obtained from a manufacturer or preparer licensed pursuant to C.5.5(j) or the equivalent regulations of another Agreement State, a Licensing State or the U.S. Nuclear Regulatory Commission;~~ For other than unit dosages, this determination shall be made by:

(1) Direct measurement of radioactivity;

(2) Combination of measurement of radioactivity and mathematical calculations; or

(3) Combination of volumetric measurements and mathematical calculations, based on the measurement made by:

(i) A manufacturer or preparer licensed pursuant to C.5.5(j) or the equivalent regulations of the U.S. Nuclear Regulatory Commission or another Agreement State; or

(ii) An Agency, U.S. Nuclear Regulatory Commission or another Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

(iii) A PET radioactive drug producer licensed under C.5.3(e) or equivalent regulations of the U.S. Nuclear Regulatory Commission or another Agreement State.

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C.8.17 **Authorization for Calibration, Transmission and Reference Sources.** Any person authorized by this subpart for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration, transmission[22] and reference use:

(a) Sealed sources manufactured and distributed by a person specifically licensed pursuant to C.5.5(l) of these regulations or equivalent provisions of the U.S. Nuclear Regulatory Commission~~,~~ or another Agreement

[22] This general license is not applicable to any transmission source whose Sealed Source & Device Registry Sheet recommends distribution only to a specific licensee and/or recommends that source replacement be conducted only by source manufacturer or other specifically authorized licensed person.

State ~~or Licensing State~~ and that do not exceed 1.11 GBq (30 mCi) each;
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C.8.18 **Requirements for Possession of Sealed Sources and Brachytherapy Sources.**

(a) A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer or equivalent instructions approved by the Agency and shall maintain the instructions for the duration of source use in a legible form convenient to users.

(b) A licensee in possession of a sealed source shall assure that:

(1) The source is tested for leakage in accordance with A.3.1; and

(2) The source is tested for leakage at intervals not to exceed six (6) months or at intervals approved by the Agency, another Agreement State~~, a Licensing State~~ or the U.S. Nuclear Regulatory Commission in the Sealed Source and Device Registry.

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C.8.27 **Decay-In-Storage.**

(a) A licensee may hold radioactive material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if the licensee:
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C.8.28 **Use of Unsealed Radioactive Material for Uptake, Dilution, or Excretion Studies for Which a Written Directive is Not Required.** ~~(a)~~ A licensee may use any unsealed radioactive material, in quantities that do not require a written directive pursuant to C.8.6(b), for a diagnostic use involving measurements of uptake, dilution or excretion studies that is:

(a) Obtained from:

(1) ~~Obtained from~~ A manufacturer or preparer licensed pursuant to C.5.5(j) of these regulations or the equivalent requirements of an Agreement State~~, a Licensing State~~ or the U.S. Nuclear Regulatory Commission; or

(2) A PET radioactive drug producer licensed under C.5.3(e) or equivalent regulations of the U.S. Nuclear Regulatory Commission or another Agreement State; or

(b) Excluding production of PET radionuclides, ~~(2)~~ prepared by:

(1) An authorized nuclear pharmacist;

(2) A physician who is an Authorized User and who meets the requirements specified in C.8.65 or C.8.66 and C.8.65(c)(1)(ii)(g); or

(3) An individual under the supervision of either as specified in C.8.8; or

(c) ~~(3)~~ Obtained from and prepared by an Agency, U.S. Nuclear Regulatory Commission~~,~~ or other Agreement State ~~or Licensing State~~ licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

(d) ~~(4)~~ Prepared by the licensee in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA for use in research.

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C.8.30 **Use of Unsealed Radioactive Material for Imaging and Localization Studies for Which a Written Directive is Not Required.** ~~(a)~~ A licensee may use, for imaging and localization studies, any unsealed radioactive material (except aerosol or gaseous forms) prepared for medical use, in quantities that do not require a written directive pursuant to C.8.6(b), that is:

(a) Obtained from:

(1) ~~Obtained from~~ a manufacturer or preparer licensed pursuant to C.5.5(j) of these regulations or the equivalent requirements of an Agreement State~~, a Licensing State~~ or the U.S. Nuclear Regulatory Commission; or

(2) A PET radioactive drug producer licensed under C.5.3(e) or equivalent regulations of the U.S. Nuclear Regulatory Commission or another Agreement State; or

(b) Excluding production of PET radionuclides, ~~(2)~~ prepared by:

(1) An authorized nuclear pharmacist;

(2) A physician who is an Authorized User and who meets the requirements specified in C.8.65 or C.8.66 and C.8.65(c)(1)(ii)(g); or

(3) An individual under the supervision of either as specified in C.8.8 of these regulations; or

(c) ~~(3)~~ Obtained from and prepared by an Agency, U.S. Nuclear Regulatory Commission~~,~~ or other Agreement State ~~or Licensing State~~ licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or.

(d) ~~(4)~~ Prepared by the licensee in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

(e) ~~(b)~~ Provided the conditions of C.8.32 are met, a licensee shall use radioactive aerosols or gases only if specific application is made to and approved by the Agency.

(f) (c) Technetium-99m pentetate as an aerosol for lung function studies is not subject to the restrictions in ~~C.8.30(b)~~ C.8.30(e).

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C.8.34 **Use of Unsealed Radioactive Material for Which a Written Directive is Required.**

(a) A licensee may use any unsealed radioactive material for diagnostic or therapeutic medical use for which a written directive is required that has been:

(1) Obtained from a manufacturer or preparer licensed pursuant to C.5.5(j) of these regulations or the equivalent regulations of another Agreement State~~, a Licensing State~~ or the U.S. Nuclear Regulatory Commission; or

(2) Prepared by an authorized nuclear pharmacist, a physician who is an Authorized User and who meets the requirements specified in C.8.65 or C.8.66 or an individual under the supervision of either as specified in C.8.8 of these regulations; or

(3) Obtained from and prepared by an Agency, U.S. Nuclear Regulatory Commission~~,~~ or another Agreement State~~, or Licensing State~~ licensee in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by the FDA for use in research; or

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C.8.47 **Installation, Maintenance, Adjustment and Repair.**

(a) Only a person specifically licensed by the Agency, the U.S. Nuclear Regulatory Commission~~,~~ or another Agreement State to perform such services shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source(s), reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

(b) Except for low dose-rate remote afterloader units, only a person specifically licensed by the Agency, the U.S. Nuclear Regulatory Commission~~,~~ or another Agreement State ~~or Licensing State~~ to perform such services shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic units.

(c) For a low dose-rate remote afterloader unit, only a person specifically licensed by the Agency, the U.S. Nuclear Regulatory Commission~~,~~ or another Agreement State ~~or Licensing State~~ to perform such services, or an Authorized Medical Physicist shall install, replace, relocate, or remove a sealed source(s) contained in the unit.

(d) A licensee shall retain a record of the installation, maintenance, adjustment and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units for three (3) years. For each installation, maintenance, adjustment and repair, the record shall include the date, description of the service, and name(s) of the individual(s) who performed the work.

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C.8.50 **Safety Precautions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.**

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(f) In addition to the requirements specified in C.8.50(a) through (e), a licensee shall:

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(3) For gamma stereotactic radiosurgery units, require an authorized user and an Authorized Medical Physicist to be ~~readily available~~ physically present throughout all patient treatments involving the unit.

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C.8.62 **Training for Radiation Safety Officer.** ~~Prior to 29 April 2008 an individual may qualify under either this section or C.8.83. Effective 29 April 2008,~~ Except as provided in C.8.63, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer (RSO) as provided in C.8.4 to be an individual who:

(a) Is certified by a specialty board whose certification process has been recognized by the Agency, an Agreement State or the U.S. Nuclear Regulatory Commission[23], and who meets the requirements in C.8.62(d) and (e). To have its certification process recognized, a specialty board shall require all candidates for certification to:

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(2) (i) 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;

[23] The names of board certifications which have been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State will be posted on the NRC Web page.

(ii) Have 2 years of full-time practical training and/or supervised experience in medical physics:

(a) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Agency, an Agreement State or the U.S. Nuclear Regulatory Commission; or

(b) In clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of physicians who meet the requirements for Authorized Users in C.8.65, ~~or~~ C.8.66 or C.8.72;

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C.8.63 **Training for Experienced Radiation Safety Officer.** An individual identified as a Radiation Safety Officer on an Agency, Agreement State~~, Licensing State~~ or U.S. Nuclear Regulatory Commission license on 27 September 2004 who oversees only the use of radioactive material for which the licensee was authorized on that date need not comply with the training requirements of C.8.62 of these regulations. Individuals who need not comply with training requirements as described in this section may serve as preceptors for, and supervisors of, applicants seeking authorization on Agency licenses for the same uses for which these individuals are authorized.

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C.8.64 **Training for Uptake, Dilution and Excretion Studies.** ~~Prior to 1 January 2007 an individual may qualify under either this section or C.8.84. Effective 1 January 2007,~~ Except as provided in C.8.72, the licensee shall require the Authorized User of an unsealed radioactive material for the uses authorized under C.8.28 to be a physician who:

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(b) Is an Authorized User under C.8.65 or C.8.66 [or the equivalent requirements of an Agreement State~~, a Licensing State~~ or the U.S. Nuclear Regulatory Commission];

OR

(c) (1) Has completed 60 hours of training and experience, including a minimum of 8 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies. The training and experience shall include:

(i) Classroom and laboratory training in the following areas:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

(c) Mathematics pertaining to the use and measurement of radioactivity;

(d) Chemistry of radioactive material for medical use; and

(e) Radiation biology;

AND

(ii) Work experience, under the supervision of an Authorized User who meets the requirements in C.8.64, C.8.65, ~~or~~ C.8.66 or C.8.72 [or equivalent requirements of another Agreement State~~, a Licensing State~~ or the U.S. Nuclear Regulatory Commission] involving:

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(2) Has obtained written attestation, signed by a preceptor Authorized User who meets the requirements in C.8.64, C.8.65, ~~or~~ C.8.66 or C.8.72 [or equivalent requirements of another Agreement State~~, a Licensing State~~ or the U.S. Nuclear Regulatory Commission] that the individual has satisfactorily completed the requirements in C.8.64(a)(1) or (c)(1) and has achieved a level of competency sufficient to function independently as an Authorized User for the medical uses authorized under C.8.28.

C.8.65 **Training for Imaging and Localization Studies.** ~~Prior to 1 January 2007 an individual may qualify under either this section or C.8.85. Effective 1 January 2007,~~ Except as provided in C.8.72, the licensee shall require an Authorized User of unsealed radioactive material for the uses authorized under C.8.30 to be a physician who:

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(b) Is an Authorized User under C.8.66 and meets the requirements in C.8.65(c)(1)(ii)(f) [or the equivalent requirements of an Agreement State~~, a Licensing State~~ or the U.S. Nuclear Regulatory Commission];

OR

(c) (1) Has completed 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies. The training and experience shall include, at a minimum:

(i) Classroom and laboratory training in the following areas:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

(c) Mathematics pertaining to the use and measurement of radioactivity;

(d) Chemistry of radioactive material for medical use;

(e) Radiation biology;

AND

(ii) Work experience, under the supervision of an Authorized User who meets the requirements in C.8.65, or C.8.66 and C.8.65(c)(1)(ii)(f), or C.8.72 [or equivalent requirements of another Agreement State~~, a Licensing State~~ or the U.S. Nuclear Regulatory Commission] involving:

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(2) Has obtained written attestation, signed by a preceptor Authorized User who meets the requirements in C.8.65, or C.8.66 and C.8.65 (c)(1)(ii)(f) , or C.8.72 [or equivalent requirements of another Agreement State~~, a Licensing State~~ or the U.S. Nuclear Regulatory Commission] that the individual has satisfactorily completed the requirements in C.8.65 (a)(1) or C.8.65 (c) (1) and has achieved a level of competency sufficient to function independently as an Authorized User for the medical uses authorized under C.8.28 and C.8.30.

C.8.66 **Training for Unsealed Radioactive Material for Which a Written Directive is Required.** ~~Prior to 1 January 2007 an individual may qualify under either this section or C.8.86. Effective 1 January 2007,~~ Except as provided in C.8.72, the licensee shall require an Authorized User of unsealed radioactive material for the uses authorized under C.8.34 to be a physician who:

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(b) (1) Has completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical

use of unsealed radioactive material requiring a written directive. The training and experience shall include:

(i) Classroom and laboratory training in the following areas:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

(c) Mathematics pertaining to the use and measurement of radioactivity;

(d) Chemistry of radioactive material for medical use; and

(e) Radiation biology;

AND

(ii) Work experience, under the supervision of an Authorized User who meets the requirements in C.8.66 or C.8.72 [or equivalent requirements of another Agreement State~~, a Licensing State~~ or the U.S. Nuclear Regulatory Commission]. A supervising Authorized User, who meets the requirements in C.8.66(b) shall also have experience in administering dosages in the same dosage category or categories (i.e., C.8.66(b)(1)(ii)(f)) as the individual requesting Authorized User status. The work experience shall involve:

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(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in C.8.66(a)(1) and (b)(1)(ii)(f) or C.8.66(b)(1) [or equivalent requirements of another Agreement State~~, a Licensing State~~ or the U.S. Nuclear Regulatory Commission], and has achieved a level of competency sufficient to function independently as an Authorized User for the medical uses authorized under C.8.66. The written attestation shall be signed by a preceptor Authorized User who meets the requirements in C.8.66 or C.8.72 [or equivalent requirements of another Agreement State~~, a Licensing State~~ or the U.S. Nuclear Regulatory Commission. The preceptor Authorized User, who meets the requirements in C.8.66(b) shall have experience in administering dosages in the same dosage category or categories (i.e., C.8.66(b)(1)(ii)(f)) as the individual requesting Authorized User status.

C.8.67 **Training for Use of Manual Brachytherapy Sources.** ~~Prior to 1 January 2007 an individual may qualify under either this section or C.8.87. Effective 1 January 2007,~~ Except as provided in C.8.72, the licensee shall require the Authorized User of a manual brachytherapy source for the uses authorized under C.8.40 to be a physician who:

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(b) (1) Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes:

(i) 200 hours of classroom and laboratory training in the following areas:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

(c) Mathematics pertaining to the use and measurement of radioactivity; and

(d) Radiation biology;

AND

(ii) 500 hours of work experience, under the supervision of an Authorized User who meets the

requirements in C.8.67 or C.8.72 [or equivalent requirements of another Agreement State~~, a Licensing State~~ or the U.S. Nuclear Regulatory Commission] at a medical institution, involving:

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(2) Has completed 3 years of supervised clinical experience in radiation oncology, under an Authorized User who meets the requirements in C.8.67 or C.8.72 [or equivalent requirements of another Agreement State~~, a Licensing State~~ or the U.S. Nuclear Regulatory Commission], as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by C.8.67(b)(1)(ii);

AND

(3) Has obtained written attestation, signed by a preceptor Authorized User who meets the requirements in C.8.67 or C.8.72 [or equivalent requirements of another Agreement State~~, a Licensing State~~ or the U.S. Nuclear Regulatory Commission], that the individual has satisfactorily completed the requirements in paragraphs C.8.67(a)(1), or C.8.67(b)(1) and C.8.67(b)(2) and has achieved a level of competency sufficient to function independently as an Authorized User of manual brachytherapy sources for the medical uses authorized under C.8.67.

C.8.68 **Training for Ophthalmic Use of Strontium-90.** ~~Prior to 1 January 2007 an individual may qualify under either this section or C.8.88. Effective 1 January 2007,~~ Except as provided in C.8.72, the licensee shall require the Authorized User of strontium-90 for ophthalmic radiotherapy to be a physician who:

(a) Is an Authorized User under C.8.67 [or equivalent requirements of an Agreement State~~, a Licensing State~~ or the U.S. Nuclear Regulatory Commission];

OR

(b) (1) Has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training shall include:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity; and

(iv) Radiation biology;

AND

(2) Supervised clinical training in ophthalmic radiotherapy under the supervision of an Authorized User at a medical institution, clinic, or private practice that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training shall involve:

(i) Examination of each individual to be treated;

(ii) Calculation of the dose to be administered;

(iii) Administration of the dose; and

(iv) Follow up and review of each individual's case history;

AND

(3) Has obtained written attestation, signed by a preceptor Authorized User who meets the requirements in C.8.67, ~~or~~ C.8.68 or C.8.72 [or equivalent requirements of another Agreement State~~, a Licensing State~~ or the U.S. Nuclear Regulatory Commission], that the individual has satisfactorily completed the requirements in ~~C.8.68(a) and (b)~~ C.8.68(b)(1) and (b)(2) and has achieved a level of competency sufficient to function independently as an Authorized User of strontium-90 for ophthalmic use.

C.8.69 **Training for Use of Sealed Sources for Diagnosis.** ~~Prior to 1 January 2007 an individual may qualify under either this section or C.8.89. Effective 1 January 2007,~~ Except as provided in C.8.72, the licensee shall require the Authorized User of a diagnostic sealed source for use in a device authorized under C.8.38 to be a physician, dentist, or podiatrist who:

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C.8.70 **Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.** ~~Prior to 1 January 2007 an individual may qualify under either this section or C.8.90. Effective 1 January 2007,~~ Except as provided in C.8.72, the licensee shall require an Authorized User of a sealed source for a use authorized under C.8.46 to be a physician who:

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(b) (1) Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes:

(i) 200 hours of classroom and laboratory training in the following areas:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

(c) Mathematics pertaining to the use and measurement of radioactivity; and

(d) Radiation biology;

AND

(ii) 500 hours of work experience, under the supervision of an Authorized User who meets the requirements in C.8.70 or C.8.72 [or equivalent requirements of another Agreement State~~, a Licensing State~~ or the U.S. Nuclear Regulatory Commission] at a medical institution, involving:

(a) Reviewing full calibration measurements and periodic spot-checks;

(b) Preparing treatment plans and calculating treatment doses and times;

(c) Using administrative controls to prevent a misadministration involving the use of radioactive material;

(d) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;

(e) Checking and using survey meters; and

(f) Selecting the proper dose and how it is to be administered;

AND

(2) Has completed 3 years of supervised clinical experience in radiation therapy, under an Authorized User who meets the requirements in C.8.70 or C.8.72 [or equivalent requirements of another

Agreement State~~, a Licensing State~~ or the U.S. Nuclear Regulatory Commission], as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by C.8.70(b)(1)(ii);

AND

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in C.8.70(a)(1) or C.8.70(b)(1) and C.8.70(b)(2), and C.8.70(c), and has achieved a level of competency sufficient to function independently as an Authorized User of each type of therapeutic medical unit for which the individual is requesting Authorized User status. The written attestation shall be signed by a preceptor Authorized User who meets the requirements in C.8.70 or C.8.72 [or equivalent requirements of another Agreement State~~, a Licensing State~~ or the U.S. Nuclear Regulatory Commission] for an Authorized User for each type of therapeutic medical unit for which the individual is requesting Authorized User status;

AND

(c) Has received training in device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an Authorized User or authorized medical physicist, as appropriate, who is authorized for the type(s) of use for which the individual is seeking authorization.

C.8.71 **Training for Authorized Medical Physicist.** ~~Prior to 1 January 2007 an individual may qualify under either this section or C.8.91. Effective 1 January 2007,~~ Except as provided in C.8.73, the licensee shall require the Authorized Medical Physicist to be an individual who:

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(b) Is certified by a specialty board whose certification process has been recognized by the Agency, an Agreement State or the U.S. Nuclear Regulatory Commission[24] and who meets the requirements in C.8.71(c)(2) and (d). To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) 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;

(2) Have 2 years of full-time practical training and/or supervised experience in medical physics:

(i) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Agency, an Agreement State or the U.S. Nuclear Regulatory Commission; or

(ii) In clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements for Authorized Users in C.8.67, ~~or~~ C.8.70 or C.8.72; and

(3) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and

[24] The names of board certifications which have been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State will be posted on the NRC Web page.

treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery;

OR

(c) (1) Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and has completed 1 year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type(s) of use for which the individual is seeking authorization. This training and work experience shall be conducted in clinical radiation facilities that provide high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services and shall include:

(i) Performing sealed source leak tests and inventories;

(ii) Performing decay corrections;

(iii) Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(iv) Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable;

AND

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in C.8.71(d) and C.8.71(b)(1) and (2), or C.8.71(c)(1) and (d), and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation shall be signed by a preceptor authorized medical physicist who meets the requirements in C.8.71 or C.8.73 [or equivalent requirements of another Agreement State~~, a Licensing State~~ or the U.S. Nuclear Regulatory Commission] for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status;

AND

(d) Has training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the type(s) of use for which the individual is seeking authorization.

C.8.72 **Training for Experienced Authorized Users.** Physicians, dentists, or podiatrists identified as Authorized Users for the medical, dental or podiatric use of radioactive material on an Agency, Nuclear Regulatory Commission or another Agreement State license or on a permit issued by an Agency Nuclear Regulatory Commission or another Agreement State broad scope licensee that authorizes medical use, before 27 September 2004, who perform only those medical uses for which they were authorized on that date need not comply with the training requirements of C.8.64, C.8.65, C.8.66, C.8.67, C.8.68, C.8.69 and C.8.70. Individuals who need not comply with training requirements as described in this section may serve as preceptors for, and supervisors of, applicants seeking authorization on Agency licenses for the same uses for which these individuals are authorized.

C.8.73 **Training for Experienced Medical Physicists.**

(a) An individual identified as a teletherapy physicist, medical physicist or Authorized Medical Physicist on an Agency, another Agreement State or Nuclear Regulatory Commission license or on a permit issued by an

Agency, Nuclear Regulatory Commission or another Agreement State broad scope licensee that authorizes medical use, before 24 October 2004, who oversees only the use of radioactive material for which the licensee was authorized on that date need not comply with the training requirements of C.8.71 of these regulations. Individuals who need not comply with training requirements as described in this section may serve as preceptors for, and supervisors of, applicants seeking authorization on Agency licenses for the same uses for which these individuals are authorized.

(b) An individual who does not qualify as an Experienced Medical Physicist pursuant to C.8.73(a), but has, prior to 24 October 2004, registered with the Agency, under the provisions of Subpart B.4, as a provider of Radiation Physics Services for the therapeutic modality(s) in which the individual is seeking approval as an Authorized Medical Physicist need not comply with the training requirements of C.8.71 of these regulations. Individuals who need not comply with training requirements as described in this section may serve as preceptors for, and supervisors of, applicants seeking authorization on Agency licenses for the same uses for which these individuals are authorized.

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C.8.76 **Training for an Authorized Nuclear Pharmacist.** ~~Prior to 1 January 2007 an individual may qualify under either this section or C.8.92. Effective 1 January 2007,~~ Except as provided in C.8.77, the licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

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C.8.77 **Training for Experienced Nuclear Pharmacists.** A licensee may apply for and must receive a license amendment identifying an experienced nuclear pharmacist as an authorized nuclear pharmacist before it allows this individual to work as an Authorized Nuclear Pharmacist. An individual identified as a nuclear pharmacist on an Agency, Agreement State~~, Licensing State~~ or U.S. Nuclear Regulatory Commission license or on a permit issued by an Agency, Nuclear Regulatory Commission or another Agreement State broad scope licensee that authorizes medical use or the practice of nuclear pharmacy, before 27 September 2004 need not comply with the training requirements of C.8.76(b) or (c). Individuals who need not comply with training requirements as described in this section may serve as preceptors for, and supervisors of, applicants seeking authorization on Agency licenses for the same uses for which these individuals are authorized.

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C.8.80 **Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities Less Than or Equal to 1.22 gigabecquerels (33 millicuries).** Except as provided in C.8.72, the licensee shall require an Authorized User for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries), to be a physician who:

(a) Is certified by a medical specialty board whose certification includes all of the requirements in C.8.80(c)(1) and (c)(2), and whose certification process has been recognized by the Agency, an Agreement State or the U.S. Nuclear Regulatory Commission[25], and who meets the requirements in C.8.80(c)(3);

OR

(b) Is an Authorized User under C.8.66(a), C.8.66(b) for uses listed in C.8.66(b)(1)(ii)(f)(1) or (2), or C.8.81 [or equivalent requirements of an Agreement State~~, a Licensing State~~ or the U.S. Nuclear Regulatory

[25] The names of board certifications which have been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State will be posted on the NRC Web page.

Commission];

OR

(c) (1) Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training shall include:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of radioactive material for medical use; and

(v) Radiation biology;

AND

(2) Has work experience, under the supervision of an Authorized User who meets the requirements in C.8.66(a), C.8.66(b), C.8.72, C.8.80 or C.8.81 [or equivalent requirements of another Agreement State~~, a Licensing State~~ or the U.S. Nuclear Regulatory Commission]. A supervising Authorized User who meets the requirements in C.8.66(b) shall also have experience in administering dosages as specified in C.8.66(b)(1)(ii)(f)(1) or (2). The work experience shall involve:

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent a misadministration involving the use of radioactive material;

(v) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

(vi) Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131;

AND

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in C.8.80(c)(1) and (c)(2), and has achieved a level of competency sufficient to function independently as an Authorized User for medical uses authorized under C.8.34. The written attestation shall be signed by a preceptor Authorized User who meets the requirements in C.8.66, C.8.72, C.8.80, or C.8.81 [or equivalent requirements of another Agreement State~~, a Licensing State~~ or the U.S. Nuclear Regulatory Commission]. A preceptor Authorized User, who meets the requirement in C.8.66(b), shall also have experience in administering dosages as specified in C.8.66 (b)(1)(ii)(f)(1) or (2).

C.8.81 **Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities Greater Than 1.22 gigabecquerels (33 millicuries).** Except as provided in C.8.72, the licensee shall require an Authorized User for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries), to be a physician who:

(a) Is certified by a medical specialty board whose certification includes all of the requirements in

C.8.81(c)(1) and (c)(2), and whose certification process has been recognized by the Agency, an Agreement State or the U.S. Nuclear Regulatory Commission[26], and who meets the requirements in C.8.81(c)(3);

OR

(b) Is an Authorized User under C.8.66(a), C.8.66(b) for uses listed in C.8.66(b)(1)(ii)(f)(2), or C.8.81 [or equivalent requirements of an Agreement State~~, a Licensing State~~ or the U.S. Nuclear Regulatory Commission];

OR

(c) (1) Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training shall include:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of radioactive material for medical use; and

(v) Radiation biology;

AND

(2) Has work experience, under the supervision of an Authorized User who meets the requirements in C.8.66(a), C.8.66(b), C.8.72 or C.8.81 [or equivalent requirements of another Agreement State~~, a Licensing State~~ or the U.S. Nuclear Regulatory Commission]. A supervising Authorized User, who meets the requirements in C.8.66(b), shall also have experience in administering dosages as specified in C.8.66(b)(1)(ii)(f)(2). The work experience shall involve:

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent a misadministration involving the use of Radioactive material;

(v) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

(vi) Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131;

AND

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in C.8.81(c)(1) and (c)(2), and has achieved a level of competency sufficient to function independently as an Authorized User for medical uses authorized under C.8.34. The written attestation shall be signed by a preceptor Authorized User who meets the requirements in C.8.66, C.8.72 or C.8.81 [or equivalent

[26] The names of board certifications which have been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State will be posted on the NRC Web page.

requirements of another Agreement State~~, a Licensing State~~ or the U.S. Nuclear Regulatory Commission]. A preceptor Authorized User, who meets the requirements in C.8.66(b), shall also have experience in administering dosages as specified in C.8.66(b)(1) (ii)(f)(2).

C.8.82 **Training for the Parenteral Administration of Unsealed Radioactive Material Requiring a Written Directive.** Except as provided in C.8.72, the licensee shall require an Authorized User for the parenteral administration requiring a written directive, to be a physician who:

(a) Is an Authorized User under C.8.66 ~~or, prior to 1 January 2007,~~ for uses listed in C.8.66(b)(1)(ii)(f)(3) or (f)(4) [or equivalent requirements of an Agreement State~~, a Licensing State~~ or the U.S. Nuclear Regulatory Commission];

OR

(b) Is an Authorized User under C.8.67 or C.8.70 [or equivalent requirements of an Agreement State~~, a Licensing State~~ or the U.S. Nuclear Regulatory Commission], and who meets the requirements in C.8.82(d);

OR

(c) Is certified by a medical specialty board whose certification process has been recognized by the Agency, an Agreement State or the U.S. Nuclear Regulatory Commission under C.8.67 or C.8.70, and who meets the requirements in C.8.82(d);

OR

(d) (1) Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations, for which a written directive is required, of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. The training shall include:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of radioactive material for medical use; and

(v) Radiation biology;

AND

(2) Has work experience, under the supervision of an Authorized User who meets the requirements in C.8.66, C.8.72 or C.8.82 70 [or equivalent requirements of another Agreement State~~, a Licensing State~~ or the U.S. Nuclear Regulatory Commission] in the parenteral administration, for which a written directive is required, of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. A supervising Authorized User who meets the requirements in C.8.66 shall have experience in administering dosages as specified in C.8.66(b)(1)(ii)(f)(3) and/or (f)(4). The work experience shall involve:

(i) Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;

(ii) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent a misadministration involving the use of unsealed

radioactive material;

(v) Using procedures to contain spilled radioactive material safely, and using proper decontamination procedures; and

(vi) Administering dosages to patients or human research subjects, that include at least 3 cases involving the parenteral administration, for which a written directive is required, of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV and/or at least 3 cases involving the parenteral administration of any other radionuclide, for which a written directive is required;

AND

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in C.8.82(b) or (c), and has achieved a level of competency sufficient to function independently as an Authorized User for the parenteral administration of unsealed radioactive material requiring a written directive. The written attestation shall be signed by a preceptor Authorized User who meets the requirements in C.8.66, C.8.72 or C.8.82 [or equivalent requirements of another Agreement State~~, a Licensing State~~ or the U.S. Nuclear Regulatory Commission]. A preceptor Authorized User, who meets the requirements in C.8.66 shall have experience in administering dosages as specified in C.8.66(b)(1)(ii)(f)(3) and/or (f)(4).

C.8.83 through C.8.92 [Removed and reserved]

~~C.8.83 **Alternate Training for Radiation Safety Officer.** Prior to 29 April 2008 an individual may qualify under either this section or C.8.62. Except as provided in C.8.63, an individual fulfilling the responsibilities of the Radiation Safety Officer (RSO) as provided in C.8.4 shall:~~

~~(a) Be certified by the:~~

~~(1) American Board of Health Physics in Comprehensive Health Physics;~~

~~(2) American Board of Radiology in Radiological Physics, Therapeutic Radiological Physics, or Medical Nuclear Physics;~~

~~(3) American Board of Nuclear Medicine;~~

~~(4) American Board of Science in Nuclear Medicine~~

~~(5) Board of Pharmaceutical Specialties in Nuclear Pharmacy; or~~

~~(6) American Osteopathic Board of Radiology or American Osteopathic Board of Nuclear Medicine; or~~

~~(7) American Board of Medical Physics in radiation oncology physics; or~~

~~(8) Royal College of Physicians and Surgeons of Canada in nuclear medicine; or~~

~~(b) Have had 200 hours of classroom and laboratory training as follows:~~

~~(1) Radiation physics and instrumentation;~~

~~(2) Radiation protection;~~

~~(3) Mathematics pertaining to the use and measurement of radioactivity;~~

~~(4) Radiation biology;~~

~~(5) Radiopharmaceutical chemistry; and~~

~~(6) One year of full time experience in radiation safety at a medical institution under the supervision~~

~~of the individual identified as the Radiation Safety Officer on an Agency, Agreement State, Licensing State, or U.S. Nuclear Regulatory Commission license that authorizes the medical use of radioactive material; or~~

~~(c) Is an authorized user, Authorized Medical Physicist, or Authorized Nuclear Pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual has Radiation Safety Officer responsibilities.~~

~~C.8.84~~ **Alternate Training for Uptake, Dilution and Excretion Studies.** ~~Prior to 1 January 2007 an individual may qualify under either this section or C.8.64. Except as provided in C.8.72, the licensee shall require the authorized user of an unsealed radioactive material for the uses authorized under C.8.28 to be a physician who:~~

~~(a) Is certified in:~~

~~(1) Nuclear medicine by the American Board of Nuclear Medicine;~~

~~(2) Diagnostic radiology by the American Board of Radiology;~~

~~(3) Diagnostic radiology or radiology within the previous five years by the American Osteopathic Board of Radiology; or~~

~~(4) Nuclear Medicine by the American Osteopathic Board of Nuclear Medicine; or~~

~~(5) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or~~

~~(b) Has completed 40 hours of instruction in basic radionuclide handling techniques applicable to the use of prepared radiopharmaceuticals, and 20 hours of supervised clinical experience:~~

~~(1) To satisfy the basic instruction requirement, 40 hours of Classroom and laboratory instruction shall include:~~

~~(i) Radiation physics and instrumentation;~~

~~(ii) Radiation protection;~~

~~(iii) Mathematics pertaining to the use and measurement of radioactivity;~~

~~(iv) Radiation biology; and~~

~~(v) Radiopharmaceutical Chemistry.~~

~~(2) To satisfy the requirement for 20 hours of supervised clinical experience, training must be under the supervision of an authorized user at a medical institution and shall include:~~

~~(i) Examining patients or human research subjects and reviewing their case histories to determine their suitability for radionuclide diagnosis, limitations, or contraindications;~~

~~(ii) Selecting the suitable radiopharmaceuticals and calculating, measuring and safely preparing the dosages;~~

~~(iii) Administering dosages to patients or human research subjects and using syringe radiation shields;~~

~~(iv) Collaborating with the authorized user in the interpretation of radionuclide test results;~~

~~(v) Patient or human research subjects follow-up; or~~

~~(c) Has successfully completed a 6-month training program in nuclear medicine as part of a training program that has been approved by the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and that included classroom and~~

~~laboratory training, work experience, and supervised clinical experience in all the topics identified in C.8.84(b).~~

~~C.8.85~~ **Alternate Training for Imaging and Localization Studies.** ~~Prior to 1 January 2007 an individual may qualify under either this section or C.8.65. Except as provided in C.8.72, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under C.8.30 to be a physician who:~~

~~(a) Is certified in:~~

~~(1) Nuclear medicine by the American Board of Nuclear Medicine;~~

~~(2) Diagnostic radiology by the American Board of Radiology;~~

~~(3) Diagnostic radiology or radiology within the previous 5 years by the American Osteopathic Board of Radiology; or~~

~~(4) Nuclear Medicine by the American Osteopathic Board of Nuclear Medicine; or~~

~~(5) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or~~

~~(b) Has completed 200 hours of instruction in basic radionuclide handling techniques applicable to the use of prepared radiopharmaceuticals, generators, and reagent kits, 500 hours of supervised work experience, and 500 hours of supervised clinical experience.~~

~~(1) To satisfy the basic instruction requirement, 200 hours of Classroom and laboratory training shall include:~~

~~(i) Radiation physics and instrumentation;~~

~~(ii) Radiation protection;~~

~~(iii) Mathematics pertaining to the use and measurement of radioactivity;~~

~~(iv) Radiopharmaceutical chemistry; and~~

~~(v) Radiation biology;~~

~~(2) To satisfy the requirement for 500 hours of supervised work experience, training shall be under the supervision of an authorized user at a medical institution and shall include:~~

~~(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;~~

~~(ii) Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;~~

~~(iii) Calculating and safely preparing patient or human research subject dosages;~~

~~(iv) Using administrative controls to prevent the a misadministration involving the use of unsealed radioactive material;~~

~~(v) Using emergency procedures to contain spilled radioactive material safely and using proper decontamination procedures; and~~

~~(vi) Eluting technetium-99m from generator systems, assaying and testing the eluate for molybdenum-99 and alumina contamination, and processing the eluate with reagent kits to prepare technetium-99m labeled radiopharmaceuticals.~~

~~(3) To satisfy the requirement for 500 hours of supervised clinical experience, training shall be under the supervision of an authorized user at a medical institution and shall include:~~

~~(i) Examining patients or human research subjects and reviewing their case histories to~~

~~determine their suitability for radionuclide diagnosis, limitations, or contraindications;~~

~~(ii) Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;~~

~~(iii) Administering dosages to patients or human research subjects and using syringe radiation shields;~~

~~(iv) Collaborating with the authorized user in the interpretation of radionuclide test results; and~~

~~(v) Patient or human research subjects follow-up; or~~

~~(c) Has successfully completed a 6 month training program in nuclear medicine that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in C.8.85(b).~~

~~C.8.86~~ **Alternate Training for Unsealed Radioactive Material for Which a Written Directive is Required.** ~~Prior to 1 January 2007 an individual may qualify under either this section or C.8.66. Except as provided in C.8.72, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under C.8.34 to be a physician who:~~

~~(a) Is certified by:~~

~~(1) The American Board of Nuclear Medicine; or~~

~~(2) The American Board of Radiology in radiology, radiation oncology or therapeutic radiology; or~~

~~(3) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or~~

~~(4) The American Osteopathic Board of Radiology after 1984; or~~

~~(b) Has completed 80 hours of instruction in basic radionuclide handling techniques applicable to the use of therapeutic radiopharmaceuticals, and has had supervised clinical experience.~~

~~(1) To satisfy the requirement for instruction, 80 hours of classroom and laboratory training shall include:~~

~~(i) Radiation physics and instrumentation;~~

~~(ii) Radiation protection;~~

~~(iii) Mathematics pertaining to the use and measurement of radioactivity; and~~

~~(iv) Radiation biology;~~

~~(2) To satisfy the requirement for supervised clinical experience, training shall be under the supervision of an authorized user at a medical institution and shall include:~~

~~(i) Use of iodine-131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in ten individuals;~~

~~(ii) Use of soluble phosphorus-32 for the treatment of ascites, polycythemia vera, leukemia, or bone metastases in three individuals;~~

~~(iii) Use of iodine-131 for treatment of thyroid carcinoma in three individuals; and~~

~~(iv) Use of colloidal chromic phosphorus-32 or of colloidal gold-198 for intra-cavitary treatment of malignant effusions in three individuals.~~

~~C.8.87~~ **Alternate Training for Use of Manual Brachytherapy Sources.** ~~Prior to 1 January 2007 an individual may qualify under either this section or C.8.67. Except as provided in C.8.72, the licensee shall require the authorized user of a manual brachytherapy source for the uses authorized under C.8.40 to be a~~

~~physician who:~~

~~(a) Is certified in:~~

~~(1) Radiology, radiation oncology or therapeutic radiology by the American Board of Radiology;~~

~~(2) Radiation oncology by the American Osteopathic Board of Radiology;~~

~~(3) Radiology, with a specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or~~

~~(4) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or~~

~~(b) Is in the active practice of therapeutic radiology, has completed 200 hours of instruction in basic radionuclide handling techniques applicable to the tuse of manual brachytherapy sources and 500 hours of supervised work experience and a minimum of 3 years of supervised clinical experience.~~

~~(1) To satisfy the requirement for instruction, 200 hours of classroom and laboratory training shall include:~~

~~(i) Radiation physics and instrumentation;~~

~~(ii) Radiation protection;~~

~~(iii) Mathematics pertaining to the use and measurement of radioactivity; and~~

~~(iv) Radiation biology.~~

~~(2) To satisfy the requirement for 500 hours of supervised work experience, training shall be under the supervision of an authorized user at a medical institution, and shall include:~~

~~(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;~~

~~(ii) Checking survey meters for proper operation;~~

~~(iii) Preparing, implanting, and removing sealed sources;~~

~~(iv) Using administrative controls to prevent a misadministration involving the use of radioactive material; and~~

~~(v) Using emergency procedures to control radioactive material;~~

~~(3) To satisfy the requirement for a period of supervised clinical experience training shall include 1 year in a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association, and an additional 2 years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution. The supervised clinical experience shall include:~~

~~(i) Examining individuals and reviewing their case histories to determine their suitability for brachytherapy treatment, and any limitations or contraindications;~~

~~(ii) Selecting the proper brachytherapy sources, dose, and method of administration;~~

~~(iii) Calculating the dose; and~~

~~(iv) Post-administration follow-up and review of case histories in collaboration with the authorized user.~~

~~C.8.88 **Alternate Training for Ophthalmic Use of Strontium-90.** Prior to 1 January 2007 an individual may qualify under either this section or C.8.68. Except as provided in C.8.72, the licensee shall require the~~

~~authorized user of strontium-90 for ophthalmic radiotherapy to be a physician who:~~

~~(a) Is certified in radiology or therapeutic radiology by the American Board of Radiology; or~~

~~(b) Is in the active practice of therapeutic radiology or ophthalmology, and has completed 24 hours of instruction in basic radionuclide handling techniques applicable to the use of strontium-90 for ophthalmic radiotherapy, and a period of supervised clinical training in ophthalmic radiotherapy.~~

~~(1) To satisfy the requirement for instruction, The classroom and laboratory training shall include:~~

~~(i) Radiation physics and instrumentation;~~

~~(ii) Radiation protection;~~

~~(iii) Mathematics pertaining to the use and measurement of radioactivity; and~~

~~(iv) Radiation biology~~

~~(2) To satisfy the requirement for a period of supervised clinical training in ophthalmic radiotherapy, training shall be under the supervision of an authorized user at a medical institution, clinic or private practice and shall include the use of strontium-90 for the ophthalmic treatment of five individuals that includes:~~

~~(i) Examination of each individual to be treated;~~

~~(ii) Calculation of the dose to be administered;~~

~~(iii) Administration of the dose; and~~

~~(iv) Follow-up and review of each individual's case history.~~

~~C.8.89~~ **~~Alternate Training for Use of Sealed Sources for Diagnosis~~.** ~~Prior to 1 January 2007 an individual may qualify under either this section or C.8.69. Except as provided in C.8.72, the licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized under C.8.38 to be a physician, dentist, or podiatrist who:~~

~~(a) Is certified in:~~

~~(1) Radiology, diagnostic radiology with special competence in nuclear radiology, or therapeutic radiology by the American Board of Radiology;~~

~~(2) Nuclear medicine by the American Board of Nuclear Medicine;~~

~~(3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or~~

~~(4) Nuclear Medicine by the American Osteopathic Board of Nuclear Medicine; or~~

~~(5) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or~~

~~(b) Has completed 8 hours of instruction in basic radionuclide handling techniques specifically applicable to the use of the device. To satisfy the requirement for instruction, the training shall include:~~

~~(1) Radiation physics, mathematics pertaining to the use and measurement of radioactivity, and instrumentation;~~

~~(2) Radiation biology; and~~

~~(3) Radiation protection and training in the use of the device for the purposes authorized by the license.~~

~~C.8.90~~ **~~Alternate Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units~~**. ~~Prior to 1 January 2007 an individual may qualify under either this section~~

~~or C.8.70. Except as provided in C.8.72, the licensee shall require an authorized user of a sealed source for a use authorized under C.8.46 to be a physician who:~~

~~(a) Is certified in:~~

~~(1) Radiology, radiation oncology or therapeutic radiology by the American Board of Radiology;~~

~~(2) Radiation oncology by the American Osteopathic Board of Radiology;~~

~~(3) Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or~~

~~(4) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or~~

~~(b) Is in the active practice of therapeutic radiology, and has completed 200 hours of instruction in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit, 500 hours of supervised work experience, and a minimum of 3 years of supervised clinical experience.~~

~~(1) To satisfy the requirement for instruction, the classroom and laboratory training shall include:~~

~~(i) Radiation physics and instrumentation;~~

~~(ii) Radiation protection;~~

~~(iii) Mathematics pertaining to the use and measurement of radioactivity; and~~

~~(iv) Radiation biology.~~

~~(2) To satisfy the requirement for supervised work experience, training shall be under the supervision of an authorized user who meets the requirements in C.8.70 or equivalent Agreement State, Licensing State or U.S. Nuclear Regulatory Commission requirements at an institution and shall include:~~

~~(i) Review of the full calibration measurements and periodic spot-checks;~~

~~(ii) Preparing treatment plans and calculating treatment doses and times;~~

~~(iii) Using administrative controls to prevent a misadministrations involving the use of radioactive material;~~

~~(iv) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console; and~~

~~(v) Checking and using survey meters.~~

~~(3) To satisfy the requirement for a period of supervised clinical experience, training shall include 1 year in a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional 2 years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution. The supervised clinical experience shall include:~~

~~(i) Examining individuals and reviewing their case histories to determine their suitability for teletherapy treatment, and any limitations or contraindications;~~

~~(ii) Selecting the proper dose and how it is to be administered;~~

~~(iii) Calculating the therapeutic medical doses and collaborating with the authorized user in the review of patients' or human research subjects' progress and consideration of the need to modify originally prescribed doses as warranted by patients' or human research subjects' reaction to radiation; and~~

~~(iv) Post-administration follow-up and review of case histories.~~

~~C.8.91 **Alternate Training for Authorized Medical Physicist.** Prior to 1 January 2007 an individual may qualify under either this section or C.8.71. Except as provided in C.8.73, the licensee shall require the Authorized Medical Physicist to:~~

~~(a) Be registered with the Agency, under the provisions of Subpart B.4, as a provider of Radiation Physics Services for the therapeutic modality(s) in which the individual is seeking approval as an Authorized Medical Physicist; and~~

~~(b) Be certified by the:~~

~~(1) American Board of Radiology in:~~

~~(i) Therapeutic radiological physics; or~~

~~(ii) Roentgen-ray and gamma-ray physics; or~~

~~(iii) X-ray and radium physics; or~~

~~(iv) Radiological physics; or~~

~~(2) American Board of Medical Physics in radiation oncology physics; or~~

~~(3) X-ray and radium physics; or~~

~~(4) Radiological physics; or~~

~~(c) Hold a master's or doctor's degree in physics, biophysics, radiological physics or health physics, and has completed 1 year of full time training in therapeutic radiological physics and an additional year of full time work experience under the supervision of an Authorized Medical Physicist at a medical institution. To meet this requirement, the individual shall have performed the tasks listed in C.8.18, C.8.52, C.8.53, C.8.55, C.8.56, C.8.57, C.8.58, and C.8.59 of these regulations, as applicable, under the supervision of an Authorized Medical Physicist during the year of work experience.~~

~~C.8.92 **Alternate Training for an Authorized Nuclear Pharmacist.** Except as provided in C.8.77, the licensee shall require the authorized nuclear pharmacist to be a pharmacist who:~~

~~(a) Possesses a current license as a pharmacist in accordance with the Rules and Regulations Pertaining to Pharmacists, Pharmacies and Manufacturers, Wholesalers and Distributors [R5-19-PHAR] of the Rhode Island Department of Health; and~~

~~(b) Has current board certification as a nuclear pharmacist by the Board of Pharmaceutical Specialties; or~~

~~(c) (1) Has completed 700 hours in a structured educational program consisting of both:~~

~~(i) Didactic training in the following areas:~~

~~(a) Radiation physics and instrumentation;~~

~~(b) Radiation protection;~~

~~(c) Mathematics pertaining to the use and measurement of radioactivity; and~~

~~(d) Chemistry of radioactive material for medical use; and~~

~~(e) Radiation biology; and~~

~~(ii) Supervised experience in a nuclear pharmacy involving the following:~~

~~(a) Shipping, receiving, and performing related radiation surveys;~~

~~(b) Using and performing checks for dose calibrators, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;~~

~~(c) Calculating, assaying, and safely preparing dosages for patients or human research subjects;~~

~~(d) Using administrative controls to prevent the misadministration of radioactive material;~~

~~(e) Using procedures to prevent or minimize contamination and using proper decontamination procedures; and~~

~~(2) Has obtained written certification, signed by a preceptor Authorized Nuclear Pharmacist, that the above training has been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.~~

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PART C
APPENDIX B

EXEMPT QUANTITIES

Radioactive Material	Microcuries
*****	
Bismuth-207 (Bi-207)	~~10~~ 0.1
*****	
Carbon-11 (C-11)	~~10~~ 0.1
*****	
Cerium-139 (Ce-139)	~~1~~ 0.1
*****	
Cobalt-56 (Co-56)	~~1~~ 0.1
*****	
Nitrogen-13 (N-13)	~~10~~ 0.1
*****	
Oxygen-15 (O-15)	~~10~~ 0.1
*****	
Vanadium-49 (V-49)	~~1~~ 0.1
*****	
Ytterbium-169 (Yb-169)	~~1~~ 0.1
*****	

*****

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PART C
APPENDIX F

QUANTITIES OF RADIOACTIVE MATERIALS REQUIRING CONSIDERATION OF THE NEED FOR AN EMERGENCY PLAN FOR RESPONDING TO A RELEASE

Radioactive Material	Release Fraction	Quantity (Curies)
*****	*****	*****
Radium-226	0.0001	100
*****	*****	*****

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PART C
APPENDIX G

DETERMINATION OF A_1 AND A_2

I. Values of A_1 and A_2 for individual radionuclides, which are the bases for many activity limits elsewhere in these regulations, are given in Table I. The curie (Ci) values specified are obtained by converting from the Terabecquerel (TBq) figure. The curie values are expressed to three significant figures to assure that the difference in the TBq and Ci quantities is one tenth of one percent or less. Where values of A_1 or A_2 are unlimited, it is for radiation control purposes only. For nuclear criticality safety, some materials are subject to controls placed on fissile material.

II. (a) For individual radionuclides whose identities are known, but which are not listed in Table I, the A_1 and A_2 values contained in Table II may be used. Otherwise, the licensee shall obtain prior Agency approval of ~~the determination of the values~~ of the A_1 and A_2 values for radionuclides not listed in Table I, before shipping the material. ~~requires Agency approval, except that the values of A_1 and A_2 in Table II may be used without obtaining Agency approval~~.

(b) For individual radionuclides whose identities are known, but which are not listed in Table IV, the exempt material activity concentration and exempt consignment activity values contained in Table II may be used. Otherwise, the licensee shall obtain prior Agency approval of the exempt material activity concentration and exempt consignment activity values for radionuclides not listed in Table IV, before shipping the material.

III. In the calculations of A_1 and A_2 for a radionuclide not in Table I, a single radioactive decay chain, in which radionuclides are present in their naturally occurring proportions, and in which no daughter nuclide has a half-life either longer than ten (10) days, or longer than that of the parent nuclide, shall be considered as a single radionuclide, and the activity to be taken into account, and the A_1 or A_2 value to be applied shall be those corresponding to the parent nuclide of that chain. In the case of radioactive decay chains in which any daughter nuclide has a half-life either longer than ten (10) days, or greater than that of the parent nuclide, the parent and those daughter nuclides shall be considered as mixtures of different nuclides.

IV. For mixtures of radionuclides whose identities and respective activities are known, the following conditions apply:

(a) For special form radioactive material, the maximum quantity transported in a Type A package is as follows:

$$\sum_i \frac{B(i)}{A_1(i)} \leq 1$$

where B(i) is the activity of radionuclide I, and $A_1(i)$ is the A_1 value for radionuclide I.

(b) For normal form radioactive material, the maximum quantity transported in a Type A package is as follows:

$$\sum_i \frac{B(i)}{A_2(i)} \leq 1$$

where B(i) is the activity of radionuclide I and ~~$A_1(i)$ and~~ $A_2(i)$ ~~are the A_1 and~~ is the A_2 value~~s~~ for radionuclide I ~~respectively~~.

(c) Alternatively, an A_1 value for mixtures of special form material may be determined as follows:

$$A_1 = \frac{1}{\sum_i \frac{f(i)}{A_1(i)}}$$

where f(i) is the fraction of activity of radionuclide I in the mixture and $A_1(i)$ is the appropriate A_1 value for radionuclide I.

(d) An A_2 value for mixtures of normal form material may be determined as follows:

$$A_2 = \frac{1}{\sum_i \frac{f(i)}{A_2(i)}}$$

where f(i) is the fraction of activity of nuclide I in the mixture and $A_2(i)$ is the appropriate A_2 value for nuclide I.

(e) The exempt activity concentration for mixtures of nuclides may be determined as follows:

$$[A] = \frac{1}{\sum_i \frac{f(i)}{[A](i)}}$$

where f(i) is the fraction of activity concentration of radionuclide I in the mixture, and [A] is the activity concentration for exempt material containing radionuclide I.

(f) The activity limit for an exempt consignment for mixtures of radionuclides may be determined as follows:

$$A = \frac{1}{\sum_i \frac{f(i)}{A(i)}}$$

where f(i) is the fraction of activity of radionuclide I in the mixture, and A is the activity limit for exempt consignments for radionuclide I.

V. When the identity of each radionuclide is known, but the individual activities of some of the radionuclides are not known, the radionuclides may be grouped, and the lowest A_1 or A_2 value, as appropriate, for the radionuclides in each group may be used in applying the formulas in paragraph IV. Groups may be based on the total alpha activity and the total beta/gamma activity when these are known, using the lowest A_1 or A_2 values for the alpha emitters and beta/gamma emitters.

TABLE I
A_1 AND A_2 VALUES FOR RADIONUCLIDES

Symbol of Element and Radionuclide	Atomic No.	A_1 (TBq)	A_1 (Ci)	A_2 (TBq)	A_2 (Ci)	Specific Activity (TBq/g)	Specific Activity (Ci/g)

COMPILER'S NOTE: The current Table I will be deleted in its entirety and replaced with the table contained in 10 CFR 71, Appendix A – Table A-1. However, due to the length and complexity of both tables, only the column headings have been included. The column headings are identical in both the current and revised Table I. The complete revised Table I will appear in the final regulations.

TABLE II
GENERAL VALUES FOR A_1 AND A_2

	A_1		A_2	
Contents	**TBq**	**Ci**	**TBq**	**Ci**
Only beta- or gamma-emitting nuclides are known to be present.	0.2	5	0.02	0.5
Alpha-emitting nuclides are known to be present, or no relevant data are available.	0.10	2.70	$2x10^{-5}$	$5.4x10^{-4}$

TABLE III
ACTIVITY-MASS RELATIONSHIPS FOR URANIUM

Uranium Enrichment[27] weight % U-235 present	Specific Activity Ci/g	Specific Activity TBq/g
0.45	$1.8x10^{-8}$	$5.0x10^{-7}$
0.72	$2.6x10^{-8}$	$7.1x10^{-7}$
1.0	$2.8x10^{-8}$	$7.6x10^{-7}$
1.5	$3.7x10^{-8}$	$1.0x10^{-6}$
5.0	$1.0x10^{-7}$	$2.7x10^{-6}$
10.0	$1.8x10^{-7}$	$4.8x10^{-6}$
20.0	$3.7x10^{-7}$	$1.0x10^{-5}$
35.0	$7.4x10^{-7}$	$2.0x10^{-5}$
50.0	$9.3x10^{-7}$	$2.5x10^{-5}$
90.0	$2.2x10^{-6}$	$5.8x10^{-5}$
93.0	$2.6x10^{-6}$	$7.0x10^{-5}$
95.0	$3.4x10^{-6}$	$9.1x10^{-5}$

[27] The figures for uranium include representative values for the activity of the uranium-235 which is concentrated during the enrichment process.

TABLE IV

EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)

COMPILER'S NOTE: Table IV is new in its entirety and identical to the table contained in 10 CFR 71, Appendix A – Table A-2. However, due to the length and complexity of this table, only the column headings have been included as proposed text. The complete Table IV will appear in the final regulations.

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PART E

RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OR WIRELINE SERVICE OPERATIONS AND ~~ANALYTICAL X-RAY EQUIPMENT~~ INDUSTRIAL RADIATION MACHINES

E.1 PURPOSE

The regulations in this part establish radiation safety requirements for persons utilizing sources of radiation for industrial radiography or wireline service operations (including mineral logging, radioactive markers and subsurface tracer studies), and provides special requirements for industrial radiation machines ~~analytical and research and development X-ray equipment~~. The requirements of this part are in addition to and not in substitution for the other requirements of these regulations.

E.2 INDUSTRIAL RADIOGRAPHY

E.2.1 **Scope ~~and Exemptions~~.**

~~(a)~~ **~~Scope.~~** ~~Except as provided by Paragraph E.2.1(b)~~ for industrial radiation machines regulated pursuant to Subpart E.3 of these Regulations, the regulations in this subpart apply to all licensees or registrants who use sources of radiation for industrial radiography; provided, however, that nothing in this subpart shall apply to the use of sources of radiation in the healing arts.

~~(b) **Exemptions.** Uses of certified and certifiable cabinet x-ray systems are exempt from the requirements of this part except for the following:~~

~~(1) For certified and certifiable cabinet x-ray systems, including those designed to allow admittance of individuals:~~

~~(i) No registrant shall permit any individual to operate a cabinet x-ray system until the individual has received a copy of and instruction in the operating procedures for the unit. Records that demonstrate compliance with this subparagraph shall be maintained for Agency inspection until disposal is authorized by the Agency.~~

~~(ii) Tests for proper operation of interlocks must be conducted and recorded at intervals not to exceed six months. Records of these tests shall be maintained for Agency inspection until disposal is authorized by the Agency.~~

~~(iii) The registrant shall perform an evaluation of the radiation dose limits to determine compliance with A.2.11(a), (b) and (c) of these regulations, and 21 CFR 1020.40, Cabinet X-Ray Systems (39 Federal Register 12986, April 10, 1974), at intervals not to exceed one year. Records of these evaluations shall be maintained for Agency inspection for two years after the evaluation.~~

~~(2) Certified cabinet x-ray systems shall be maintained in compliance with 21 CFR 1020.40, Cabinet X-Ray Systems (39 Federal Register 12986, April 10, 1974), and no modification shall be made to the system unless prior Agency approval has been granted.~~

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E.2.18 **Performance Requirements for Radiography Equipment.** Equipment used in industrial radiographic operations must meet the following minimum criteria:

(a) Each radiographic exposure device, source assembly or sealed source, and all associated equipment

must meet the requirements specified in American National Standards Institute (ANSI), N432-1980 "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography" [published as NBS Handbook 136, issued January 1981][28].

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~~E.3 ANALYTICAL AND RESEARCH AND DEVELOPMENT X-RAY EQUIPMENT~~

[DELETED IN ENTIRETY – Existing Subpart E.3 text is not shown for space considerations]

[28] This publication may be purchased from the American National Standards Institute, Inc., 25 West 43rd Street, New York, New York 10036; Telephone: (212) 642-4900.

E.3 INDUSTRIAL RADIATION MACHINES

E.3.1 **Purpose**. This Subpart establishes requirements for the use of industrial radiation machines not otherwise covered by these Regulations. For the purposes of this Subpart:

(a) **Category A Industrial Radiation Machine**: A device capable of generating or emitting fields of radiation in an open beam configuration during normal conditions of use. This includes, but is not limited to, portable/handheld fluorescence x-ray, fluoroscopy hand held intensified, fluoroscopy x-ray, flash x-ray, flash x-ray for bomb detection, spectrography x-ray, diffraction x-ray and uncertified cabinet x-ray.

(b) **Category B Industrial Radiation Machine:** A device capable of generating or emitting fields of radiation where the beam is contained during normal conditions of use. This includes, but is not limited to, package x-ray, certified and certifiable cabinet x-ray, x-ray fluorescence units and similar devices.

E.3.2 **Exemptions**. Uses of portable/handheld fluorescence x-ray (open beam) devices that are manufactured without safety devices are exempt from the requirements of §E.3.4(a) of these Regulations.

E.3.3 **General Requirements – All Industrial Radiation Machines.**

(a) **Radiation Levels.** The local components of an industrial radiation machine shall be located and arranged and shall include sufficient shielding or access control such that no radiation levels exist in any area surrounding the local component group which could result in a dose to an individual present in the area in excess of the dose limits given in §A.2.11 of these Regulations.

(b) **Warning Devices.**

(1) The x-ray control shall provide visual indication whenever x rays are produced.

(2) All ancillary warning devices shall be labeled so that their purpose is easily identified and shall have fail-safe characteristics.

(c) **Posting.** Each area or room containing industrial radiation machines shall be conspicuously posted with a sign or signs bearing the radiation symbol and the words **"CAUTION - X-RAY EQUIPMENT"**, or words having a similar intent.

(d) **Ports.** Unused ports on industrial radiation machine source housings shall be secured in the closed position in a manner which will prevent inadvertent opening.

(e) **Labeling.** Each registrant shall ensure that each industrial radiation machine is labeled in a conspicuous manner to caution individuals that radiation is produced when it is energized. This label shall be affixed in a clearly visible location on the face of the control unit. If the industrial radiation machine is not visible from the control unit, the industrial radiation machine shall have a visible indication that it is energized.

(f) **Radiation Source Housing**. Each radiation source housing shall be equipped with an interlock that shuts off the tube if it is removed from the radiation source housing or if the housing is disassembled.

E.3.4 **Additional Requirements – Category A Industrial Radiation Machines.**

(a) **Safety Device.** A safety device shall be provided on all open-beam configurations which prevents the entry of any portion of an individual's body into the primary X-ray beam path or which causes the beam to be shut off upon entry into its path shall be provided on all open-beam configurations.

(1) A registrant may apply to the Agency for an exemption from the requirement of a safety device. Such application shall include:

(i) A description of the various safety devices that have been evaluated,

(ii) The reason each of these devices cannot be used, and

(iii) A description of the alternative methods that will be employed to minimize the possibility of an accidental exposure, including procedures to assure that operators and others in the area will be informed of the absence of safety devices.

(b) **Warning Devices. O**pen-beam configurations shall be provided with a visible indication of:

(1) X-ray tube status (**ON-OFF**) located near the radiation source housing, if the primary beam is controlled in this manner; and/or

(2) Shutter status (**OPEN-CLOSED**) located near each port on the radiation source housing, if the primary beam is controlled in this manner.

(c) **Shutters.** On open-beam configurations each port on the radiation source housing shall be equipped with a shutter that cannot be opened unless a collimator or a coupling has been connected to the port.

(d) **Surveys.**

(1) Radiation surveys, as required by §A.3.2 of these Regulations, of industrial radiation machines sufficient to show compliance with §E.3.3(a) of these regulations shall be performed:

(i) Upon installation of the equipment, and at least once every twelve (12) months thereafter;

(ii) Following any change in the initial arrangement, number, or type of local components in the system;

(iii) Following any maintenance requiring the disassembly or removal of a local component in the system;

(iv) During the performance of maintenance and alignment procedures if the procedures require the presence of a primary X-ray beam when any local component in the system is disassembled or removed; and

(v) Any time a visual inspection of the local components in the system reveals an abnormal condition.

(vi) Whenever personnel monitoring devices show a significant increase over the previous monitoring period or the readings are approaching the radiation dose limits.

(2) Radiation survey measurements shall not be required if a registrant can demonstrate, to the satisfaction of the Agency, compliance with §E.3.3(a) of these regulations in some other manner.

(e) **Generator Cabinet.** Each X-ray generator shall be supplied with a protective cabinet which limits leakage radiation measured at a distance of five (5) cm from its surface such that it is not capable of producing a dose in excess of 0.5 mrem (5 μSv) in any one (1) hour.

E.3.5 **Additional Requirements – Category B Industrial Radiation Machines.**

(a) All Category B industrial radiation machines shall be evaluated in accordance with the following requirements:

(1) The registrant shall perform an evaluation of the radiation dose limits to determine compliance with §§A.2.11(a), (b) and (c) of these Regulations at intervals not to exceed twelve (12) months. The registrant shall ensure that radiation emitted five (5) centimeters from the external surface of the cabinet x-ray system does not exceed 0.5 millirem (5.0 μSv) in any one (1) hour;

(2) Tests for proper operation of interlocks shall be conducted and recorded at intervals not to exceed twelve (12) months;

(3) Records that demonstrate compliance with §E.3.5(a) of these Regulations shall be maintained by the registrant for ten (10) years for inspection by the Agency.

(b) **Certified and Certifiable Cabinet X-ray Systems**. Certified and certifiable cabinet x-ray systems, including those designed to allow admittance of individuals shall also be maintained in compliance with 21 CFR 1020.40, and no modification shall be made to the system unless prior Agency approval has been granted.

E.3.6 **Operating Requirements.**

(a) **Procedures.** Operating and safety procedures shall be written and made available to all industrial radiation machine operators. No individual shall be permitted to operate an industrial radiation machine in any manner other than that specified in the procedures unless such individual has obtained written approval of the radiation safety officer.

(b) **Bypassing.** No individual shall bypass a safety device or interlock unless such individual has obtained the written approval of the radiation safety officer. Such approval shall be for a specified period of time. When a safety device or interlock has been bypassed, a readily discernible sign bearing the words **"SAFETY DEVICE NOT WORKING"**, or words having a similar intent, shall be placed on the radiation source housing.

(c) **Repair or Modification of Industrial Radiation Machines.** Except as specified in §E.3.6(b), no operation involving removal of covers, shielding materials or tube housing or modifications to shutters, collimators, or beam stops shall be performed without ascertaining that the tube is off and will remain off until safe conditions have been restored. The main switch, rather than interlocks, shall be used for routine shutdown in preparation for repairs.

E.3.7 **Personnel Requirements.**

(a) **Instruction.** No individual shall be permitted to operate or maintain an industrial radiation machine unless the individual has received instruction in and demonstrated competence in the following:

(1) Identification of radiation hazards associated with the use of the industrial radiation machine;

(2) Radiation warning and safety devices incorporated into the industrial radiation machine, or the reasons they have not been installed on certain pieces of equipment and the extra precautions required in such cases;

(3) Operating and safety procedures for the industrial radiation machine; and

(4) Proper procedures for reporting an actual or suspected exposure in excess of the limits specified in §A.2.11 of these Regulations.

(b) **Instructions for Bomb Detection Radiation Machines**. All personnel operating bomb detection radiation machines shall be trained in the set-up and operation of the radiation machine and in establishing a restricted area.

(c) **Individual Monitoring.** In addition to the requirements of §A.3.3(a)(1), finger dosimetric devices shall be provided to and shall be used by:

(1) Industrial radiation machine workers using systems having an open-beam configuration and not equipped with a safety device; and

(2) Personnel maintaining industrial radiation machines if the maintenance procedures require the presence of a primary X-ray beam when any local component in the X-ray system is disassembled or removed.

(d) Reported dose values shall not be used for the purpose of determining compliance with §A.2.3 of these

Regulations unless evaluated by an individual registered with the Agency to provide General Radiation Physics Services.

(e) **Records and Documentation**. Records that demonstrate compliance with §§E.3.7(a)-(c) of these Regulations shall be maintained by the registrant for ten (10) years for inspection by the Agency. In addition to complying with the requirements of §§E.3.7(a)-(c), records of individual monitoring results shall be maintained by the registrant in accordance with §A.5.7 of these Regulations.

E.4 WIRELINE SERVICE OPERATIONS AND SUBSURFACE TRACER STUDIES

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E.3.4 **Personnel Requirements.**

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(b) **Personnel Monitoring.** Finger or wrist dosimetric devices shall be provided to and shall be used by:

(1) Analytical and research and development X-ray equipment workers using systems having an open-beam configuration and not equipped with a safety device; and

(2) Personnel maintaining analytical or research and development X-ray equipment if the maintenance procedures require the presence of a primary X-ray beam when any local component in the analytical or research and development X-ray system is disassembled or removed.

Reported dose values shall not be used for the purpose of determining compliance with Section A.2.3 of these regulations unless evaluated by an individual registered with the Agency to provide ~~Health~~ General Radiation Physics Services.

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E.4.7 **Leak Testing of Sealed Sources.**

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(b) **Method of Testing.** The wipe of a sealed source shall be performed using a leak test kit or method approved by the Agency, the U.S. Nuclear Regulatory Commission~~,~~ or another Agreement State~~, or a Licensing State~~. The wipe sample shall be taken from the nearest accessible point to the sealed source where contamination might accumulate. The wipe sample shall be analyzed for radioactive contamination. The analysis shall be capable of detecting the presence of 0.005 microcurie (185 Bq) of radioactive material on the test sample and shall be performed by a person approved by the Agency, the U.S. Nuclear Regulatory Commission~~,~~ or another Agreement State~~, or a Licensing State~~ to perform the analysis.

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E.4.12 **Inspection and Maintenance.**

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(c) The repair, opening, or modification of any sealed source shall be performed only by persons specifically authorized to do so by the Agency, the U.S. Nuclear Regulatory Commission~~,~~ or another Agreement State~~, or a Licensing State~~.

(d) If a sealed source is stuck in the source holder, the licensee shall not perform any operation, such as drilling, cutting or chiseling, on the source holder unless the licensee is specifically approved by the Agency, the U.S. Nuclear Regulatory Commission~~,~~ or another Agreement State~~, or a Licensing State~~ to perform this operation.

E.4.13 **Training Requirements.**

(a) No licensee or registrant shall permit any individual to act as a logging supervisor as defined in these regulations until such individual has:

(1) received, in a course recognized by the Agency, the U.S. Nuclear Regulatory Commission~~,~~ or another Agreement State, ~~or a Licensing State,~~ instruction in the subjects outlined in Appendix B of this part and demonstrated an understanding thereof;

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PART F

DIAGNOSTIC X-RAYS AND ASSOCIATED IMAGING SYSTEMS IN THE HEALING ARTS

F.1 SCOPE

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F.1.3 The use of diagnostic X-ray equipment and associated imaging systems in the practice of veterinary medicine shall be by or under the supervision of an individual authorized by and licensed in accordance with ~~State statutes~~ RIGL Chapter 5-25 to practice ~~engage in~~ veterinary medicine.

F.2 GENERAL AND ADMINISTRATIVE REQUIREMENTS

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F.2.3 (a) Individuals who will be operating the X-ray systems for healing arts use shall possess a current license in accordance with the *Rules and Regulations for the Licensure of Radiographers, Nuclear Medicine Technologists, ~~and~~ Radiation Therapists and Radiologist Assistants* [*R5-68.1-RAD*] of the Rhode Island Department of Health, unless the individual is specifically exempted from licensure by said regulations. Individuals who will be operating the X-ray systems and who are not subject to licensure under R5-68.1-RAD shall be adequately instructed in the safe operating procedures and be competent in the safe use of the equipment. As a minimum, such instruction shall consist of subjects outlined in Appendix B ~~of this part~~ to Part F of these Regulations.

(b) The names and qualifications of all personnel operating X-ray equipment for healing arts use must be kept on file for Agency inspection at each facility location.

(c) Effective 1 July 2014, all individuals operating fluoroscopic X-ray systems shall have completed at least the following training before using fluoroscopy independently:

(1) Biological effects of X-ray;

(2) Principles of radiation protection;

(3) Factors affecting fluoroscopic outputs;

(4) Dose reduction techniques for fluoroscopic X-ray systems;

(5) Principles and operation of the specific fluoroscopic X-ray system(s) to be used;

(6) Fluoroscopic and fluorographic outputs of each mode of operation on the system(s) to be used clinically; and

(7) Applicable requirements of these Regulations.

(d) Effective 1 July 2014, the registrant shall either provide in-service training for all operators of

fluoroscopic x-ray systems used for high dose, high risk procedures, as defined in F.4.15 of these Regulations, at intervals not to exceed twenty-four (24) months or require evidence of continuing medical education, in fluoroscopic radiation safety and patient dose management at intervals not to exceed twenty-four (24) months.

(e) Documentation pertaining to the requirements of F.2.3(c) and (d) of these Regulations shall be maintained for review for three (3) years.

F.2.4 ~~A chart~~ Written technique information shall be provided in the vicinity of the diagnostic X-ray system's control panel, which specifies, for all examinations performed with that system, the following information:

(a) Patient's body part and anatomical size, or body part thickness, or age (for pediatrics), versus technique factors to be utilized;

(b) Equivalent manual technique information if AEC is not available; ~~Type and size of the film or film-screen combination to be used~~;

(c) Type and ~~focal distance of the grid~~ size of the image receptor combination to be used, if any;

(d) Source to image receptor distance to be used (except for dental intraoral radiography, which shall list cone length to be used);

(e) Type and location of placement of patient shielding (e.g., gonad, thyroid, lap apron, etc.); and

(f) For mammography, indication of kVp/target/filter combination and, if phototimed setting is used, the density setting.

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F.2.6 Except for patients who cannot be moved out of the room, only the staff, ancillary personnel or other persons required for the medical procedure or training shall be in the room during the radiographic exposure. Other than the patient being examined:

(a) All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by not less than 0.5 millimeter lead equivalent material.

(b) The X-ray operator, other staff, ancillary personnel and other persons required for the medical procedure shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent material.

(c) Human patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of not less than 0.25 millimeter lead equivalent or shall be so positioned that the nearest portion of the body is at least two (2) meters from both the tube head and the nearest edge of the image receptor.

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F.2.9 **When a Patient or ~~Film~~ Image Receptor Must be Provided with Auxiliary Support During a Radiation Exposure:**

(a) Mechanical holding devices shall be used when the technique permits. The written safety procedures, required by F.2.5, shall list individual projections where holding devices cannot be utilized;

(b) Written safety procedures, as required by F.2.5, shall indicate the requirements for selecting a holder and the procedure the holder shall follow;

(c) The human holder shall be instructed in personal radiation safety and protected as required by F.2.6;

(d) No individual shall be used routinely to hold ~~film~~ image receptor or patients;

(e) In those cases where the patient must hold the ~~film~~ image receptor, except during dental examinations covered in Subpart F.6, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 millimeter lead equivalent material; and

(f) Each facility shall have protective aprons and gloves available in sufficient numbers to provide protection ~~to~~ for all personnel who are involved with X-ray operations and who are otherwise not shielded.

(g) A record shall be made of the examination and shall include the name of the human holder; date of the examination, number of exposures and technique factors utilized for the exposure(s).

F.2.10 Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized.

(a) The ~~speed of the screen and film combinations used shall be the~~ fastest imaging system ~~speed~~ consistent with the diagnostic objective of the examinations shall be used. Film cassettes without intensifying screens shall not be used for any diagnostic radiological imaging, with the exception of veterinary radiography and standard film packets for intraoral use in dental radiography.

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(e) **X-ray Film ~~Developing Requirements~~ Processing Facilities and Practices.** ~~Compliance with this paragraph is required of all healing arts registrants and is designed to ensure that the patient and operator exposure is minimized and to produce optimum image quality and diagnostic information~~ Each installation using a radiographic X-ray system and using analog image receptors (e.g., radiographic film) shall have available suitable equipment for handling and processing radiographic film in accordance with the following provisions:

(1) **Manual Processing of Films:**

(i) Processing of film: ~~All films shall be processed to achieve optimum performance. This criterion shall be adjudged to have been met if the manufacturer's published minimum recommendations for time and temperature are followed~~ The temperature of solutions in the tanks shall be maintained within the range of 60° F to 80° F (16° C to 27° C). Film shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer.

(ii) Devices shall be ~~available~~ utilized which will:

(a) ~~Give~~ Indicate the actual temperature of the developer; and

(b) Give an audible or visible signal indicating the termination of a preset time.

(iii) ~~Chemical film processing control~~ Processing tanks shall be constructed of mechanically rigid, corrosion resistant material.

~~(a) Chemicals shall be mixed in accordance with the chemical manufacturer's recommendations.~~

~~(b) Developer replenisher shall be periodically added to the developer tank based on the recommendations of the chemical or film manufacturer. Solution may be removed from the tank to permit the addition of an adequate volume of replenisher.~~

~~(c) All processing chemicals shall be completely replaced at least every two months.~~

(2) **Automatic Processors and Other Closed Processing Systems.**

(i) Films shall be processed in accordance with the time temperature relationships recommended by the film manufacturer ~~commensurate with the automatic processor and~~

~~chemistry in use~~; and

(ii) ~~The specific developer temperature and immersion time shall be posted on the automatic processor. For automatic processors capable of two or more pre-selectable settings, the posting shall include both a description of each processor cycle setting (e.g. standard, extended, rapid or cycle in seconds) and the specific developer temperature and immersion time associated with that processor cycle setting~~. Processing deviations from the requirements of F.2.10(e)(2)(i) shall be documented by the registrant in such manner that the requirements are shown to be met or exceeded (e.g., extended processing, and special rapid chemistry).

(f) **[RESERVED]**

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(i) The tube housing and the position indicating device (PID) for a permanently mounted intraoral dental system shall not be hand-held during an exposure. Appendix D specifies requirements for the use of intraoral dental radiographic units designed to be hand-held during patient examination.

(j) Dental fluoroscopy without image intensification shall not be used.

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F.2.14 **X-Ray Utilization Log.**

(a) Except for veterinary facilities, each facility shall maintain a record containing the patient's name, the type of examinations, and the dates the examinations were performed. The record shall also include the following information:

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(4) When applicable, the ~~cumulative fluoro on-time~~ fluoro recordkeeping requirements of F.4.3(e).

(5) When applicable, the X-ray system used.

(6) When the patient or ~~film~~ image receptor must be provided with human auxiliary support, the name of the human holder.

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F.2.15 **Report and Notification of a Dose to an Embryo/Fetus.**

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(c) The registrant shall submit a written report to the Agency within fifteen (15) days after discovery of a dose to the embryo/fetus that requires a report in F.2.15(a).

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(d) The registrant shall provide notification of the event to the referring physician and also notify the pregnant individual, no later than twenty-four (24) hours after discovery of an event that would require reporting under F.2.15(a), unless the referring physician personally informs the registrant either that he or she will inform the pregnant individual or that, based on medical judgment, telling the pregnant individual would be harmful. The registrant is not required to notify the pregnant individual without first consulting with the referring physician. If the referring physician or pregnant individual cannot be reached within 24 hours, the registrant shall make the appropriate notifications as soon as possible thereafter. The registrant may not delay any appropriate medical care for the embryo/fetus, including any necessary remedial care as a result of the

event, because of any delay in notification. To meet the requirements of this paragraph, the notification may be made to the pregnant individual's responsible relative or guardian instead of the pregnant individual. If a verbal notification is made, the registrant shall inform the pregnant individual, or the pregnant individual's 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.

(e) A registrant shall:

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(2) Provide a copy of the annotated report to the referring physician, if other than the registrant, no later than fifteen (15) days after the discovery of the event.

F.3 GENERAL REQUIREMENTS FOR ALL DIAGNOSTIC X-RAY SYSTEMS

F.3.1 In addition to other requirement of ~~this~~ Part F, all diagnostic X-ray systems shall meet the requirements of ~~this~~ Subpart F.3.

F.3.2 **~~Certified Systems and Components~~ Maintaining Compliance.** Diagnostic X-ray systems and their associated components used on humans and certified pursuant to the Federal X-ray Equipment Performance Standard (21 CFR Part 1020) shall be maintained in compliance with applicable requirements of that standard.

F.3.3 **Warning Label.** The control panel containing the main power switch shall bear the warning statement, legible and accessible to view: **"WARNING: This X-ray unit may be dangerous to patient and operator unless safe exposure factors, ~~and~~ operating instructions and maintenance schedules are observed"**.

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F.3.5 **Leakage Radiation from the Diagnostic Source Assembly.** The leakage radiation from the diagnostic source assembly measured at a distance of one (1) meter in any direction from the source shall not exceed ~~25.8 µC/kg~~ 0.88 milligray (mGy) air kerma [100 milliroentgens (mR) exposure] in one (1) hour when the X-ray tube is operated at its leakage technique factors. If the maximum rated peak tube potential of the tube housing assembly is greater than the maximum rated peak tube potential for the diagnostic source assembly, positive means shall be provided to limit the maximum X-ray tube potential to that of the diagnostic source assembly. Compliance shall be determined by measurements averaged over an area of ~~100~~ one-hundred square centimeters (100 cm^2) with no linear dimension greater than ~~10~~ twenty (20) centimeters.

F.3.6 **Radiation from Components Other Than the Diagnostic Source Assembly.** The radiation emitted by a component other than the diagnostic source assembly shall not exceed ~~0.5 µC/kg~~ an air kerma of eighteen (18) µgray (two (2) milliroentgens exposure) in one (1) hour at five (5) centimeters from any accessible surface of the component when it is operated in an assembled X-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of ~~100~~ one-hundred square centimeters (100 cm^2) with no linear dimension greater than twenty (20) centimeters.

F.3.7 **Beam Quality.**

(a) **Half-Value Layer (HVL)**

(1) The ~~half-value layer~~ HVL of the useful beam for a given X-ray tube potential shall not be less than the values shown in Table 1 of F.3.7 under the heading "Specified Dental Systems," for any dental X-ray system designed for use with intraoral image receptors and manufactured after 1 December 1980;

under the heading," Other X-Ray Systems[2]" for any dental X-ray system designed for use with intraoral image receptors and manufactured before or on 1 December 1980, and all other X-ray systems subject to this section and manufactured before 10 June 2006; and under the heading, "Other X-Ray Systems[3]" for all X-ray systems, except dental X-ray systems designed for use with intraoral image receptors, subject to this section and manufactured on or after 10 June 2006. If it is necessary to determine such half-value layer at an X-ray tube potential which is not listed in Table 1, linear interpolation or extrapolation may be made. Positive means shall be provided to ensure that at least the minimum filtration needed to achieve beam quality requirements is in the useful beam during each exposure. In the case of a system, which is to be operated with more than one thickness of filtration, this requirement can be met by a filter interlocked with the kilovoltage selector which will prevent X-ray emissions if the minimum required filtration is not in place.

(2) Optional Filtration. Fluoroscopic systems manufactured on or after 10 June 2006, incorporating an X-ray tube(s) with a continuous output of one (1) kilowatt or more and an anode heat storage capacity of one-million (1,000,000) heat units or more shall provide the option of adding X-ray filtration to the diagnostic source assembly in addition to the amount needed to meet the half-value layer provisions of F.3.7(a)(1). The selection of this additional X-ray filtration shall be either at the option of the user or automatic as part of the selected mode of operation. A means of indicating which combination of additional filtration is in the X-ray beam shall be provided.

(b) Beryllium window tubes shall have a minimum of 0.5 millimeter aluminum equivalent filtration permanently installed in the useful beam.

(c) **Measuring Compliance**. For capacitor energy storage equipment, compliance ~~with the half-value layer requirement~~ shall be determined with the maximum selectable quantity of charge per ~~system fully charged and an mAs setting as close as practical to 10 mAs for each~~ exposure.

~~**TABLE I**~~

~~**Design operating range (Kilovolts peak)**~~	~~**Measured potential (Kilovolts peak)**~~	~~**HVL (Millimeters of aluminum) Dental Intra-Oral Manufactured Before Aug. 1, 1974 and On or After Dec. 1, 1980**~~	~~**All Other Diagnostic X-Ray Systems**~~
~~Below 51~~	~~30~~	~~N/A~~	~~0.3~~
	~~40~~	~~N/A~~	~~0.4~~
	~~50~~	~~1.5~~	~~0.5~~
~~51 to 70~~	~~51~~	~~1.5~~	~~1.2~~
	~~60~~	~~1.5~~	~~1.3~~
	~~70~~	~~1.5~~	~~1.5~~
~~Above 70~~	~~71~~	~~2.1~~	~~2.1~~
	~~80~~	~~2.3~~	~~2.3~~
	~~90~~	~~2.5~~	~~2.5~~
	~~100~~	~~2.7~~	~~2.7~~
	~~110~~	~~3.0~~	~~3.0~~
	~~120~~	~~3.2~~	~~3.2~~
	~~130~~	~~3.5~~	~~3.5~~

~~140~~	~~3.8~~	~~3.8~~
~~150~~	~~4.1~~	~~4.1~~

~~The half-value layer requirement will be considered to have been met if it can be demonstrated that the aluminum equivalent of the total filtration in the primary beam is not less than that shown in Table II.~~

~~**TABLE II**~~

~~**Filtration Required vs. Operating Voltage**~~

~~Operating Voltage (kVp)~~	~~Total Filtration (inherent plus added) (millimeters aluminum equivalent)~~
~~Below 50~~	~~0.5 millimeters~~
~~50 - 70~~	~~1.5 millimeters~~
~~Above 70~~	~~2.5 millimeters~~

TABLE 1
X-Ray Tube Voltage (kilovolt peak)

Design Operating Range	Measured Operating Potential	Minimum HVL (mm in Aluminum)		
		Specified Dental Systems[1]	Other X-Ray Systems[2]	Other X-Ray Systems[3]
Below 51	30	1.5	0.3	0.3
	40	1.5	0.4	0.4
	50	1.5	0.5	0.5
51 to 70	51	1.5	1.2	1.3
	60	1.5	1.3	1.5
	70	1.5	1.5	1.8
Above 70	71	2.1	2.1	2.5
	80	2.3	2.3	2.9
	90	2.5	2.5	3.2
	100	2.7	2.7	3.6
	110	3.0	3.0	3.9
	120	3.2	3.2	4.3
	130	3.5	3.5	4.7
	140	3.8	3.8	5.0
	150	4.1	4.1	5.4

[1] Dental X-ray systems designed for use with intraoral image receptors and manufactured after 1 December 1980

[2] Dental X-ray systems designed for use with intraoral image receptors and manufactured before or on 1 December 1980, and all other X-ray systems subject to this section and manufactured before 10 June 2006

[3] All X-ray systems, except dental X-ray systems designed for use with intraoral image receptors, subject to this section and manufactured on or after 10 June 2006.

~~(d) The required minimal half-value layer of the useful beam shall include the filtration contributed by all materials which are permanently between the source and the patient.~~

(d) **Aluminum Equivalent of Material Between Patient and Image Receptor.** Except when used in a CT X-ray system, the aluminum equivalent of each of the items listed in Table 2 of F.3.7, which are used between the patient and the image receptor, shall not exceed the indicated limits. Compliance shall be determined by X-ray measurements made at a potential of one-hundred (100) kilovolts peak and with an X-ray beam that has an HVL specified in Table 1 of F.3.7 for the potential. This requirement applies to front panel(s) of cassette holders and film changers provided by the manufacturer for patient support or for prevention of foreign object intrusions. It does not apply to screens and their associated mechanical support panels or grids.

TABLE 2

ITEM	Maximum Aluminum Equivalent (millimeters)
1. Front panel(s) of cassette holders (total of all)	1.2
2. Film panel(s) of film changer (total of all)	1.2
3. Cradle	2.3
4. Tabletop, stationary, without articulated joints	1.2
5. Tabletop, movable, without articulated joint(s) (including stationary subtop)	1.7
6. Tabletop, with radiolucent panel having one articulated joint	1.7
7. Tabletop, with radiolucent panel having two or more articulated joints	2.3
8. Tabletop, cantilevered	2.3
9. Tabletop, radiation therapy simulator	5.0

~~(e) For X-ray system which have variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filter(s) and shall prevent an exposure unless the minimum amount of filtration necessary to produce the HVL required by F.3.7(a) is in the useful beam for the given kVp which has been selected.~~

(e) **Modification of Certified Diagnostic X-ray Components and Systems.**

(1) Diagnostic X-ray components and systems certified in accordance with 21 CFR Part 1020 shall not be modified such that the component or system fails to comply with any applicable provision of Part F of these Regulations unless a variance in accordance with 21 CFR 1010.4 or an exemption under §534(a)(5) or §538(b) of the Federal Food, Drug, and Cosmetic Act has been granted..

(2) The owner of a diagnostic X-ray system who uses the system in a professional or commercial capacity may modify the system provided the modification does not result in the failure of the system or component to comply with the applicable requirements of Part F of these Regulations. The owner who causes such modification need not submit the reports required by these

Regulations, provided the owner records the date and the details of the modification in the system records and maintains this information, and provided the modification of the X-ray system does not result in a failure to comply with these Regulations.

(f) **kVp Limitations**. Dental X-ray machines with a nominal fixed kVp of less than fifty (50) kVp shall not be used to make diagnostic dental radiographs of humans.

F.3.8 **Multiple Tubes.** Where two (2) or more radiographic tubes are controlled by one (1) exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the X-ray control panel and at or near the tube housing assembly which has been selected.

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F.3.10 **Technique Indicators.**

(a) **X-ray Equipment Capable of Displaying Technique Factors**. The technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic EXPOSURE controls are used, the technique factors which are set prior to the exposure shall be indicated.

(b) ~~This~~ The requirement of F.3.10(a) may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator's position except in the case of spot films ~~made by the fluoroscopist~~.

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F.3.13 **Use of Calibrated Dosimetry System.** The measurement of the radiation output of an X-ray system shall be performed with a calibrated dosimetry system. The calibration of such a system shall be traceable to a national standard. The dosimetry system shall have been calibrated within the preceding two (2) years.

F.3.14 **Reports and Notifications of Radiation Medical Events.**

(a) Other than events that result from intervention by a patient or human research subject, a registrant shall report any event in which the administration of ionizing radiation from a diagnostic radiation machine:

(1) Results in a patient or human research subject receiving an unintended dose to the skin greater than two (2) Gy [two-hundred (200) rads] to the same area for a procedure or series; or

(2) Results in a patient or human research subject receiving an unintended dose greater than five-hundred (500) mGy [fifty (50) rads] to an organ/tissue; or

(3) Results in a patient or human research subject receiving an unintended dose greater than fifty (50) mSv [five (5) rem] total effective dose; or

(4) Involves the wrong patient or wrong site for the entire diagnostic exam (procedure or service)[29] and exceeds five-hundred (500) mGy [fifty (50) rads] to an organ/tissue or fifty (50) mSv [five (5) rem] total effective dose; or

(5) Involves equipment failure, personnel error, accident, mishap or other unusual occurrence with the administration of ionizing radiation that exceeds fifty (50) mGy [five (5) rads] total effective dose.

[29] Any wrong patient or wrong site imaged regardless of dose received should be reported, documented and addressed internally within the facility.

(b) The registrant shall notify the Agency by telephone[30] no later than the next calendar day after discovery of the radiation medical event.

(c) The registrant shall submit a written report to the Agency within fifteen (15) days after discovery of the radiation medical event. The written report shall include:

(1) The registrant's name;

(2) Date of event and date discovered;

(3) The total estimated dose received;

(4) The imaging procedure(s) performed;

(5) The type of equipment in use (e.g., CT, fluoroscopy, radiographic, other);

(6) The manufacturer and model of the unit used:

(7) Why the event occurred;

(8) How the event was discovered;

(9) The effect, if any, on the individuals(s) who is the subject of the radiation medical event;

(10) Actions, if any, that have been taken, or are planned, to prevent recurrence;

(11) Certification that the registrant notified the individual (or the individual's responsible relative or guardian), and if not, why not; and

(12) If there was notification, what information was provided to the individual.

(d) The report shall not contain the individual's name or any other information that could lead to the identification of the individual. To meet the requirements of F.3.14, the notification of the individual who is the subject of the radiation medical event may be made instead to that individual's responsible relative or guardian, when appropriate.

(e) (1) The registrant shall provide notification of the event to the referring physician and also notify the individual who is the subject of the radiation medical event no later than twenty-four (24) hours after its discovery, unless the referring physician personally informs the registrant either that he or she 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 twenty-four (24) hours, the registrant shall notify the individual as soon as possible thereafter. The registrant shall not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the radiation medical event, because of any delay in notification.

(2) To meet the requirements of F.3.14(a)(1), the notification of the individual who is the subject of the radiation medical event 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 either a copy of the report that was submitted to the Agency, or a written description of both the event and the consequences as they may effect the can be obtained from the registrant upon request. The registrant shall provide such a written description if requested.

(f) Aside from the notification requirement, nothing in F.3.14 affects any rights or duties of registrants

[30] During normal business hours, the Agency may be contacted at (401) 222-2566. At other times, this number will allow you to leave a message on the answering machine. In case of an emergency when it is necessary to immediately contact the Agency, utilize the RI Department of Health 24 hour number [(401) 272-5952] and indicate the nature of your emergency. FAX communication may be sent 24 hours a day to (401) 222-5901.

and physicians in relation to each other, to individuals affected by the radiation medical event, or to that individual's responsible relatives or guardians.

(g). The registrant shall retain a record of a radiation medical event in accordance with F.3.15. A copy of the record required shall be provided to the referring physician if other than the registrant within fifteen (15) days after discovery of the radiation medical event.

F.3.15 **Records of Radiation Medical Events.** A registrant shall retain a record of radiation medical events reported in accordance with F.3.14 for three (3) years. The record shall contain the following:

(a) The registrant's name and the names of the individuals involved (including allied health personnel, the individual who is the subject of the radiation medical event, and the individual's referring physician, if applicable);

(b) The social security number or other identification number, if one has been assigned, of the individual who is the subject of the radiation medical event;

(c) A brief description of the event; why it occurred; the effect, if any, on the individual;

(d) The actions, if any, taken or planned to prevent recurrence; and

(e) 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.

F.4 FLUOROSCOPIC ~~X-RAY SYSTEMS~~ EQUIPMENT

F.4.1 ~~The requirements of F.3.2 for Certified Systems and Components shall apply to certified fluoroscopic X-ray systems and components, including radiation therapy simulation systems. Other fluoroscopic X-ray systems shall meet the requirements of the remainder of this subpart~~. The provisions of Subpart F.4 apply to equipment for fluoroscopic imaging or for recording images from the fluoroscopic image receptor, except computed tomography X-ray systems manufactured on or after 29 November 1984.

F.4.2 ~~**Limitation of Useful Beam**~~ **Primary Protective Barrier.**

~~(a) The X-ray tube used for fluoroscopy shall not produce X-rays unless the primary protective barrier is in position to intercept the entire useful beam at all times, and~~

(a) **Limitation of Useful Beam**. The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID. The X-ray tube used for fluoroscopy shall not produce X-rays unless the barrier is in position to intercept the entire useful beam. The air kerma (exposure) rate due to transmission through the barrier with the attenuation block in the useful beam combined with radiation from the fluoroscopic imaging receptor shall not exceed 3.34×10^{-3} percent of the entrance air kerma (exposure) rate, at a distance of ten (10) cm from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor.

~~(b) The entire cross section of the useful beam shall be intercepted by the primary protective barrier of the fluoroscopic image assembly at any source-image receptor distance (SID).~~

(b) **Measuring Compliance**. The air kerma (exposure) rate shall be measured in accordance with F.4.6. The air kerma (exposure) rate due to transmission through the primary barrier combined with radiation from the fluoroscopic image receptor shall be determined by measurements averaged over an area of one-hundred square centimeters (100 cm^2) with no linear dimension greater than twenty (20) cm. If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned thirty (30) cm above the tabletop. If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can

be placed, provided that it shall not be closer than thirty (30) cm. Movable grids and compression devices shall be removed from the useful beam during the measurement. For all measurements, the attenuation block shall be positioned in the useful beam ten (10) cm from the point of measurement of entrance air kerma (exposure) rate and between this point and the input surface of the fluoroscopic imaging assembly.

~~F.4.3 **Prohibition on Use of Non-Image-Intensified Fluoroscopy.** The use of non-image-intensified fluoroscopy on humans is prohibited.~~

F.4.3 **Equipment Operation.**

(a) All imaging formed by the use of fluoroscopic x-ray systems shall be viewed, directly or indirectly, and interpreted by a licensed practitioner of the healing arts.

(b) The operation of mobile or portable fluoroscopic x-ray systems, for positioning purposes only, by radiologic technologists shall be performed under the direct supervision of a licensed practitioner of the healing arts who meets the requirements of F.2.3(c) of these Regulations.

(c) Radiologic technology students shall not be allowed to operate fluoroscopic x-ray systems unless in the physical presence of a licensed practitioner of the healing arts and a radiologic technologist, as specified in F.2.3(c) of these Regulations.

(d) Overhead fluoroscopy shall not be used as a positioning tool for general purpose radiographic examinations.

(e) Each registrant that uses fluoroscopic x-ray systems shall maintain a record of the cumulative fluoroscopic exposure time used and the number of images recorded from the fluoroscopic image receptor for each examination. This record shall include patient identification, type and date of examination, the fluoroscopic system used, and operator's name. The record shall be maintained for five (5) years.

~~F.4.4 **Image-Intensified Fluoroscopy and Spot Filming Requirements.**~~

~~(a) For image-intensified fluoroscopic equipment, neither the length nor the width of the X-ray field in the plane of the image receptor shall exceed the visible area of the image receptor by more than 3 percent of the SID. The sum of the excess length and the excess width shall be no greater than 4 percent of the SID. In addition:~~

~~(1) means shall be provided to permit further limitation of the field. Beam-limiting devices manufactured after 22 May 1979, and incorporated in equipment with a variable SID and/or a visible image receptor area of greater than 300 square centimeters, shall be provided with means for stepless adjustment of the X-ray field;~~

~~(2) all equipment with a fixed SID and a visible image receptor area of 300 square centimeters or less shall be provided with either stepless adjustment of the X-ray field or means to further limit the X-ray field size at the image receptor to 125 square centimeters or less. Stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum obtainable to a field size of 5 centimeters by 5 centimeters or less;~~

~~(3) for equipment manufactured after 25 February 1978, when the angle between the image receptor and the beam axis of the X-ray beam is variable, means shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor;~~

~~(4) compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor. For rectangular X-Ray fields used with circular image reception, the error in alignment shall be determined along the length and width dimensions of the X-ray field which pass through the center of the visible area of the image receptor; and~~

~~(5) for uncertified image-intensified fluoroscopic equipment with a spot film device, the X-ray beam with the shutters wide open (during either fluoroscopy itself or spot films) shall be no larger than the dimension of the largest spot film size for which the device is designed. Measurements shall be made at 30 centimeter table top to the film plane distance.~~

~~(b) Spot film devices which are certified components shall meet the following additional requirements:~~

~~(1) means shall be provided between the source and the patient for adjustment of the X-ray field size in the plane of the film to the size of that portion of the film which has been selected on the spot film selector. Such adjustment shall be automatically accomplished except when the X-ray field size in the plane of the film is smaller than that of the selected portion of the film. For spot film devices manufactured after 21 June 1979, if the X-ray field size is less than the size of the selected portion of the film, the means for adjustment of the field size shall be only at the operator's option;~~

~~(2) it shall be possible to adjust the X-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID shall be equal to, or less than, 5 centimeters by 5 centimeters;~~

~~(3) the center of the X-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within 2 percent of the SID; and~~

~~(4) on spot film devices manufactured after 25 February 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.~~

~~(c) For equipment manufactured on or after 29 November 1984, if a means exists to override any of the automatic X-ray field size adjustments required in Section F.4.4, that means:~~

~~(1) shall be designed for use only in the event of system failure;~~

~~(2) shall incorporate a signal visible at the fluoroscopist's position which will indicate whenever the automatic field size adjustment is overridden; and~~

~~(3) shall be clearly and durably labeled as follows:~~

~~**FOR X-RAY FIELD LIMITATION SYSTEM FAILURE**~~

F.4.4 **Field Limitation**.

(a) **Angulation.** For fluoroscopic equipment manufactured after 25 February 1978, when the angle between the image receptor and the beam axis of the X-ray beam is variable, means shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor. Compliance with F.4.4(d) and (e) shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

(b) **Further Means for Limitation**. Means shall be provided to permit further limitation of the X-ray field to sizes smaller than the limits of F.4.4(d) and (e). Beam-limiting devices manufactured after 22 May 1979, and incorporated in equipment with a variable SID and/or capability of a visible area of greater than three-hundred square cm (300 cm^2), shall be provided with means for stepless adjustment of the X-ray field. Equipment with a fixed SID and the capability of a visible area of no greater than three-hundred square cm (300 cm^2) shall be provided with either stepless adjustment of the X-ray field or with a means to further limit the X-ray field size at the plane of the image receptor to one-hundred twenty five square cm (125 cm^2) or less. Stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum obtainable to a field size containable in a square of five (5) cm by five (5) cm. This paragraph does not apply to non-image-intensified fluoroscopy.

(c) **Non-Image-Intensified Fluoroscopy**. The X-ray field produced by non-image-intensified fluoroscopic equipment shall not extend beyond the entire visible area of the image receptor. Means shall be provided for stepless adjustment of field size. The minimum field size, at the greatest SID, shall be containable in a square of five (5) cm by five (5) cm.

(d) **Fluoroscopy and Radiography Using the Fluoroscopic Imaging Assembly With Inherently Circular Image Receptors**.

(1) For fluoroscopic equipment manufactured before 10 June 2006, other than radiation therapy simulation systems, the following applies:

(i) Neither the length nor width of the X-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than three percent (3%) of the SID. The sum of the excess length and the excess width shall be no greater than four percent (4%) of the SID.

(ii) For rectangular X-ray fields used with circular image receptors, the error in alignment shall be determined along the length and width dimensions of the X-ray field which pass through the center of the visible area of the image receptor.

(2) For fluoroscopic equipment manufactured on or after 10 June 2006, other than radiation therapy simulation systems, the maximum area of the X-ray field in the plane of the image receptor shall conform with one of the following requirements:

(i) When any linear dimension of the visible area of the image receptor measured through the center of the visible area is less than or equal to thirty-four (34) cm in any direction, at least eighty percent (80%) of the area of the X-ray field overlaps the visible area of the image receptor, or

(ii) When any linear dimension of the visible area of the image receptor measured through the center of the visible area is greater than thirty-four (34) cm in any direction, the X-ray field measured along the direction of greatest misalignment with the visible area of the image receptor does not extend beyond the edge of the visible area of the image receptor by more than two (2) cm.

(e) **Fluoroscopy and Radiography Using Fluoroscopic Imaging Assembly With Inherently Rectangular Image Receptors**. For X-ray systems manufactured on or after 10 June 2006, the following applies:

(1) Neither the length nor width of the X-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than three percent (3%) of the SID. The sum of the excess length and the excess width shall be no greater than four percent (4%) of the SID.

(2) The error in alignment shall be determined along the length and width dimensions of the X-ray field which pass through the center of the visible area of the image receptor.

(f) **Override Capability**. If the fluoroscopic X-ray field size is adjusted automatically as the SID or image receptor size is changed, a capability may be provided for overriding the automatic adjustment in case of system failure. If it is so provided, a signal visible at the operator's position shall indicate whenever the automatic field adjustment is overridden. Each such system failure override switch shall be clearly labeled as follows:

FOR X-RAY FIELD LIMITATION SYSTEM FAILURE

F.4.5 **Activation of the ~~Fluoroscopic~~ Tube.** X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the ~~fluoroscopist~~ operator for the entire time of any

exposure. When recording serial fluoroscopic images from the fluoroscopic image receptor, the ~~fluoroscopist~~ operator shall be able to terminate the X-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

~~F.4.6 **EXPOSURE Rate Limits.** The entrance **EXPOSURE** rate allowable limits are as follows:~~

~~(a) For uncertified fluoroscopic equipment, the EXPOSURE rate at the point where the center of the useful beam enters the patient shall not exceed 10 roentgens (2.58 mC/kg) per minute, except during recording of fluoroscopic images, or when provided with an optional high level control.~~

~~(b) For uncertified fluoroscopic equipment, when provided with optional high level control, the equipment shall not be operable at any combination of tube potential and current which will result in an EXPOSURE rate in excess of 10 roentgens (2.58 mC/kg) per minute at the point where the center of the useful beam enters the patient unless the high level control is activated.~~

~~(1) Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator.~~

~~(2) A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.~~

~~(c) **Certified Fluoroscopic Equipment:**~~

~~(1) Fluoroscopic equipment manufactured before 19 May 1995 must meet the requirements of 21 CFR 1020, Section 1020.32, Paragraph (d).~~

~~(2) Fluoroscopic equipment manufactured on or after 19 May 1995 must meet the requirements of 21 CFR 1020, Section 1020.32, Paragraph (e).~~

~~(d) Compliance with the requirements of this section, for both certified and uncertified fluoroscopic equipment, shall be determined as follows:~~

~~(1) Movable grids and compression devices shall be removed from the useful beam during the measurement.~~

~~(2) If the source is below the table, **EXPOSURE** rate shall be measured 1 centimeter above the tabletop or cradle.~~

~~(3) If the source is above the table, the **EXPOSURE** rate shall be measured at 30 centimeters above the tabletop with the end of the beam limiting device or spacer positioned as closely as possible to the point of measurement.~~

~~(4) In a mobile C-arm type of fluoroscope, the **EXPOSURE** rate shall be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly.~~

~~(5) In a stationary C-arm type of fluoroscope where an integral patient support device (table) is provided, the entrance **EXPOSURE** rate shall be measured at 30 centimeters from the input surface of the fluoroscopic imaging assembly, with the source positioned at the minimum available SID, provided that the end of the beam limiting device or spacer is no closer than 30 centimeters from the input surface of the fluoroscopic imaging assembly.~~

~~(6) In a lateral type of fluoroscope, the entrance **EXPOSURE** rate shall be measured at a point 15 centimeters from the centerline of the X-ray table and in the direction of the X-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral X-ray source, with the end of the beam-limiting device or spacer no closer than 15 centimeters to the centerline of the X-ray table.~~

F.4.6 **Air Kerma (Exposure) Rates**. For fluoroscopic equipment, the following requirements apply:

(a) Fluoroscopic equipment manufactured before 19 May 1995.

(1) Equipment provided with automatic exposure rate control (AERC) shall not be operable at any combination of tube potential and current that will result in an air kerma (exposure) rate in excess of 88 mGy per minute (10 R/min exposure rate) at the measurement point specified in F.4.6(c), except as specified in F.4.6(a)(5).

(2) Equipment provided without AERC shall not be operable at any combination of tube potential and current that will result in an air kerma (exposure) rate in excess of 44 mGy per minute (5 R/min exposure rate) at the measurement point specified in F.4.6(c), except as specified in F.4.6(a)(5)..

(3) Equipment provided with both an AERC mode and a manual mode shall not be operable at any combination of tube potential and current that will result in an air kerma (exposure) rate in excess of 88 mGy per minute (10 R/min exposure rate) in either mode at the measurement point specified in F.4.6(c), except as specified in F.4.6(a)(5).

(4) Equipment may be modified in accordance with F.3.7(e)(1) to comply with F.4.6(b). When the equipment is modified, it shall bear a label indicating the date of the modification and the statement:

MODIFIED TO COMPLY WITH 21 CFR 1020.32(H)(2)

(5) Exceptions:

(i) During recording of fluoroscopic images, or

(ii) When a mode of operation has an optional high-level control, in which case that mode shall not be operable at any combination of tube potential and current that will result in an air kerma (exposure) rate in excess of the rates specified in F.4.6(a)(1), (2) and (3) at the measurement point specified in F.4.6(c), unless the high-level control is activated. Special means of activation of high-level controls shall be required. The high-level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the operator shall indicate that the high-level control is being employed.

(b) Fluoroscopic equipment manufactured on or after 19 May 1995.

(1) Shall be equipped with AERC if operable at any combination of tube potential and current that results in an air kerma (exposure) rate greater than 44 mGy per minute (5 R/min exposure rate) at the measurement point specified in F.4.6(c). Provision for manual selection of technique factors may be provided.

(2) Shall not be operable at any combination of tube potential and current that will result in an air kerma (exposure) rate in excess of 88 mGy per minute (10 R/min exposure rate) at the measurement point specified in F.4.6(c), except as specified in F.4.6(b)(3).

(3) Exceptions:

(i) For equipment manufactured prior to 10 June 2006, during the recording of images from a fluoroscopic image receptor using photographic film or a video camera when the X-ray source is operated in a pulsed mode.

(ii) For equipment manufactured on or after 10 June 2006, during the recording of images from the fluoroscopic image receptor for the purpose of providing the user with a recorded image(s) after termination of the exposure. Such recording does not include images resulting from a last-image-hold feature that are not recorded.

(iii) When a mode of operation has an optional high-level control and the control is activated, in which case the equipment shall not be operable at any combination of tube potential and

current that will result in an air kerma (exposure) rate in excess of 176 mGy per minute (20 R/min exposure rate) at the measurement point specified in F.4.6(c). Special means of activation of high-level controls shall be required. The high-level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the operator shall indicate that the high-level control is employed.

F.4.7 **~~Periodic~~ Measurement of Entrance ~~EXPOSURE~~ Air Kerma (Exposure) Rate.** ~~Periodic~~ Measurement of entrance ~~**EXPOSURE**~~ air kerma (exposure) rate shall be performed ~~by, or under the direction of, a person registered with the Agency to provide Diagnostic X-ray Physics Services. These measurements shall be performed~~ for both maximum and typical values and shall be made ~~at least annually~~ at intervals not to exceed twelve (12) months or after any maintenance of the system which might affect the ~~**EXPOSURE**~~ air kerma (exposure) rate. Results of these measurements shall be posted where any operator may have ready access to such results ~~while using the fluoroscope~~ during the fluoroscopic procedure and in the record required in F.2.13(e). Results of the measurements shall include the ~~roentgens~~ mGy per minute (R/min exposure rate), as well as the technique factors used to determine such results. The name of the ~~person, registered with the Agency to provide Diagnostic X-ray Physics Services,~~ Qualified Medical Physicist performing the measurements and the date the measurements were performed shall be included in the results.

(a) Conditions of ~~periodic~~ measurement of maximum ~~entrance **EXPOSURE**~~ air kerma (exposure) rate are as follows:

(1) The measurements shall be made under conditions that satisfy the requirements of F.4.6(a) & (b) ~~(c)~~;

(2) The kVp, mA and/or other selectable parameters shall be adjusted to those settings which give the maximum ~~entrance **EXPOSURE**~~ air kerma (exposure) rate; and

(3) ~~The~~ An X-ray system~~(s)~~ that incorporates automatic ~~**EXPOSURE**~~ exposure rate control (AERC) shall have sufficient material placed in the useful beam to produce the maximum output of that system ~~(in R/minute)~~.

(b) Conditions of ~~periodic~~ measurement of typical ~~entrance **EXPOSURE**~~ air kerma (exposure) rate are as follows:

(1) The measurements shall be made under conditions that satisfy the requirements of ~~F.4.6(c)(2)-(c)(6)~~ F.4.7(c) and are typical of clinical use of the X-ray system;

(2) The kVp shall be that typical of clinical use of the X-ray system;

(3) ~~The~~ An X-ray system~~(s)~~ that incorporates AERC ~~automatic **EXPOSURE** rate control~~ shall have sufficient material placed in the useful beam to produce operating parameters typical of the use of the X-ray system; and

(4) An X-ray system~~(s)~~ that does not incorporate an AERC ~~automatic **EXPOSURE** rate control~~ shall utilize a milliamperage typical of the clinical use of the X-ray system.[31]

~~(c) Entrance **EXPOSURE** rate measurements shall be performed with a calibrated dosimetry system. The calibration of such a system shall be traceable to a national standard either directly or indirectly through intercomparison with a dosimetry system whose calibration is directly traceable to a national standard. The dosimetry system shall have been calibrated or intercompared within the preceding 2 years, or after servicing which may have affected calibration. Such intercomparisons shall be performed under the supervision of a person registered with the Agency to provide Diagnostic X-ray Physics Services.~~

[31] Material should be placed in the useful beam when conducting these periodic measurements to protect the imaging system.

(c) **Measuring Compliance.** Compliance with this subsection shall be determined as follows:

(1) If the source is below the X-ray table, the air kerma (exposure) rate shall be measured at one (1) cm above the tabletop or cradle.

(2) If the source is above the X-ray table, the air kerma (exposure) rate shall be measured at thirty (30) cm above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.

(3) In a C-arm type of fluoroscope, the air kerma (exposure) rate shall be measured at thirty (30) cm from the input surface of the fluoroscopic imaging assembly, with the source positioned at any available SID, provided that the end of the beam-limiting device or spacer is no closer than thirty (30) cm from the input surface of the fluoroscopic imaging assembly.

(4) In a C-arm type of fluoroscope having an SID less than forty-five (45) cm, the air kerma (exposure) rate shall be measured at the minimum SSD.

(5) In a lateral type of fluoroscope, the air kerma (exposure) rate shall be measured at a point fifteen (15) cm from the centerline of the X-ray table and in the direction of the X-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral X-ray source, with the end of the beam-limiting device or spacer no closer than fifteen (15) cm to the centerline of the X-ray table.

F.4.8 ~~**[DELETED]** **Barrier Transmitted Radiation Rate Limits.** The **EXPOSURE** rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with the radiation from the image intensifier, if provided, shall not exceed 2 milliroentgens (0.5 μC/kg) per hour at 10 centimeters from any accessable surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each Roentgen (mC/kg) per minute of entrance exposure rate. The **EXPOSURE** rate due to transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters. If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop. If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters. Movable grids and compression devices shall be removed from the useful beam during the measurement. If the entrance **EXPOSURE** rate and the barrier transmission are measured at the same time during one activation of the fluoroscopic tube, the attenuation block shall be positioned in the useful beam at least 10 centimeters from the point of measurement of entrance **EXPOSURE** rate~~.

F.4.9 **[RESERVED]**

F.4.10 **Indication of Potential and Current.** During fluoroscopy and cinefluorography, the ~~kilovoltage (kV) and the milliamperage (mA)~~ X-ray tube potential and current shall be continuously indicated. Deviation of X-ray tube potential and current from the indicated value shall not exceed the maximum deviation as stated by the manufacturer.

F.4.11 **Source-Skin Distance.** ~~The source to skin distance shall not be less than:~~

~~(a) 38 centimeters on stationary fluoroscopes manufactured on or after 1 August 1974;~~

(a) Means shall be provided to limit the source-skin distance to not less than thirty-eight (38) cm on stationary fluoroscopes and to not less than thirty (30) cm on mobile and portable fluoroscopes. In addition, for fluoroscopes intended for specific surgical application that would be prohibited at the source-skin distances

specified in this paragraph, provisions may be made for operating at shorter source-skin distances but in no case less than twenty (20) cm.

~~(b) 35.5 centimeters on stationary fluoroscopes manufactured prior to 1 August 1974;~~

(b) For stationary, mobile, or portable C-arm fluoroscopic systems manufactured on or after 10 June 2006, having a maximum source-image receptor distance of less than forty-five (45) cm, means shall be provided to limit the source-skin distance to not less than nineteen (19) cm. Such systems shall be labeled for extremity use only. In addition, for those systems intended for specific surgical application that would be prohibited at the source-skin distance specified in this paragraph, provisions may be made for operation at shorter source-skin distances but in no case less than ten (10) cm.

~~(c) 30 centimeters on all mobile fluoroscopes; and~~

~~(d) 20 centimeters for image intensified fluoroscopes used for specific surgical application. Written safety procedures must provide precautionary measures to be adhered to during the use of this type of fluoroscope.~~

~~F.4.12 **Fluoroscopic Timer.** Means shall be provided to preset the cumulative on-time of the fluoroscopic tube. The maximum cumulative time of the timing device shall not exceed five (5) minutes without resetting. A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on-time. Such signal shall continue to sound while X-rays are produced until the timing device is reset.~~

F.4.12 **Fluoroscopic Irradiation Time, Display and Signal.**

(a) Fluoroscopic equipment manufactured before 10 June 2006

(1) Shall be provided with means to preset the cumulative irradiation time of the fluoroscopic tube. The maximum cumulative time of the timing device shall not exceed five (5) minutes without resetting. A signal audible to the operator shall indicate the completion of any preset cumulative irradiation time. Such signal shall continue to sound while X-rays are produced until the timing device is reset. Fluoroscopic equipment may be modified in accordance with 21 CFR 1020.30(q) to comply with the requirements of F.4.12. When the equipment is modified, it shall bear a label indicating the statement:

MODIFIED TO COMPLY WITH 21 CFR 1020.32(H)(2)

(b) For X-ray controls manufactured on or after 10 June 2006, there shall be provided for each fluoroscopic tube:

(1) A display of the fluoroscopic irradiation time at the operator's working position. This display shall function independently of the audible signal described in this subsection. The following requirements apply:

(i) When the X-ray tube is activated, the fluoroscopic irradiation time in minutes and tenths of minutes shall be continuously displayed and updated at least once every six (6) seconds.

(ii) The fluoroscopic irradiation time shall also be displayed within six (6) seconds of termination of an exposure and remain displayed until reset.

(iii) Means shall be provided to reset the display to zero prior to the beginning of a new examination or procedure.

(2) A signal audible to the operator shall sound for each passage of five (5) minutes of fluoroscopic irradiation time during an examination or procedure. The signal shall sound until manually reset or, if automatically reset, for at least two (2) seconds.

F.4.13 **Mobile and Portable Fluoroscopes.** In addition to the other requirements of Subpart F.4, mobile and

portable fluoroscopes shall provide ~~intensified imaging~~ an image receptor incorporating more than a simple fluorescent screen.

F.4.14 **Control of Scattered Radiation**.

(a) Fluoroscopic table designs when combined with procedures utilized shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to unattenuated scattered radiation which originates from under the table. The attenuation required shall be not less than 0.25 millimeter lead equivalent.

(b) Equipment configuration when combined with procedures shall be such that no portion of any staff or ancillary individual's body, except the extremities, shall be exposed to the unattenuated scattered radiation emanating from above the tabletop unless that individual:

(1) Is at least one-hundred twenty (120) centimeters from the center of the useful beam, or

(2) The radiation has passed through not less than 0.25 millimeter lead equivalent material (e.g., drapes, Bucky-slot cover-sliding or folding panel, or self supporting curtains) in addition to any lead equivalency provided by the protective apron referred to in Section F.2.6.

(c) ~~Exceptions may be made in some special procedures~~ The Agency may grant exemptions to F.4.14(b) where a sterile field will not permit the use of the normal protective barriers. Where the use of prefitted sterilized covers for the barriers is practical, the Agency shall not permit such exception.

~~F.4.15 **Spot Film Exposure Reproducibility.** Fluoroscopic systems equipped with spot film (radiographic) mode shall meet the exposure reproducibility requirements of F.5.6. when operating in the spot film mode.~~

F.4.15 **Patient Dose Evaluation.**

(a) Each registrant performing fluoroscopically-guided interventional procedures shall develop written policies and procedures to:

(1) Identify those procedures which have a potential to result in patient doses exceeding the threshold for injury;

(2) Reduce the probability of such exposures; and

(3) Ensure that appropriate action occurs for patients receiving doses that warrant follow-up.

(b) The registrant shall have a patient dose monitoring procedures in place and shall document (in the patient's medical record) an estimate of the absorbed dose to the skin. When the fluoroscopy unit is equipped with an Air-Kerma dose readout, the recording of this value shall suffice as a patient dose record.

(c) The registrant shall conduct patient dose evaluation for any procedure that has a reasonable probability of resulting in a deterministic injury (i.e., a cumulative absorbed dose to the skin equal to or greater than 1 Gy (100 rads)). This evaluation shall be noted in the patients medical record and reviewed by the Radiation Safety Committee[32].

~~F.4.16 **Radiation Therapy Simulation Systems.** Radiation therapy simulation systems shall be exempt from all the requirements of F.4.6. In addition, these systems shall be exempt from:~~

~~(a) The requirements of F.4.2 and F.4.8, provided such systems are designed and used in such a manner that no individual other than the patient is in the X-ray room during periods of time when the system is producing X-rays; and~~

[32] If the registrant does not have a Radiation Safety Committee, the review shall be conducted by the Radiation Safety Officer and the registrant's medical physicist.

~~(b) The requirements of F.4.12 if such systems are provided with a means of indicating the cumulative time that an individual patient has been exposed to X-rays. Procedures shall require in such cases that the timer be reset between examinations.~~

F.4.16 **Radiation Therapy Simulation Systems.**

(a) Radiation therapy simulation systems shall be exempt from the requirements of F.4.2(a), provided such systems are intended only for remote control operation.

(b) Radiation therapy simulation systems shall be exempt from all the requirements of F.4.4(d), F.4.6 and F.5.12(b)(2) when used for therapy simulation purposes.

(c) As an alternative to the requirements of F.4.12, radiation therapy simulation systems may be provided with a means to indicate the total cumulative exposure time during which X-rays were produced, and which is capable of being reset between X-ray examinations.

F.4.17 **Display of Last-Image-Hold (LIH)**. Fluoroscopic equipment manufactured on or after 10 June 2006, shall be equipped with means to display LIH image following termination of the fluoroscopic exposure.

(a) For an LIH image obtained by retaining pretermination fluoroscopic images, if the number of images and method of combining images are selectable by the user, the selection shall be indicated prior to initiation of the fluoroscopic exposure.

(b) For an LIH image obtained by initiating a separate radiographic-like exposure at the termination of fluoroscopic imaging, the technique factors for the LIH image shall be selectable prior to the fluoroscopic exposure, and the combination selected shall be indicated prior to initiation of the fluoroscopic exposure.

(c) Means shall be provided to clearly indicate to the user whether a displayed image is the LIH radiograph or fluoroscopy. Display of the LIH radiograph shall be replaced by the fluoroscopic image concurrently with re-initiation of fluoroscopic exposure, unless separate displays are provided for the LIH radiograph and fluoroscopic images.

F.4.18 **Displays of Values of Air Kerma (Exposure) Rate and Cumulative Air Kerma**. Fluoroscopic equipment manufactured on or after 10 June 2006, shall display at the operator's working position the air kerma (exposure) rate and cumulative air kerma. The following requirements apply for each X-ray tube used during an examination or procedure:

(a) When the X-ray tube is activated and the number of images produced per unit time is greater than six (6) images per second, the air kerma (exposure) rate in mGy/min shall be continuously displayed and updated at least once every second.

(b) The cumulative air kerma in units of mGy shall be displayed either within five (5) seconds of termination of an exposure or displayed continuously and updated at least once every five (5) seconds.

(c) The display of the air kerma (exposure) rate shall be clearly distinguishable from the display of the cumulative air kerma.

(d) The air kerma (exposure) rate and cumulative air kerma shall represent the value for conditions of free-in-air irradiation at one of the following reference locations specified according to the type of fluoroscope.

(1) For fluoroscopes with X-ray source below the X-ray table, X-ray source above the table, or of lateral type, the reference location shall be the respective locations specified in F.4.7(c)(1), (c)(2) or (c)(5).

(2) For C-arm fluoroscopes, the reference location shall be fifteen (15) cm from the isocenter toward the X-ray source along the beam axis. Alternatively, the reference location shall be at a point specified by the manufacturer to represent the location of the intersection of the X-ray beam with the patient's

skin.

(e) Means shall be provided to reset to zero the display of cumulative air kerma prior to the commencement of a new examination or procedure.

(f) The displayed air kerma (exposure) rate and cumulative air kerma shall not deviate from the actual values by more than ± thirty-five percent (± 35%) over the range of 6 mGy/min and 100 mGy to the maximum indication of air kerma (exposure) rate and cumulative air kerma, respectively. Compliance shall be determined with an irradiation time greater than three (3) seconds.

F.5 RADIOGRAPHIC ~~SYSTEMS OTHER THAN FLUOROSCOPIC, DENTAL INTRAORAL, BONE DENSITOMETRY, OR COMPUTED TOMOGRAPHY X-RAY SYSTEMS~~ EQUIPMENT[33]

F.5.1 Beam Limitation, Except Mammographic Systems. The useful beam shall be limited to the area of clinical interest. This shall be deemed to have been met if a positive beam limiting device meeting manufacturer's specifications and the requirements of F.3.2 has been properly used or if evidence of collimation is shown on at least three sides or three corners of the film (for example, projections from the shutters of the collimator, cone cutting at the corners, or borders at the film's edge).

~~(a) **General Purpose Stationary and Mobile X-Ray Systems, Including Veterinary Systems (Other than Portable).**~~

~~(1) Only X-ray systems provided with means for independent stepless adjustment of at least two dimensions of the X-ray field shall be used.~~

~~(2) A method shall be provided for visually defining the perimeter of the X-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the X-ray field along either the length or width of the visually defined field shall not exceed 2 percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the X-ray beam.~~

~~(3) The Agency may grant an exemption on non-certified X-ray systems to F.5.1(a)(1) and (2) provided the registrant makes a written application for such exemption and in that application:~~

~~(i) Demonstrates it is impractical to comply with F.5.1(a)(1) and (2); and~~

~~(ii) The purpose of F.5.1(a)(1) and (2) will be met by other methods.~~

~~(b) **Additional Requirements for Stationary General Purpose X-Ray Systems.** In addition to the requirements of F.5.1(a), stationary general purpose X-ray systems, both certified and noncertified, shall meet the following requirements:~~

~~(1) A method shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor, to align the center of the X-ray field with respect to the center of the image receptor to within 2 percent of the SID, and to indicate the SID to within 2 percent;~~

~~(2) The beam-limiting device shall numerically indicate the field size in the plane of the image receptor to which it is adjusted; and~~

~~(3) Indication of field size dimensions and SID shall be specified in inches and/or centimeters, and shall be such that aperture adjustments result in X-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam limiting device to within 2 percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.~~

~~(c) **X-Ray Systems Designed for One Image Receptor Size.** Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the X-ray field with the center of the image receptor to within 2 percent of the SID, or shall be provided with means to both size and align the X-ray field such that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.~~

~~(d) **Veterinary X-Ray Systems and X-Ray Systems Other Than Those Described in F.5.1(a)-(c).**~~

[33] Dental intra-oral radiographic equipment previously regulated pursuant to Subpart F.6 of these Regulations is now being regulated pursuant to Subpart F.5. Subpart F.6 has been deleted in its entirety.

~~(1) Means shall be provided to limit the X-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than 2 percent of the SID when the axis of the X-ray beam is perpendicular to the plane of the image receptor.~~

~~(2) Means shall also be provided to align the center of the X-ray field with the center of the image receptor to within 2 percent of the SID, or means shall be provided to both size and align the X-ray field such that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. Compliance shall be determined with the axis of the X-ray beam perpendicular to the plane of the image receptor.~~

~~(3) F.5.1(d)(1) and (2) may be met with a system that meets the requirements for a general purpose X-ray system as specified in F.5.1(a) or, when alignment means are also provided, may be met with either:~~

~~(i) An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed with each such device having clear and permanent markings to indicate the image receptor size and SID for which it is designed; or~~

~~(ii) A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.~~

~~(e) Portable X-ray systems shall have an evaluation of light field vs. X-ray field alignment and actual vs. indicated setting performed at least every 6 months to determine compliance with both F.5.1(a) and F.5.1(b)(3). Records must be maintained for all such evaluations.~~

F.5.2 **Radiation Exposure Control.**

***

~~(c) **Exposure Termination.** Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. Except for dental panoramic systems, termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "zero." It shall not be possible to make an exposure when the timer is set to a zero or off position if either position is provided.~~

(c) **Operator Protection, Except Veterinary Systems**.

(1) **Stationary Systems.** Stationary X-ray systems shall be required to have the X-ray control permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure.

(2) **Mobile and Portable Systems**. Mobile and portable X-ray systems which are:

(i) Used continuously for greater than one (1) week in the same location (i.e., a room or suite) shall meet the requirements of F.5.2(c)(1);

(ii) Used for less than one (1) week at the same location shall be provided with either a protective barrier at least two (2) meters (6.5 feet) high for operator protection during exposures, or means shall be provided to allow the operator to be at least 2.7 meters (9 feet) from the tube housing assembly during the exposure.

~~(d) **Manual Exposure Control.** An X-ray control shall be incorporated into each X-ray system such that an exposure can be terminated by the operator at any time except:~~

~~(1) For exposure of one-half second or less, or~~

~~(2) During serial radiography when means shall be provided to permit completion of any single exposure of the series in process.~~

(d) **Operator Protection for Veterinary Systems**.

(1) All stationary, mobile or portable X-ray systems used for veterinary work shall be provided with either a two (2) meter (6.5 feet) high protective barrier for operator protection during exposures, or shall be provided with means to allow the operator to be at least 2.7 meters (9 feet) from the tube housing assembly during exposures. No individual other than the operator shall be in the X-ray room while exposures are being made unless such individual's assistance is required. Refer to Appendix D for hand-held intraoral dental radiographic units used in veterinary practice.

(2) When an animal must be held in position during radiography, mechanical supporting or restraining devices should be used. If necessary, general anesthesia, sedation or tranquilization should be used. If the animal must be held by an individual, that individual shall be protected with appropriate shielding devices, such as protective gloves and apron, and shall be so positioned that no part of their body will be struck by the useful beam. No individual shall be used routinely to hold animals or film during radiation exposures. The exposure of any individual used for this purpose shall be monitored, and a record shall be made of the examination, including the name of the human holder, date of the examination, number of exposures and technique factors utilized for the exposure(s).

~~F.5.3 **Automatic EXPOSURE Controls.** When an automatic **EXPOSURE** control is provided:~~

~~(a) Indication shall be made on the control panel when this mode of operation is selected;~~

~~(b) If the X-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to 2 pulses and the minimum exposure time for all other equipment shall be equal to or less than one-sixtieth (1/60) second or a time interval required to deliver 5 mAs, whichever is greater;~~

~~(c) Either the product of peak X-ray tube potential, current, and exposure time shall be limited to not more than 60 kWs per exposure, or the product of X-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure except that, when the X-ray tube potential is less than 50 kVp the product of X-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure; and~~

~~(d) A visible signal shall indicate when an exposure has been terminated at the limits required by F.5.3(c), and manual resetting shall be required before further automatically timed exposures can be made.~~

F.5.3 **Control and Indication of Technique Factors.**

(a) **Visual Indication**. The technique factors to be used during an exposure shall be indicated before the exposure begins, except when automatic exposure controls are used, in which case the technique factors which are set prior to the exposure shall be indicated. On equipment having fixed technique factors, this requirement may be met by permanent markings. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the operator.

(b) **Timers.** Means shall be provided to terminate the exposure at a preset time interval, a preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor.

(1) Except during serial radiography, the operator shall be able to terminate the exposure at any time during an exposure of greater than one-half (0.5) second. Except during panoramic dental radiography, termination of exposure shall cause automatic resetting of the timer to its initial setting or to zero. It shall not be possible to make an exposure when the timer is set to a zero or off position if either position is provided.

(2) During serial radiography, the operator shall be able to terminate the X-ray exposure(s) at any

time, but means may be provided to permit completion of any single exposure of the series in process.

(c) **Automatic Exposure Controls.** When an automatic exposure control is provided:

(1) Indication shall be made on the control panel when this mode of operation is selected;

(2) When the X-ray tube potential is equal to or greater than fifty-one (51) kilovolts peak (kVp), the minimum exposure time for field emission equipment rated for pulse operation shall be equal to or less than a time interval equivalent to two pulses and the minimum exposure time for all other equipment shall be equal to or less than 1/60 second or a time interval required to deliver five (5) milliampere-seconds (mAs), whichever is greater;

(3) Either the product of peak X-ray tube potential, current, and exposure time shall be limited to not more than sixty (60) kilowatt-seconds (kWs) per exposure or the product of X-ray tube current and exposure time shall be limited to not more than six-hundred (600) mAs per exposure, except when the X-ray tube potential is less than fifty-one (51) kVp, in which case the product of X-ray tube current and exposure time shall be limited to not more than two-thousand (2,000) mAs per exposure; and

(4) A visible signal shall indicate when an exposure has been terminated at the limits described in F.5.3(c)(3), and manual resetting shall be required before further automatically timed exposures can be made.

(d) **Accuracy.** Deviation of technique factors from indicated values shall not exceed the limits given by the manufacturer.

~~F.5.4 **Timer Reproducibility and Linearity.**~~

~~(a) With a timer setting of 0.5 seconds or less, the average exposure period (T) shall be greater than or equal to 5 times the maximum exposure period (T_{max}) minus the minimum exposure period (T_{min}) when 4 timer tests are performed using the same timer setting:~~

~~$$\text{i.e., } T \geq 5\,(T_{max} - T_{min}).$$~~

~~(b) For systems having independent selection of exposure time settings, the average ratios (X^i) of exposure to the indicated timer setting, in units of C kg^{-1}s^{-1} (mR/s), obtained at any two clinically used timer settings shall not differ by more than 0.10 times their sum. This is written as:~~

~~$$(X_1 - X_2) \leq 0.1\,(X_1 + X_2)$$~~

F.5.4 **Positive Beam Limitation (PBL).** The requirements of F.5.4 shall apply to radiographic systems which contain PBL.

(a) **Field Size.** When a PBL system is provided, it shall prevent X-ray production when:

(1) Either the length or width of the X-ray field in the plane of the image receptor differs from the corresponding image receptor dimension by more than three percent (3%) of the SID; or

(2) The sum of the length and width differences stated in F.5.4(a)(1) without regard to sign exceeds four percent (4%) of the SID.

(3) The beam-limiting device is at an SID for which PBL is not designed for sizing.

(b) **Conditions For PBL**. When provided, the PBL system shall function as described in §F.5.4(a) whenever all the following conditions are met:

(1) The image receptor is inserted into a permanently mounted cassette holder;

(2) The image receptor length and width are less than fifty (50) cm;

(3) The X-ray beam axis is within ± three degrees (±3°) of vertical and the SID is ninety (90) cm to

one-hundred thirty (130) cm inclusive; or the X-ray beam axis is within ± three degrees (±3°)of horizontal and the SID is ninety (90) cm to two-hundred five (205) cm inclusive;

(4) The X-ray beam axis is perpendicular to the plane of the image receptor to within ± three degrees (±3°); and

(5) Neither tomographic nor stereoscopic radiography is being performed.

(c) **Measuring Compliance**. Compliance with the requirements of §F.5.4(a) shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor and the provisions of §F.5.4(b) are met. Compliance shall be determined no sooner than five (5) seconds after insertion of the image receptor.

(d) **Operator Initiated Undersizing**. The PBL system shall be capable of operating such that, at the discretion of the operator, the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. Each dimension of the minimum field size at an SID of one-hundred (100) cm shall be equal to or less than five (5) cm. Return to PBL function as described in §F.5.4(a) shall occur automatically upon any change of image receptor size or SID.

(e) **Override of PBL**. A capability may be provided for overriding PBL in case of system failure and for servicing the system. This override may be for all SIDs and image receptor sizes. A key shall be required for any override capability that is accessible to the operator. It shall not be possible to remove the key while PBL is overridden. Each such key switch or key shall be clearly and durably labeled as follows:

FOR X-RAY FIELD LIMITATION SYSTEM FAILURE

The override capability is considered accessible to the operator if it is referenced in the operator's manual or in other material intended for the operator or if its location is such that the operator would consider it part of the operational controls.

F.5.5 **Source-to-Skin Distance.** ~~All mobile or portable radiographic systems shall be provided with means to limit the source-to-skin distance to not less than 30 centimeters, except for veterinary systems.~~

(a) X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit the source-skin distance to not less than:

(1) Eighteen (18) cm if operable above fifty (50) kVp; or

(2) Ten (10) cm if not operable above fifty (50) kVp.

(b) Mobile and portable X-ray systems other than dental shall be provided with means to limit the source-skin distance to not less than thirty (30) cm.

F.5.6 ~~**EXPOSURE**~~ **Air Kerma (Exposure) Reproducibility.** The following requirements shall apply when the equipment is operated on an adequate power supply as specified by the manufacturer:

(a) For any specific combination of selected technique factors, the coefficient of variation of the air kerma (exposure) shall not exceed 0.10 when all technique factors are held constant. This requirement shall be deemed to have been met if, when four **EXPOSURES** are made at identical technique factors, the value of the average **EXPOSURE** (E) is greater than or equal to 5 times the maximum **EXPOSURE** (E_{max}) minus the minimum **EXPOSURE** (E_{min});

$$\text{i.e., } E \geq 5\,(E_{max} - E_{min}).$$

(b) For equipment having automatic exposure controls, compliance shall be determined with a sufficient thickness of attenuating material in the useful beam such that the technique factors can be adjusted to provide individual exposures of a minimum of twelve (12) pulses on field emission equipment rated for pulsed

operation or no less than one-tenth (0.1) second per exposure on all other equipment.

~~F.5.7 **Radiation from Capacitor Energy Storage Equipment in Standby Status.** Radiation emitted from the X-ray tube when the exposure switch or timer is not activated shall not exceed a rate of 0.5 μC/kg (2 milliroentgens) per hour at 5 centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.~~

F.5.7 **Radiation from Capacitor Energy Storage Equipment**. Radiation emitted from the X-ray tube shall not exceed:

(a) An air kerma of 0.26 μGy (0.03 mR exposure) in one (1) minute at five (5) cm from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open, the system fully charged, and the exposure switch, timer, or any discharge mechanism not activated. Compliance shall be determined by measurements averaged over an area of one-hundred square cm (100 cm^2), with no linear dimensions greater than twenty (20) cm: and

(b) An air kerma of 0.88 mGy (100 mR exposure) in one (1) hour at one-hundred (100) cm from the X-ray source, with beam-limiting device fully open, when the system is discharged through the X-ray tube either manually or automatically by use of a discharge switch or deactivation of the input power. Compliance shall be determined by measurements of the maximum air kerma per discharge multiplied by the total projected number of discharges in one (1) hour. The measurements shall be averaged over an area of one-hundred square cm (100 cm^2)with no linear dimension greater than twenty (20) cm.

~~F.5.8 **Additional Requirements Applicable to Certified Systems Only.**~~

~~(a) Diagnostic X-ray systems incorporating one or more certified components shall be required to comply with the requirement of F.3.2.~~

~~(b) Transmission limit for image receptor supporting devices used for mammography shall comply with F.3.2.~~

F.5.8 **Tube Stands for Portable X-Ray Systems.** A tube stand or other mechanical support shall be used for portable X-ray systems, so that the X-ray tube housing assembly need not be hand-held during exposures.

F.5.9 ~~[RESERVED]~~ **Measurement of Radiation Output.**

(a) Measurement of the radiation output shall be performed at a specified distance and over a range of clinical kVp values, and shall be made at intervals not to exceed twelve (12) months or after any maintenance of the system which might affect the radiation output. These measurements shall be performed in-air with minimum scatter conditions. Results of the measurements shall include the μGy/mas (mR/mas), as well as the technique factors used to determine such results.

(b) The name and signature of the Qualified Medical Physicist performing the measurements, and the date the measurements were performed, shall be included in the results.

(c) These measurements may be used to estimate entrance skin exposure (ESE) for the average adult patient for selected routine radiographic procedures. These values should be compared with available national reference values.

~~F.5.10. **Exposure Control Location**. The X-ray exposure control shall be so placed that the operator can view the patient while making any exposure.~~

F.5.10 **Beam-on Indicators**. The X-ray control shall provide visual indication whenever X-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

~~F.5.11 **Operator Protection, Except Veterinary Systems**.~~

~~(a) **Stationary Systems**. Stationary X-ray systems shall be required to have the X-ray control permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure.~~

~~(b) **Mobile and Portable Systems**. Mobile and portable X-ray systems which are:~~

~~(1) Used continuously for greater than one week in the same location, i.e., a room or suite, shall meet the requirements of F.5.11(a);~~

~~(2) Used for less than one week at the same location shall be provided with either a protective barrier at least 2 meters (6.5 feet) high for operator protection during exposures, or means shall be provided to allow the operator to be at least 2 meters (6.5 feet) from the tube housing assembly during the exposure.~~

F.5.11 **Primary Protective Barrier For Mammography X-ray Systems.**

(a) For X-ray systems manufactured after 5 September 1978, and before 30 September 1999, which are designed only for mammography, the transmission of the primary beam through any image receptor support provided with the system shall be limited such that the air kerma five (5) cm from any accessible surface beyond the plane of the image receptor supporting device does not exceed 0.88 μGy (0.1 mR exposure) for each activation of the tube.

(b). For mammographic X-ray systems manufactured on or after 30 September 1999:

(1) At any SID where exposures can be made, the image receptor support device shall provide a primary protective barrier that intercepts the cross section of the useful beam along every direction except at the chest wall edge.

(2) The X-ray system shall not permit exposure unless the appropriate barrier is in place to intercept the useful beam as required in F.5.11(b)(1).

(3) The transmission of the useful beam through the primary protective barrier shall be limited such that the air kerma five (5) cm from any accessible surface beyond the plane of the primary protective barrier does not exceed 0.88 μGy (0.1 mR exposure) for each activation of the tube.

(c) Compliance with the requirements of F.5.11(a) and (b)(3) for transmission shall be determined with the X-ray system operated at the minimum SID for which it is designed, at maximum rated peak tube potential, at the maximum rated product of X-ray tube current and exposure time (mAs) for the maximum rated peak tube potential, and by measurements averaged over an area of one-hundred square cm (100 cm^2) with no linear dimension greater than twenty (20) cm. The sensitive volume of the radiation measuring instrument shall not be positioned beyond the edge of the primary protective barrier along the chest wall side.

~~F.5.12 **Operator Protection for Veterinary Systems**. All stationary, mobile or portable X-ray systems used for veterinary work shall be provided with either a 2 meter (6.5 feet) high protective barrier for operator protection during exposures, or shall be provided with means to allow the operator to be at least 2 meters (6.5 feet) from the tube housing assembly during exposures. No individual other than the operator shall be in the X-ray room while exposures are being made unless such individual's assistance is required.~~

F.5.12 **Field Limitation and Alignment for Mobile, Portable and Stationary General Purpose X-ray Systems**. Except when spot-film devices are in service, mobile, portable and stationary general purpose radiographic X-ray systems shall meet the following requirements:

(a) **Variable X-ray Field Limitation**. A means for stepless adjustment of the size of the X-ray field shall be provided. Each dimension of the minimum field size at an SID of one-hundred (100) cm shall be equal to

or less than five (5) cm.

(b) **Visual Definition**.

(1) Means for visually defining the perimeter of the X-ray field shall be provided. The total misalignment of the edges of the visually defined field with the respective edges of the X-ray field along either the length or width of the visually defined field shall not exceed two percent (2%) of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the X-ray beam.

(2) When a light localizer is used to define the X-ray field, it shall provide an average illuminance of not less than 160 lux (15 footcandles) at one-hundred (100) cm or at the maximum SID, whichever is less. The average illuminance shall be based on measurements made in the approximate center of each quadrant of the light field.

(3) The edge of the light field at one-hundred (100) cm or at the maximum SID, whichever is less, shall have a contrast ratio, corrected for ambient lighting, of not less than four (4) in the case of beam-limiting devices designed for use on stationary equipment, and a contrast ratio of not less than three (3) in the case of beam-limiting devices designed for use on mobile and portable equipment. The contrast ratio is defined as I_1/I_2, where I_1 is the illuminance three (3) mm from the edge of the light field toward the center of the field; and I_2 is the illuminance three (3) mm from the edge of the light field away from the center of the field. Compliance shall be determined with a measuring aperture of one (1) mm.

(c) (1) Portable X-ray systems shall have an evaluation of light field vs. X-ray field alignment performed at least every six (6) months to determine compliance with both F.5.12(b)(1) and F.5.13(c).

(2) Portable X-ray systems shall have an evaluation of centering alignment performed at least every six (6) months to determine compliance with F.5.13(a).

~~F.5.13 **Accuracy**. Deviation of measured technique factors from indicated values of kVp and exposure time shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications, the deviation shall not exceed 10 percent of the indicated value for kVp and 20 percent for time.~~

F.5.13 **Field Indication and Alignment on Stationary General Purpose X-ray Equipment**. Except when spot-film devices are in service, stationary general purpose X-ray systems shall meet the following requirements in addition to those prescribed in F.5.12:

(a) Means shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor, to align the center of the X-ray field with respect to the center of the image receptor to within two percent (2%) of the SID, and to indicate the SID to within two percent (2%);

(b) The beam-limiting device shall numerically indicate the field size in the plane of the image receptor to which it is adjusted;

(c) Indication of field size dimensions and SIDs shall be specified in centimeters and/or inches and shall be such that aperture adjustments result in X-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within two percent (2%) of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor; and

(d) Compliance measurements will be made at discrete SIDs and image receptor dimensions in common clinical use (such as SIDs of 100, 150, and 200 cm and/or 36, 40, 48, 72 inches and nominal image receptor dimensions of 13, 18, 24, 30, 35, 40, and 43 cm and/or 5, 7, 8, 9, 10, 11, 12, 14, and 17 inches) or at any other specific dimensions at which the beam-limiting device or its associated diagnostic X-ray system is uniquely designed to operate.

F.5.14 ~~**mA/mAs**~~ **Linearity**. The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer in accordance with 21 CFR Part 1020 for any fixed X-ray tube potential within the range of ~~40~~ forty percent (40%) to ~~100~~ one-hundred percent (100%) of the maximum rated.

(a) **Equipment Having Independent Selection of X-Ray Tube Current (mA)**. The average ratios ~~(X_i) of exposure~~ of air kerma (exposure) to the indicated milliampere-seconds product (mGy/mAs or mR/mAs) ~~(C kg^{-1} mAs^{-1} (or mR/mAs))~~ obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$X_1 - X_2 \leq 0.10 (X_1 + X_2)$$

where X_1 and X_2 are the average mGy/mAs (mR/mAs) values obtained at each of two (2) consecutive tube current settings, or at two (2) settings differing by no more than a factor of two (2) where the mA selector provides continuous selection ~~tube current selection is continuous~~.

(b) **Equipment Having ~~a Combined~~ Selection of X-Ray Tube Current-exposure Time Product (mAs) ~~Selector, But Not a Separate Tube Current (mA) Selector~~**. For equipment manufactured after 3 May 1994, the average ratios ~~(X_i)~~ of ~~exposure~~ air kerma (exposure) to the indicated milliampere-seconds product, ~~in units of C kg^{-1} mAs^{-1} (or mR/mAs),~~ (mGy/mAs or mR/mAs) obtained at any two (2) consecutive mAs selector settings shall not differ by more than 0.10 times their sum:

$$X_1 - X_2 \leq 0.10 (X_1 + X_2)$$

where X_1 and X_2 are the average mGy/mAs values obtained at any two (2) consecutive mAs selector settings, or at two (2) settings differing by no more than a factor of two (2) where the mAs selector provides continuous selection.

(c) **Measuring Compliance**. Determination of compliance will be based on consecutive exposures, made within one (1) hour. These settings may include any two (2) focal spot sizes except where one is equal to or less than 0.45 mm and the other is greater than 0.45 mm. For purposes of this requirement, focal spot size is the focal spot size specified by the X-ray tube manufacturer.

~~F.5.15 **Special Precautions for Veterinary Operations.** When an animal must be held in position during radiography, mechanical supporting or restraining devices should be used. If necessary, general anesthesia, sedation or tranquilization should be used. If the animal must be held by an individual, that individual shall be protected with appropriate shielding devices, such as protective gloves and apron, and shall be so positioned that no part of their body will be struck by the useful beam. No individual shall be used routinely to hold animals or film during radiation exposures. The exposure of any individual used for this purpose shall be monitored, and a record shall be made of the examination, including the name of the human holder, date of the examination, number of exposures and technique factors utilized for the exposure(s).~~

F.5.15 **Field Limitation on Radiographic X-ray Equipment Other Than General Purpose Radiographic Systems**

(a) **Equipment for Use With Intraoral Image Receptors**. Radiographic equipment designed for use with an intraoral image receptor shall be provided with means to limit the X-ray beam such that:

(1) If the minimum source-to-skin distance (SSD) is eighteen (18) cm or more, the X-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than seven (7) cm; and

(2) If the minimum SSD is less than eighteen (18) cm, the X-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than six (6) cm.

(b) **X-ray Systems Designed for One Image Receptor Size**. Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image

receptor to dimensions no greater than those of the image receptor, and to align the center of the X-ray field with the center of image receptor to within two percent (2%) of the SID, or shall be provided with means to both size and align the X-ray field such that the X-ray field at the plane of the image receptor does not extend beyond the edge of the image receptor.

(c) **Systems Designed for Mammography.**

(1) Radiographic systems designed only for mammography and general purpose radiography systems, when special attachments for mammography are in service, manufactured on or after 1 November 1977, and before 30 September 1999, shall be provided with means to limit the useful beam such that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor at any designated SID except the edge of the image receptor designed to be adjacent to the chest wall where the X-ray field may not extend beyond this edge by more than two percent (2%) of the SID. This requirement can be met with a system that performs as prescribed in F.5.15(d)(1), (2) and (3). When the beam-limiting device and image receptor support device are designed to be used to immobilize the breast during a mammographic procedure and the SID may vary, the SID indication specified in F.5.15(d)(2) and (3) shall be the maximum SID for which the beam-limiting device or aperture is designed.

(2) Mammographic beam-limiting devices manufactured on or after 30 September 1999, shall be provided with a means to limit the useful beam such that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor by more than two percent (2%) of the SID. This requirement can be met with a system that performs as prescribed in F.5.15(d)(1), (2) and (3). For systems that allow changes in SID, the SID indication specified in F.5.15(d) (2) and (3 shall be the maximum SID for which the beam-limiting device or aperture is designed.

(3) Each image receptor support device manufactured on or after 1 November 1977, intended for installation on a system designed for mammography shall have clear and permanent markings to indicate the maximum image receptor size for which it is designed.

(d) **Other X-ray Systems**. Radiographic systems not specifically covered in F.5.12, F.5.13, F.5.15(b), F.5.15(c), F.5.16, and systems covered in F.5.15(a), which are also designed for use with extraoral image receptors and when used with an extraoral image receptor, shall be provided with means to limit the X-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than two percent (2%) of the SID, when the axis of the X-ray beam is perpendicular to the plane of the image receptor. In addition, means shall be provided to align the center of the X-ray field with the center of the image receptor to within two percent (2%) of the SID, or means shall be provided to both size and alignment the X-ray field such that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. These requirements may be met with:

(1) A system which performs in accordance with F.5.12 and F.5.13; or when alignment means are also provided, may be met with either;

(2) An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Each such device shall have clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

(3) A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

F.5.16 **Field Limitation and Alignment for Spot-Film Devices**. The following requirements shall apply to

spot-film devices, except when the spot-film device is provided for use with a radiation therapy simulation system:

(a) Means shall be provided between the source and the patient for adjustment of the X-ray field size in the plane of the image receptor to the size of that portion of the image receptor which has been selected on the spot-film selector. Such adjustment shall be accomplished automatically when the X-ray field size in the plane of the image receptor is greater than the selected portion of the image receptor. If the X-ray field size is less than the size of the selected portion of the image receptor, the field size shall not open automatically to the size of the selected portion of the image receptor unless the operator has selected that mode of operation.

(b) Neither the length nor width of the X-ray field in the plane of the image receptor shall differ from the corresponding dimensions of the selected portion of the image receptor by more than three percent (3%) of the SID when adjusted for full coverage of the selected portion of the image receptor. The sum, without regard to sign, of the length and width differences shall not exceed four percent (4%) of the SID. On spot film devices manufactured after 25 February 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

(c) The center of the X-ray field in the plane of the image receptor shall be aligned with the center of the selected portion of the image receptor to within two percent (2%) of the SID.

(d) Means shall be provided to reduce the X-ray field size in the plane of the image receptor to a size smaller than the selected portion of the image receptor such that:

(1) For spot-film devices used on fixed-SID fluoroscopic systems which are not required to, and do not provide stepless adjustment of the X-ray field, the minimum field size, at the greatest SID, does not exceed one-hundred twenty-five square cm (125 cm^2); or

(2) For spot-film devices used on fluoroscopic systems that have a variable SID and/or stepless adjustment of the field size, the minimum field size, at the greatest SID, shall be containable in a square of five (5) cm by five (5) cm.

(e) A capability may be provided for overriding the automatic X-ray field size adjustment in case of system failure. If it is so provided, a signal visible at the operator's position shall indicate whenever the automatic X-ray field size adjustment override is engaged. Each such system failure override switch shall be clearly labeled as follows:

FOR X-RAY FIELD LIMITATION SYSTEM FAILURE

F.6 [RESERVED] ~~INTRAORAL DENTAL RADIOGRAPHIC SYSTEMS~~

~~F.6.1 **Applicability.** In addition to the provisions of Subparts F.2 and F.3, the requirements of Subpart F.6 apply to X-ray equipment and associated facilities used for dental radiography. Requirements for extraoral dental radiographic systems are covered in F.5. Only systems meeting the requirements of F.6.10 shall be used.~~

~~F.6.2 **Source-to-Skin Distance.** X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit source-to-skin distance to not less than:~~

~~(1) 18 centimeters if operable above 50 kVp, or~~

~~(2) 10 centimeters if not operable above 50 kVp.~~

~~F.6.3 **Beam Limitation.** Radiographic systems designed for use with an intraoral image receptor shall be~~

provided with means to limit the X-ray beam such that the beam at the minimum SSD shall be containable in a circle having a diameter of no more than 7 centimeters.

F.6.4 **Radiation Exposure Control.**

(a) **Exposure Initiation.**

(1) Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action; and

(2) It shall not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided.

(b) **Exposure Indication.** Means shall be provided for visual indication observable at or from the operator's protected position whenever X-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

(c) **Exposure Termination.**

(1) Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor.

(2) An X-ray exposure control shall be incorporated into each X-ray system such that an exposure can be terminated by the operator at any time, except for exposures of ½ second or less.

(3) Termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "zero".

(d) **Timer Linearity.** For systems having independent selection of exposure time settings, the average ratios (Xi) of exposure to the indicated timer setting, in units of C kg-1 s-1 (mR/s), obtained at any two clinically used timer settings shall not differ by more than 0.10 times their sum. This is written as:

$$(X_1 - X_2) \leq 0.1 (X_1 + X_2)$$

where X_1 and X_2 are the average values.

(e) **Exposure Control Location and Operator Protection**.

(1) Stationary X-ray systems shall be required to have the X-ray exposure control permanently mounted in a protected area, so that the operator is required to remain in that protected area during the entire exposure; and

(2) Mobile and portable X-ray systems which are:

(i) Used for greater than one week in the same location, i.e., a room or suite, shall meet the requirements of F.6.4(e)(1) ;

(ii) Used for less than one week in the same location shall be provided with either a protective barrier at least2 meters (6.5 feet) high for operator protection, or means to allow the operator to be at least 2 meters (6.5 feet) from the tube housing assembly while making exposures.

F.6.5 **Reproducibility and Accuracy.**

(a) **Reproducibility:**

(1) **EXPOSURE:**

(i) When the equipment is operated on an adequate power supply as specified by the manufacturer, the estimated coefficient of variation of radiation **EXPOSURES** shall be no greater than 0.05, for any specific combination of selected technique factors; or

(ii) If when 4 **EXPOSURES** are made at identical technique factors, the value of the average **EXPOSURE** (E) is greater than or equal to 5 times the maximum **EXPOSURE** (E_{max}) minus the minimum **EXPOSURE** (E_{min}):

$$\text{i.e., } E > 5\,(E_{max} - E_{min}).$$

(2) **Timers.** With a timer setting of 0.5 seconds or less, the average exposure period (T) shall be greater than or equal to 5 times the maximum exposure period (T_{max}) minus the minimum exposure period (T_{min}) when 4 timer tests are performed using the same timer setting:

$$\text{i.e., } T > 5\,(T_{max} - T_{min})$$

(b) **Accuracy.** Deviation of technique factors from indicated values for kVp and exposure time (if time is independently selectable) shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications the deviation shall not exceed 10 percent of the indicated value for kVp and 20 percent for time.

F.6.6 **mA/mAs Linearity.** The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for any fixed X-ray tube potential within the range of 40 percent to 100 percent of the maximum rated.

(a) **Equipment Having Independent Selection of X-Ray Tube Current (mA).** The average ratios (X_i) of exposure to the indicated milliampere-seconds product, in units of C kg^{-1} mAs^{-1} (or mR/mAs), obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$X_1 - X_2 \leq 0.10\,(X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at each of two consecutive tube current settings, or at two settings differing by no more than a factor of 2 where the tube current selection is continuous.

(b) **Equipment Having a Combined X-Ray Tube Current-Exposure Time Product (mAs) Selector, But Not a Separate Tube Current (mA) Selector.** The average ratios (X_i) of exposure to the indicated milliampere-seconds product, in units of C kg^{-1} mAs^{-1} (or mR/mAs), obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum:

$$X_1 - X_2 \leq 0.10\,(X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at any two mAs selector settings, or at two settings differing by no more than a factor of 2 where the mAs selector provides continuous selection.

F.6.7 **kVp Limitations.** Dental X-ray machines with a nominal fixed kVp of less than 50 kVp shall not be used to make diagnostic dental radiographs of humans.

F.6.8 **Administrative Controls.**

(a) Patient and film holding devices shall be used when the techniques permit.

(b) Neither The tube housing nor the position indicating device (shall be hand-held during an exposure.

(c) The X-ray system shall be operated in such a manner that the diameter of useful beam at the patient's skin does not exceed the requirements of F.6.3.

(d) Dental fluoroscopy without image intensification shall not be used.

~~F.6.9 **Additional Requirements Applicable to Certified Systems Only.** Diagnostic X-ray systems incorporating one or more certified components shall be required to comply with the requirements of F.3.2.~~

~~F.6.10 **Extraoral Procedures Utilizing Intraoral Dental X-ray Systems.** When X-ray equipment designed for use with intraoral image receptors is used in combination with an extraoral image receptor, the requirements of Subpart F.5 shall not apply, provided that:~~

~~(a) The procedure is conducted under the supervision of a licensed dental practitioner;~~

~~(b) The requirements of Subpart F.6 are met;~~

~~(c) A film and screen combination of the fastest speed consistent with the diagnostic objective of the examination is used;~~

~~(d) The image receptor used is positioned to show evidence that the X-ray field in the plane of the image receptor has been confined to the image receptor.~~

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F.10 COMPUTED TOMOGRAPHY ~~SYSTEMS~~ EQUIPMENT

F.10.1 **Requirements for Equipment.**

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(b) **Termination of Exposure.**

(1) Means shall be provided to terminate the X-ray exposure automatically by either de-energizing the X-ray source or shuttering the X-ray beam in the event of equipment failure affecting data collection. Such termination shall occur within an interval that limits the total scan time to no more than ~~110 percent~~ one hundred ten percent (110%) of its preset value through the use of either a backup timer or devices which monitor equipment function.

(2) A visible signal shall indicate when the X-ray exposure has been terminated through the means required by F.10.1(b)(1).

(3) The operator shall be able to terminate the X-ray exposure at any time during a scan, or series of scans under CT system control, of greater than one-half (0.5) second duration.

(c) **Tomographic Plane Indication and Alignment.**

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(3) If a device using a light source is used to satisfy F.10.1(c)(1) or (2), the light source shall provide illumination levels sufficient to permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to five-hundred (500) lux.

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(h) **Additional Requirements Applicable to CT X-Ray Systems Containing a Gantry Manufactured After 3 September 1985.**

(1) The total error in the indicated location of the tomographic plane or reference plane shall not exceed five (5) millimeters.

(2) If the X-ray production period is less than one-half (0.5) second, the indication of X-ray production shall be actuated for at least one-half (0.5) second. Indicators at or near the gantry shall be

discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible.

(3) The deviation of indicated scan increment versus actual increment shall not exceed plus or minus one (± 1) millimeter with any mass from zero (0) to one-hundred (100) kilograms resting on the support device. The patient support device shall be incremented from a typical starting position to the maximum incremented distance or thirty (30) centimeters, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment may be taken anywhere along this travel.

Premature termination of the X-ray exposure by the operator shall necessitate resetting of the CT conditions of operation prior to the initiation of another scan.

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F.10.3 **~~Surveys, Calibrations~~ Radiation Output Measurements, Spot Checks, and Operating Procedures.**

(a) **[DELETED] ~~Surveys.~~**

~~(1) All CT X-ray systems installed after 1 August 1991 and those systems not previously surveyed shall have a survey made by, or under the direction of, a person registered with the Agency to provide Diagnostic X-ray Physics Services. In addition, such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.~~

~~(2) The registrant shall obtain a written report of the survey from the person registered with the Agency to provide Diagnostic X-ray Physics Services, and a copy of the report shall be made available to the Agency upon request.~~

(b) **Radiation ~~Calibrations~~ Output Measurements.**

(1) The measurement of the radiation output of the CT X-ray system shall be performed by, or under the direction of, a ~~person registered with the Agency to provide Diagnostic X-ray Physics Service~~s Qualified Medical Physicist.

~~(2) The measurement of the radiation output of a CT X-ray system shall be performed at intervals specified by a person registered with the Agency to provide Diagnostic X-ray Physics Services and after any change or replacement of components which, in the opinion of the person registered with the Agency to provide Diagnostic X-ray Physics Services, could cause a change in the radiation output.~~

(2) The measurement of the radiation output of a CT X-ray system shall be performed:

(i) Before the first medical use following installation or reinstallation of the CT X-ray system; and

(ii) At intervals not to exceed twelve (12) months; and

(iii) After any change or replacement of components which, in the opinion of the Qualified Medical Physicist, could cause a change in the radiation output.

(3) **[DELETED]** ~~The measurement of the radiation output of a CT X-ray system shall be performed with a calibrated dosimetry system. The calibration of such a system shall be traceable to a national standard. The dosimetry system shall have been calibrated within the preceding 2 years.~~

(4) CT dosimetry phantoms shall be used in determining the radiation output of a CT X-ray system. Such phantoms shall meet the following specifications and conditions of use:

(i) CT dosimetry ~~phantom(s)~~ phantoms shall be right circular cylinders of polymethyl

methacrylate of density 1.19 plus or minus 0.01 grams per cubic centimeter (g/cm^3). The ~~phantom(s)~~ phantoms shall be at least fourteen (14) centimeters in length and shall have diameters of thirty-two (32.0) centimeters for testing CT X-ray systems designed to image any section of the body and sixteen (16.0) centimeters for systems designed to image the head or for whole body scanners operated in the head scanning mode.

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(5) These radiation output measurements shall be required for ~~each~~ a representative type of head and body~~, or whole-body~~ scans performed at the facility.

(6) ~~These radiation measurements shall meet the following requirements:~~ The CTDI[34] along the two (2) axes specified in F.10.3(b)(4)(ii) shall be measured. The CT dosimetry phantom shall be oriented so that the measurement point 1.0 centimeter from the outer surface and within the phantom is in the same angular position within the gantry as the point of maximum surface CTDI identified. The CT conditions of operation shall correspond to typical values used by the registrant.

~~(i) The dose profile along the center axis of the CT dosimetry phantom for the minimum, maximum, and midrange values of the nominal tomographic section thickness used by the registrant shall be measurable. Where less than three (3) nominal tomographic thicknesses can be selected, the dose profile determination shall be performed for each available nominal tomographic section thickness.~~

~~(ii) The CTDI along the two axes specified in F.10.3(b)(4)(ii) shall be measured. The CT dosimetry phantom shall be oriented so that the measurement point 1.0 centimeter from the outer surface and within the phantom is in the same angular position within the gantry as the point of maximum surface CTDI identified. The CT conditions of operation shall correspond to typical values used by the registrant.~~

~~(iii)~~ ~~The spot-checks specified in F.10.3(c) shall be made~~.

(7) Procedures for measurement of radiation output shall be in writing. Records of radiation measurements performed shall be maintained for inspection by the Agency.

(8) The dose profile along the center axis of the CT dosimetry phantom for the minimum, maximum, and midrange values of the nominal tomographic section thickness used by the registrant shall be readily available.

(c) **Spot-checks.**

(1) The spot-check procedures shall be in writing and shall have been developed by a ~~person registered with the Agency to provide Diagnostic X-ray Physics Services~~ Qualified Medical Physicist.

(2) The spot-check procedures shall incorporate the use of a CT imaging phantom which has ~~a~~ the capability of providing an indication of contrast scale, noise, nominal tomographic section thickness, the resolution capability of the system for low and high contrast objects, and measuring the mean CTN for water or other reference material.

(3) ~~All~~ Spot-checks shall be ~~included in~~ evaluated for compliance with tolerance limits specified pursuant to F.10.3(c)(1) at the time the radiation measurements required by F.10.3(b) are performed. ~~and at time intervals and under system conditions specified by a person registered with the Agency to provide Diagnostic X-ray Physics Services~~.

[34] For the purpose of determining the CTDI, the manufacturer's statement as to the nominal tomographic section thickness for that particular system may be utilized.

(4) Spot-checks shall include acquisition of images obtained with the CT ~~phantom(s)~~ imaging phantoms. ~~using the same processing mode and CT conditions of operation as are used to perform radiation measurements required by F.10.3(b).~~ The images shall be retained~~,~~ until a new set of radiation measurements is performed~~, in two forms~~ as follows:

(i) If applicable, photographic copies of the images obtained from the image display device; ~~and~~

(ii) Images stored in digital form on a storage medium compatible with the CT X-ray system; and

(iii) Acceptance criteria for image validation shall be documented.

(5) The registrant shall maintain a record of each spot check required by F.10.3(c) for three (3) years ~~Written records of the spot-checks performed shall be maintained for inspection by the Agency~~.

(d) **Operating Procedures.**

(1) The CT X-ray system shall not be operated except by an individual who has been specifically trained in its operation.

(2) Information shall be readily available ~~at the control panel~~ regarding the operation ~~and measurements of radiation output~~ of the system. Such information shall include the following:

(i) ~~Dates of~~ The latest set of radiation measurements and spot-checks ~~and the location within the facility where the results of those tests may be obtained~~;

(ii) Instructions ~~for performing spot-checks,~~ on the use of the CT imaging phantom including a schedule of spot-checks appropriate for the system, and allowable variations for the indicated parameters~~, and the results of at least the most recent spot-checks conducted on the system~~;

(iii) The distance in millimeters between the tomographic plane and the reference plane if a reference plane is utilized; and

(iv) ~~A~~ Current ~~technique chart~~ imaging protocols shall be available at the control panel which ~~specifies~~ specify ~~for each routine examination~~ the CT conditions of operation and the number of scans ~~per examination~~ for each routine examination.

(3) If the measurement of radiation output or spot-check of the CT X-ray system identifies that a system operating parameter has exceeded a tolerance established by a ~~person registered with the Agency to provide Diagnostic X-ray Physics Services~~ Qualified Medical Physicist, report the problem to the service engineer and notify the Qualified Medical Physicist. The registrant shall maintain a record of all such notifications for three (3) years. ~~use of the CT X-ray system on patients shall be limited to those uses permitted by established written instructions of the a person registered with the Agency to provide Diagnostic X-ray Physics Services~~.

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F.11 MAMMOGRAPHY

F.11.1 **Applicability.**

(a) The provisions of this subpart are in addition to, and not in substitution for, other applicable provisions of these Regulations.

(b) ~~In addition to the requirements contained in these regulations~~ To the extent that such provisions are consistent with the Mammography Quality Standards Reauthorization Act of 1998, Public Law 105-248, and

21 C.F.R. Part 900, all aspects of mammography services shall also be managed in accordance with the provisions of the *Rules & Regulations Related to Quality Assurance Standards for Mammography* (*R23-1-MAM*) of the Rhode Island Department of Health. ~~and applicable U.S. Food and Drug Mammography Quality Standards Act (FDA/MQSA) requirements~~ In the event of a conflict between the respective regulatory provisions, the requirements established by the Mammography Quality Standards Reauthorization Act of 1998, Public Law 105-248, and 21 C.F.R. Part 900 shall apply.

F.11.2 **Certification Requirements**.

(a) Only X-ray systems in compliance with the requirements of the Mammography Quality Standards Reauthorization Act of 1998, Public Law 105-248, and 21 C.F.R. Part 900 shall be used for screening and diagnostic mammography.

(b) A facility performing mammography shall have a valid certificate issued by the U.S. Department of Health and Human Services, pursuant to the Mammography Quality Standards Reauthorization Act of 1998, Public Law 105-248, and 21 C.F.R. Part 900.

(c) A facility performing mammography shall ensure that the additional mammography activities of processing the x-ray film, interpreting the image, and maintaining viewing conditions, wherever performed, meet all quality standards pursuant to the Mammography Quality Standards Reauthorization Act of 1998, Public Law 105-248, and 21 C.F.R. Part 900.

~~F.11.2 **Technical Requirements**.~~

~~(a) **Purpose and Scope.** This subpart establishes technical requirements for X-ray systems, X-ray film processors, phantom imaging, mammography operator training, measurement of mammographic doses and establishment of Quality Assurance Programs at all facilities providing mammographic imaging services.~~

~~(b) **X-ray System Requirements.** All X-ray systems used for mammographic imaging shall comply with, as a minimum, the following technical specifications:~~

~~(1) The X-ray system shall be designated by its manufacturer solely for use with xerography or mammographic film/screen.~~

~~(2) The X-ray system shall be equipped with compression devices which will effectively immobilize the breast.~~

~~(3) The X-ray system shall be equipped with a Molybdenum target/Molybdenum filtration combination for all film/screen modalities, or Tungsten target/Aluminum filtration for xerography. Any other target/ filtration combination must be consistent with applicable FDA/ MQSA requirements.~~

~~(4) The X-ray system focal spot size shall be maintained in accordance with the most current FDA/ MQSA requirements.~~

~~(5) The X-ray system shall have the capability of using anti-scatter grids which have been specifically designed for the mammographic (film/screen) imaging modality being utilized.~~

~~(6) All X-ray systems purchased after 15 January 1991 shall have the capability of automatic exposure control (AEC) for all film/screen imaging modalities.~~

~~(c) **X-Ray Film Processor Requirements.** Each mammographic imaging facility shall ensure that any X-ray film processor used for processing mammographic images at said facility is in compliance with, as a minimum, the following technical requirements:~~

~~(1) The processing parameters (e.g. processing temperature, cycle time, replenishment, etc.) shall be optimized to meet the manufacturer's requirements for the specific film being used for mammographic~~

~~imaging.~~

~~(2) The processing parameters shall be commensurate with the workload of the facility to ensure processing with viable chemistry.~~

~~(d) **Xerography Conditioner and Processor Requirements.** Each mammographic imaging facility performing xerography shall ensure that the conditioner and processor is optimized to meet the manufacturer's requirements for the specific mode used for xerographic imaging of the breasts.~~

~~(e) **Phantom Imaging Requirements.** The phantom images shall meet the evaluation criteria for mammography accreditation established by the American College of Radiology (ACR). The current ACR criteria is based on the RMI 156 phantom.~~

~~(f) **Measurement of Average Glandular Dose.**~~

~~(1) The average glandular dose for one (1) craniocaudal view of a 4.5 centimeter compressed breast [fifty percent (50%) adipose and fifty percent (50%) glandular tissue] shall be measured by a person registered with the Agency to provide Diagnostic X-ray Physics Services to Mammography Facilities. This measurement shall be made:~~

~~(i) Prior to the first use of the unit for mammographic imaging of humans;~~

~~(ii) Following each replacement of the X-ray tube;~~

~~(iii) Following any repair or replacement of major X-ray system components that may affect the output of the X-ray tube; and~~

~~(iv) At intervals not to exceed one (1) year.~~

~~(2) The average measured glandular dose per view shall not exceed the following parameters:~~

~~(i) 100 millirad (1.0 mGy) for film screen units without grids;~~

~~(ii) 300 millirad (3.0 mGy) for film/screen units with grids, or Xerox 175 systems;~~

~~(iii) 400 millirad (4.0 mGy) for Xerox 125 or 126 systems.~~

~~(3) The written record of the results of all measurements required by Paragraph F.11.2 (f)(1) above shall be maintained and shall include, as a minimum, average glandular dose (mrad), the name of the person performing the measurements, the date the measurements were performed, identification of the phantom(s) used to obtain such results, and the technique factors used to determine such results. Results of these measurements shall be posted where any mammographic operator shall have ready access to such results while operating the mammographic X-ray unit and also filed with the records required by Paragraph F.2.13(e) of the RI Rules and Regulations for the Control of Radiation.~~

~~(g) **Evaluation of the Adequacy and Effectiveness of the Overall Imaging Program.**~~

~~(1) Each mammographic imaging facility shall develop and implement an ongoing Quality Assurance Program specific to mammographic imaging.~~

~~(i) The Quality Assurance Program shall be developed and conducted by a Radiologist, as qualified in Section 3.0 of the Rules & Regulations related to Quality Assurance Standards for Mammography (R23-1-MAM), in conjunction with a person registered with the Agency to provide Diagnostic X-ray Physics Services to Mammography Facilities.~~

~~(ii) This Quality Assurance Program shall be performed by an ARRT registered Radiologic Technologist who has had specific training, which is acceptable to the Agency and covers Quality Assurance procedures for both the radiographic and processing systems.~~

~~(2) The Quality Assurance Program shall also include a written procedures manual which describes in~~

~~detail the tests to be performed, the frequency for each test, the criteria for acceptability of each test and the actions to be taken when test results are outside the established criteria. A log shall be kept listing the results of all Quality Assurance testing and the actions taken to correct any problems uncovered by testing.~~

~~(3) The Quality Assurance Program shall be reviewed by a Radiologist, as qualified in Section 3.0 of the Rules & Regulations related to Quality Assurance Standards for Mammography (R23-1-MAM), in conjunction with a person registered with the Agency to provide Diagnostic X-ray Physics Services to Mammography Facilities. This review shall take place at intervals not to exceed one (1) year and shall be documented in writing.~~

~~(4) The minimum Quality Assurance testing parameters and frequencies are listed in Appendix C to this part.~~

F.11.3 **Retention of Mammography X-rays.** Pursuant to RIGL §23-4.9-1, each mammographic imaging facility that takes a mammography x-ray of any individual within Rhode Island shall keep and maintain that mammography x-ray for the life of the individual. However, any mammography x-ray may be destroyed if the individual has had no contact with the mammographic imaging facility for a period exceeding fifteen (15) years.

F.12 BONE DENSITOMETRY

F.12.1 Bone densitometry systems shall be:
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(c) Maintained and operated in accordance with the manufacturer's specifications and recommendations.

F.12.2 **Equipment Requirements.** Systems with stepless collimators shall be provided with means to both size and align the X-ray field such that the X-ray field at the plane of the image receptor does not extend beyond ~~2~~ two percent (2%) of the SID.

F.12.3 Operators of bone densitometry systems shall be:

(a) Licensed as a practitioner of the healing arts; or

(b) Individuals who possess a current license in accordance with the *Rules and Regulations for the Licensure of Radiographers, Nuclear Medicine Technologists, ~~and~~ Radiation Therapists and Radiologist Assistants* [*R5-68.1-RAD*] of the Rhode Island Department of Health, unless the individual is specifically exempted from licensure by Section ~~6.0~~ 2.0 of said regulations; or

(c) Individuals who are not subject to licensure under R5-68.1-RAD and have been instructed in the proper use of the bone densitometry system. As a minimum, such instruction shall include:
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***

F.12.5 The registrant shall keep maintenance records for bone densitometry systems as prescribed by F.12.1(c). These records shall be maintained for inspection by the Agency for five (5) years from the date the maintenance action was completed.
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F.13 QUALITY ASSURANCE PROGRAM.

F.13.1 Effective 1 July 2014, all registrants[35, 36] of diagnostic X-ray imaging equipment shall establish and maintain a quality assurance program consisting of quality control assessments addressing at least the following items:

(a) **Administration**:

(1) Written standard operating procedures on radiation protection are reviewed and updated annually by management;

(2) Employee review and written acknowledgement of standard operating procedures and policies on radiation protection;

(3) Credentialing of practitioners, medical physicists, and X-ray equipment operators; and

(4) Record retention in accordance with applicable Rhode Island statutes and regulations, but in no case less than three (3) years.

(b) **Image Processing Equipment**: Compliance with Section F.2.10;

(c) **Radiographic Equipment:**

(1) Compliance with performance standards in Sections F.3 and F.5, as specified by a Qualified Medical Physicist;

(2) Estimated entrance skin exposures for selected patient examinations;

(3) Image printing and viewing equipment;

(4) Evaluation of image quality; and

(5) Radiation protection.

(d) **Fluoroscopic Equipment:**

(1) Compliance with performance standards in Sections F.3 and F.4, as specified by a Qualified Medical Physicist;

(2) Low and high contrast resolution; and

(3) Radiation protection.

(e) **Computerized Tomography Equipment:**

(1) Compliance with performance standards in Section F.10, as specified by a Qualified Medical Physicist;

(2) CT number;

(3) Low and high contrast resolution;

(4) Dosimetry of selected patient examinations to include pediatric patients if applicable;

(5) Image printing and viewing equipment; and

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[35] The requirements of Subpart F.13 do not pertain to diagnostic X-ray imaging equipment subject to the Mammography Quality Standards Reauthorization Act of 1998, Public Law 105-248, and 21 C.F.R. Part 900.

[36] Registrants performing diagnostic radiography limited to intra-oral dental procedures and/or panoramic procedures and cephalometric procedures which do not utilize an open beam configuration are only required to comply with Sections F.13.1(a)(1), (a)(2), (a)(4) and (b) of Subpart F.13.

(6) Radiation protection.

(f) **Bone Densitometry Equipment: C**ompliance with requirements in Section F.12.

F.13.2 The quality assurance program shall be in written form and available for review by the Agency.

F.13.3 **Implementation of Quality Assurance Program**

(a) The registrant shall assign qualified personnel to fully implement the quality assurance program. Quality control assessments for F.13.1(b), (c), (d) and (e) shall be conducted by, or under the direction of, a Qualified Medical Physicist.

(b) A Qualified Medical Physicist shall determine the frequency and nature of quality control tests, except when the frequency for a specific quality control test is defined by these Regulations.

(c) A Qualified Medical Physicist shall perform a review of the Quality Assurance Program at an interval not to exceed twelve (12) months, and shall provide a written report which documents the results of this review.

PART F

APPENDIX A

INFORMATION TO BE SUBMITTED BY PERSONS PROPOSING TO CONDUCT HEALING ARTS SCREENING

Persons requesting that the Agency approve a healing arts screening program shall submit the following information and evaluation:

1. Name and address of the applicant and, where applicable, the names and addresses of agents within this State.
2. Diseases or conditions for which the X-ray examinations are to be used in diagnoses.
3. A description ~~in detail~~ of the X-ray examinations proposed in the screening program (i.e., type and number of views).
4. Description of the population to be examined in the screening program (i.e., age range, ~~sex~~ gender, physical condition, and other appropriate information.
5. An evaluation of any known alternate methods not involving ionizing radiation ~~which~~ that could achieve the goals of the screening program and why these methods are not used in preference to the X-ray examinations.
6. An evaluation, conducted by a Qualified Medical Physicist, ~~expert~~ of the X-ray system(s) to be used in the screening program. The evaluation ~~by the qualified expert~~ shall ~~show that such system(s) do satisfy all requirements of these regulations~~ include the following:

   (i) Documentation that such system(s) satisfy all requirements of these Regulations; and

   (ii) Estimation of patient entrance skin exposures from the X-ray examinations to be performed;
7. A description of the diagnostic ~~film~~ X-ray quality control program.
8. ~~A copy~~ Documentation of the techniques ~~chart~~ for the X-ray examination procedures to be used.
9. The ~~qualifications~~ name and RI license number of each ~~individual~~ radiologic technologist who will be operating the X-ray system(s).
10. The ~~qualifications~~ name and RI license number of each ~~individual~~ health care provider(s) who will be supervising the operators of the X-ray system(s). The extent of supervision and the method of work performance evaluation shall be specified.
11. The name and address of the ~~individual~~ Rhode Island-licensed practitioner of the healing arts who will interpret the ~~radiograph(s)~~ images.
12. ~~A description of the~~ Procedures to be used in advising the individuals screened and their ~~private practitioners of the healing arts~~ health care provider(s) of the results of the screening procedure and any further medical needs indicated.
13. ~~A description of the~~ Procedures for the retention or disposition of the ~~radiograph(s)~~ images and other records pertaining to the X-ray examinations.
14. Frequency of screening of individuals.
15. The duration of the screening program

PART F

APPENDIX B

INSTRUCTION OF USERS OF X-RAY EQUIPMENT IN THE HEALING ARTS

I. **Fundamentals of Radiation Safety**

A. Characteristics of x-radiation

B. Units of radiation dose ~~(mrem)~~

C. Hazards of excessive exposure to radiation

D. Levels of radiation from sources of radiation

E. Methods of controlling radiation dose

1. Working time
2. Working distances
3. Shielding

II. **Radiation Detection Instrumentation to be Used**

A. Radiation survey instruments

1. Operation
2. Calibration
3. Limitations

B. Survey, monitoring and spot-check techniques

C. Personnel monitoring devices

~~1. Film badges~~
~~2. Pocket dosimeters~~
~~3. Thermoluminescent dosimeters~~

D. Interpretation of personnel monitoring reports

III. **Operation and Control of X-ray Equipment**

A. Collimation and Filtration

B. Exposure techniques for the equipment used

C. ~~Film~~ Image processing techniques

D. Anatomy and positioning

1. Relevant human anatomy
2. Relevant human physiology
3. Radiographic positioning

IV. **The requirements of pertinent federal and state regulations**

V. **The licensee's or registrant's written operating and emergency procedures**

PART F

APPENDIX C – [REMOVED]

~~**MINIMUM QUALITY ASSURANCE TESTING PARAMETERS AND FREQUENCIES**~~

~~1. **X-RAY EQUIPMENT PARAMETERS.** The following X-ray equipment parameters must be checked after any changes in exposure technique and/or imaging modality, major repair/replacement of X-ray system components, as required by F.11.2, and at intervals not to exceed one (1) year.~~

~~(a) Measurement of Average Glandular Dose~~

~~(b) Half-Value Layer (HVL)~~

~~(c) Accuracy and Reproducibility of kVp Stations~~

~~(d) Accuracy and Reproducibility of Timer Stations (If Applicable)~~

~~(e) Linearity and Reproducibility of mA Stations (If Applicable)~~

~~(f) Reproducibility of X-ray Output in AEC and Manual Modes~~

~~(g) Accuracy of Source-to-Film Distance Indicators (If Applicable)~~

~~(h) Light/X-ray Field Congruence (If Applicable)~~

~~(i) Accuracy of Thickness Indicator on Compression Device~~

~~(j) Verification of Back-up Timer for AEC Operation~~

~~2. **PROCESSOR PARAMETERS:**~~

~~(a) The following film processor parameters must be checked at intervals not to exceed those specified below:~~

~~**PARAMETER**~~	~~**FREQUENCY**~~
~~(1) Speed Index Consistency~~	~~Daily~~
~~(2) Contrast Index Consistency~~	~~Daily~~
~~(3) Base Plus Fog Consistency~~	~~Daily~~
~~(4) Developer Solution Temperature~~	~~Daily~~
~~(5) Film Fogging, Light Leaks and Safelight Filter Condition and Location~~	~~Six (6) Months~~
~~(6) Processor Artifact Identification~~	~~Continuous~~
~~(7) Processor Maintenance/Cleaning~~	~~Manufacturers' Recommendations~~

~~(b) The following xeroradiographic conditioner/processor parameters must be checked at intervals not to exceed those specified below:~~

~~**PARAMETER**~~	~~**FREQUENCY**~~
~~(1) Dark Dusting~~	~~Weekly~~

~~**[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]**~~

~~Appendix C(3)~~

~~3. **EQUIPMENT CONDITION PARAMETERS.** The following equipment condition parameters must be checked at intervals not to exceed those specified below:~~

~~PARAMETER~~	~~FREQUENCY~~
~~(a) Screen Condition Evaluated~~	~~Daily~~
~~(b) Screens Cleaned~~	~~As Required~~
~~(c) Screen/Film Contact Evaluated~~	~~Semi-Annually & When Changed~~
~~(d) Screen Artifact Identification~~	~~Continuous~~
~~(e) Viewbox Light Output Consistency Between Viewboxes and Over Time~~	~~Annual~~
~~(f) Label Cassettes~~	~~On Receipt and As Needed~~
~~(g) Xerography~~	
~~(1) Clean Aluminized Mylar Foil In Cassette~~	~~Weekly~~
~~(2) X-ray Sponges~~	~~Weekly~~

~~4. **SYSTEM CHECKS.** The following system checks must be performed at intervals not to exceed those specified below:~~

~~PARAMETER~~	~~FREQUENCY~~
~~(a) Phantom Imaging~~	~~Initial Baseline and After Major Repair or Change in Film/Screen~~
~~(b) Comparison of Phantom Image Quality to Initial Baseline and Minimum Phantom Imaging Criteria~~	~~Weekly~~

~~[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]~~

PART F

APPENDIX D

HAND-HELD INTRAORAL DENTAL RADIOGRAPHIC UNIT REQUIREMENTS FOR USE

The following requirements are applicable to intraoral dental radiographic units designed to be operated as a hand-held unit:

1. **For All Uses**:

(a) Operators of hand-held intraoral dental radiographic units shall be specifically trained to operate such equipment.

(b) When operating a hand-held intraoral dental radiographic unit, operators shall wear a protective apron and thyroid collar, unless otherwise authorized by the Agency or recommended by a Qualified Medical Physicist.

(c) A hand-held intraoral dental radiographic unit shall be held with minimal motion during a patient examination. A tube stand may be utilized to immobilize a hand-held intraoral dental radiographic unit during patient examination.

(d) Unless otherwise authorized by the Agency, a hand-held intraoral dental radiographic unit shall be used with a secondary radiation block to shield the operator.

(e) The operator shall ensure there are no bystanders within a radius of six (6) feet from the patient being examined with a hand-held intraoral radiographic unit.

(f) Hand-held intraoral dental radiographic units shall not be used for patient examinations in hallways and waiting rooms.

(g) The registrant shall comply with any facility-specific requirements established by the Agency

2. **Additional Requirements for Operatories in Permanent Facilities:** When hand-held intraoral dental radiographic units are used for patient examinations in dental operatories, that facility shall meet the structural shielding requirements specified by the Agency or by a health physicist or Qualified Medical Physicist.

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PART H
THERAPEUTIC RADIATION MACHINES

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H.2 DEFINITIONS

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Electronic Brachytherapy means a method of radiation therapy ~~in which a X-ray source is used to apply radiation directly to tissue within the body by surface, intracavitary, intraluminal or interstitial application~~ where an electrically generated source of ionizing radiation is placed in or near the tumor or target tissue to deliver a therapeutic radiation dose.

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.

***

Misadministration means an event that meets the criteria in H.5.2.

***

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.

***

Patient means an individual subjected to machine produced ~~external beam~~ radiation for the purpose(s) of medical therapy.

***

Periodic quality assurance check means a procedure which is performed to ensure that a previous ~~calibration~~ parameter or condition continues to be valid.

***

Prescribed dose means 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 radiation 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.

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~~Radiotherapy Physicist means an individual qualified in accordance with H.3.4.~~

***

Recordable event means the administration of a therapeutic radiation machine dose when the calculated weekly administered dose differs by fifteen percent (15%) or more from the weekly prescribed dose.

***

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

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Written directive means an order in writing for the administration of radiation to a specific patient or human research subject, as specified in H.5.1.

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H.3 GENERAL ADMINISTRATIVE REQUIREMENTS FOR FACILITIES USING THERAPEUTIC RADIATION MACHINES

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H.3.3 **Training for ~~External Beam Radiation Therapy~~ Therapeutic Radiation Machine Authorized Users.** The registrant for any therapeutic radiation machine subject to H.6 or H.7 shall require the Authorized User to be a physician who:

(a) Is certified in:

(1) ~~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; or

(2) Radiation oncology by the American Osteopathic Board of Radiology; or

(3) Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

(4) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

(b) Is in the active practice of therapeutic radiology, and has completed two hundred (200) hours of instruction in basic radiation techniques applicable to the use of an external beam radiation therapy unit, five hundred (500) hours of supervised work experience, and a minimum of three (3) years of supervised clinical experience.

***

(3) To satisfy the requirement for a period of supervised clinical experience, training shall include one (1) 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 (2) years of clinical experience in therapeutic radiology under the supervision of an Authorized User. The supervised clinical experience shall include:

(i) Examining individuals and reviewing their case histories to determine their suitability for external beam radiation therapy treatment, and any limitations/contraindications;

(ii) Selecting proper dose and how it is to be administered;

(iii) Calculating the ~~external beam radiation therapy~~ therapeutic radiation machine doses and collaborating with the Authorized User in the review of patients'/human research subjects' progress and consideration of the need to modify originally prescribed doses and/or treatment plans as warranted by patients'/human research subjects' reaction to radiation; and

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H.3.4 **Training for ~~Radiotherapy~~ Qualified Medical Physicist.** The registrant for any therapeutic radiation machine subject to H.6 or H.7 shall require the ~~Radiotherapy~~ Qualified Medical Physicist to:

(a) Be registered with the Agency, under the provisions of Part B of these regulations, as a provider of radiation services in the area of calibration and compliance surveys of external beam radiation therapy units.

and

(b) Be certified by the American Board of Radiology in:

(1) Therapeutic radiological physics; or

(2) Roentgen-ray and gamma-ray physics; or

(3) X-ray and radium physics; or

(4) Radiological physics; or

(5) Therapeutic medical physics; or

(c) Be certified by the American Board of Medical Physics in Radiation Oncology Physics; or

(d) Be certified by the Canadian College of Physicists in Medicine (CCPM) ~~Medical Physics~~ in Radiation Oncology Physics.

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H.3.5 **Qualifications of Operators.**

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(b) 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 (2) years beyond the last date they were authorized to operate a therapeutic radiation machine at that facility.

H.3.6 Written safety procedures and rules shall be developed by a ~~Radiotherapy~~ 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.

H.3.7 Individuals shall not be exposed to the useful beam except for medical therapy purposes and unless such exposure has been ordered in writing by ~~an external beam radiation therapy~~ a therapeutic radiation machine Authorized User. This provision specifically prohibits deliberate exposure of an individual for training, demonstration or other non-healing-arts purposes.

H.3.8 **Visiting Authorized User.** Notwithstanding the provisions of H.3.7, 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 sixty (60) days per calendar year under the following conditions:

(a) 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

(b) The Visiting Authorized User meets the requirements established for Authorized User(s) in H.3.3(a) and H.3.3(b); and

(c) The registrant ~~maintains~~ shall maintain copies of ~~all records specified by H.3.8~~ the written permission required in H.3.8(a) and documentation that the Visiting Authorized User met the requirements of H.3.8(b) for five (5) years from the date of the last visit.

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H.4 GENERAL TECHNICAL REQUIREMENTS FOR FACILITIES USING THERAPEUTIC RADIATION MACHINES

H.4.1 **Protection Surveys.**

(a) 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 H.8. The radiation protection survey shall be performed by, or under the direction of, a ~~Radiotherapy~~ Qualified Medical Physicist or a Certified Health Physicist 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:

***

(c) The survey record shall indicate all instances where the facility, in the opinion of the ~~Radiotherapy~~ Qualified Medical Physicist or a Certified Health Physicist, is in violation of applicable regulations. The survey record shall also include the date of the measurements, the reason the survey is required, the manufacturer's name, model number and serial number of the therapeutic radiation machine, the instrument(s) used to measure radiation levels, a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in microsieverts or millirems per hour, the calculated maximum level of radiation over a period of one (1) week for each restricted and unrestricted area, and the signature of the individual responsible for conducting the survey.

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H.4.3 **Dosimetry Equipment.**

(a) 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 twenty-four (24) months and after any servicing that may have affected system calibration.

***

(b) 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 H.4.3(a). This comparison shall have been performed within the previous twelve (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 H.4.3(a).

(c) The registrant shall maintain a record of each dosimetry system calibration, intercomparison, and comparison for the duration of the license and/or registration. For each calibration, intercomparison, or comparison, the record shall include the date, the model numbers and serial numbers of the instruments that were calibrated, inter-compared, or compared as required by H.4.3(a) and H.4.3(b), 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 ~~Radiotherapy~~ Qualified Medical Physicist.

H.4.4 **Reports of External Beam Radiation Therapy Surveys and Measurements.** The registrant for any therapeutic radiation machine subject to H.6 or H.7 shall furnish a copy of the records required in H.4.1 and H.4.2 to the Agency within thirty (30) days following completion of the action that initiated the record requirement.

H.5 QUALITY MANAGEMENT PROGRAM

H.5.1 ~~In addition to the definitions in H.2, the following definitions are applicable to a quality management~~

~~program:~~

~~(a) Prescribed dose means the total dose and dose per fraction as documented in the written directive.~~

~~(b) Misadministration means the administration of an external beam radiation therapy dose:~~

~~(1) Involving the wrong patient/human research subject, wrong mode of treatment, or wrong treatment site; or~~

~~(2) When the treatment consists of three (3) or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose; or~~

~~(3) When the calculated weekly administered dose differs from the weekly prescribed dose by more than 30 percent; or~~

~~(4) When the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose.~~

~~(c) Recordable event means the administration of an external beam radiation therapy dose when the calculated weekly administered dose differs by 15 percent or more from the weekly prescribed dose.~~

~~(d) Written directive means an order in writing for a specific patient/human research subject, dated and signed by an authorized user prior to the administration of radiation, containing the following information: total dose, dose per fraction, treatment site and overall treatment period.~~

~~H.5.2~~ **Scope and Applicability.** Each applicant or registrant subject to H.6, ~~or~~ H.7 or H.11 shall ~~establish~~ develop, implement and maintain a written quality management program to provide high confidence that radiation will be administered as directed by the Authorized User. The quality management program shall address, as a minimum, ~~include written policies and procedures to meet~~ the following specific objectives:

(a) **Written Directive.** ~~Prior to administration, a written directive is prepared for any external beam radiation therapy dose.~~

(1) A written directive must be dated and signed by an Authorized User prior to the administration of radiation. ~~Notwithstanding H.5.2(a), 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 administration of the external beam radiation therapy dose or the next external beam radiation therapy fractional dose~~;

(2) Notwithstanding H.5.2(a)(1), if, because of the patient's/human research subject's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's/human research subject's health, an oral revision to an existing written directive shall be acceptable, provided that the oral revision is documented immediately in writing in the patient's/human research subject's record and a revised written directive is signed by an Authorized User within forty-eight (48) hours of the oral revision;

~~(3) Notwithstanding H.5.2(a), if, because of the emergent nature of the patient's/human research subject's condition, a delay in order to provide a written directive would jeopardize the patient's/human research subject's health, an oral directive shall be acceptable, provided that the information contained in the oral directive is documented immediately in the patient's/human research subject's record and a written directive is prepared and signed by an authorized user within 24 hours of the oral directive.~~

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

(4) 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.

(5) The registrant shall retain a copy of each written directive, in an auditable form, for three (3) years after the date of administration.

(b) **Procedures for Administrations.** The registrant shall develop, implement, and maintain written procedures to provide high confidence that:

(1) Prior to the administration of each course of radiation treatments, the patient's/human research subject's identity is verified, by more than one method, as the individual named in the written directive;

~~(c)~~(2)Therapeutic radiation machine final plans of treatment and related calculations are in accordance with the respective written directives by.

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

(ii) Verifying that any manual and computer-generated calculations are correctly transferred into the consoles of therapeutic radiation machines;

~~(d)~~(3)Each administration is in accordance with the written directive. and

~~(e)~~(4)Any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

(5) A registrant shall retain a copy of the procedures required by H.5.1(b) for the duration of the registration.

H.5.2 **Reports and Notifications of Misadministrations.**

(a) A registrant shall report any event resulting from intervention by 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.

(b) Other than events that result from intervention by a patient or human research subject, a registrant shall report any event in which the administration of a therapeutic radiation machine therapy dose:

(1) Involves the wrong patient, wrong treatment modality, or wrong treatment site; or

(2) The calculated weekly administered dose differs from the weekly prescribed dose by more than thirty percent (30%); or

(3) The calculated total administered dose differs from the total prescribed dose by more than twenty percent (20%) of the total prescribed dose;

(c) The registrant shall notify the Agency by telephone[37] no later than the next calendar day after discovery of the misadministration.

(d) The registrant shall submit a written report to the Agency within fifteen (15) days after discovery of the misadministration. The written report shall include:

(1) The registrant's name;

(2) The name of the prescribing physician;

(3) A brief description of the event;

[37] During normal business hours, the Agency may be contacted at (401) 222-2566. At other times, this number will allow you to leave a message on the answering machine. In case of an emergency when it is necessary to immediately contact the Agency, utilize the RI Department of Health 24 hour number [(401) 272-5952] and indicate the nature of your emergency. FAX communication may be sent 24 hours a day to (401) 222-5901.

(4) Why the event occurred;

(5) The effect, if any, on the individuals(s) who received the misadministration;

(6) Actions, if any, that have been taken, or are planned, to prevent recurrence;

(7) Certification that the registrant notified the individual (or the individual's responsible relative or guardian), and if not, why not; and

(8) If there was notification, what information was provided to the individual.

(e) The report shall not contain the individual's name or any other information that could lead to the identification of the individual. To meet the requirements of this Section, the notification of the individual receiving the misadministration may be made instead to that individual's responsible relative or guardian, when appropriate.

(f) (1) 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 twenty-four (24) hours after its discovery, unless the referring physician personally informs the registrant either that he or she 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 twenty-four (24) hours, the registrant shall notify the individual as soon as possible thereafter. The registrant shall 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.

(2) To meet the requirements of H.5.2(b)(1), 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 either a copy of the report that was submitted to the Agency, or a written description of both the event and the consequences as they may effect the can be obtained from the registrant upon request. The registrant shall provide such a written description if requested.

(g) Aside from the notification requirement, nothing in H.5.2 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.

(h). The registrant shall retain a record of a misadministration in accordance with H.5.3. A copy of the record required shall be provided to the referring physician if other than the registrant within fifteen (15) days after discovery of the misadministration.

~~H.5.3 **Development of Quality Management Program.** Each application for registration subject to H.6 or H.7 shall include a quality management program that specifies staff, duties and responsibilities, and equipment and procedures as part of the application required by Part B of these regulations. The registrant shall implement the program upon issuance of a Certificate of Registration by the Agency.~~

H.5.3 **Records of Misadministrations.** A registrant shall retain a record of misadministrations reported in accordance with H.5.2 for three (3) years. The record shall contain the following:

(a) The registrant's name and the names of the individuals involved (including the prescribing physician, allied health personnel, the individual who received the misadministration, and the individual's referring physician, if applicable);

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

(c) A brief description of the event; why it occurred; the effect, if any, on the individual;

(d) The actions, if any, taken or planned to prevent recurrence; and

(e) 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.

H.5.4 **Implementation of Quality Management Program.** As a part of the quality management program, the registrant shall:

(a) Develop procedures for, and conduct a review of, the quality management program including, since the last review, an evaluation of a representative sample of patient/human research subject administrations, all recordable events, and all misadministrations to verify compliance with all aspects of the quality management program.

(b) Conduct these reviews at intervals not to exceed twelve (12) months.

(c) Evaluate each of these reviews to determine the effectiveness of the quality management program and, if required, make modifications to meet the requirements of ~~H.5.2~~ H.5.1; and

(d) Maintain records of each review, including the evaluations and findings of the review, in an auditable form, for three (3) years.

H.5.5 The registrant shall evaluate and respond, within thirty (30) days after discovery of the recordable event, to each recordable event by:

(a) Assembling the relevant facts including the cause;

(b) Identifying what, if any, corrective action is required to prevent recurrence; and

(c) Retaining a record, in an auditable form, for three (3) years, of the relevant facts and what corrective action, if any, was taken.

H.5.6 ~~The registrant shall retain:~~

~~(a) Each written directive; and~~

~~(b) A record of each administered radiation dose, in an auditable form, for years after the date of administration.~~

~~H.5.7~~ The registrant may make modifications to the quality management program to increase the program's efficiency provided the program's effectiveness is not decreased.

~~H.5.8 The registrant shall evaluate each misadministration and shall take the following actions in response to a misadministration:~~

~~(a) Notify the Agency by telephone[38] no later than the next calendar day after discovery of the misadministration.~~

~~(b) Submit a written report to the Agency within 15 days after discovery of the misadministration. The written report shall include: the registrant's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the individual who received the misadministration; what~~

[38] ~~During normal business hours, the Agency may be contacted at (401) 222-2438. At other times, this number will allow you to leave a message on the answering machine. In case of an emergency when it is necessary to immediately contact the Agency, utilize the RI Department of Health 24 hour number [(401) 272-5952] and indicate the nature of your emergency. FAX communication may be sent 24 hours a day to (401) 222-2456.~~

~~improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the registrant notified the individual or the individual's responsible relative or guardian, and if not, why not, and if there was notification, what information was provided to the individual. The report shall not include the individual's name or other information that could lead to identification of the individual. To meet the requirements of this Section, the notification of the individual receiving the misadministration may be made instead to that individual's responsible relative or guardian, when appropriate.~~

~~(c) Notify the referring physician and also notify the individual who received the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the registrant either that he/she 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 individual who received the misadministration cannot be reached within 24 hours, the registrant shall notify the individual as soon as possible thereafter. The registrant shall 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.~~

~~(d) If the individual was notified, furnish, within 15 days after discovery of the misadministration, a written report to the individual by sending either a copy of the report that was submitted to the Agency, or a brief description of both the event and the consequences as they may effect the individual, provided a statement is included that the report submitted to the Agency can be obtained from the registrant. and~~

~~(e) Retain a record of each misadministration for 5 years. The record shall contain the names of all individuals involved (including the prescribing physician, allied health personnel, the individual who received the misadministration, and the individual's referring physician, if applicable), the individual's social security number or identification number if one has been assigned, a brief description of the event, why it occurred, the effect on the individual, what improvements are needed to prevent recurrence, and the actions taken to prevent recurrence.~~

~~H.5.9 Aside from the notification requirement, nothing in H.5.8 affects any rights or duties of registrants and physicians in relation to each other, individuals receiving misadministrations, or the individual's responsible relatives or guardians.~~

H.6 THERAPEUTIC RADIATION MACHINES OF LESS THAN 500 kV[39]

H.6.1 **Leakage Radiation.** When the X-ray tube is operated at its maximum rated tube current for the maximum kV, the leakage air kerma rate shall not exceed the value specified at the distance specified for that classification of therapeutic radiation machine:

(a) **5-50 kV Systems.** The leakage air kerma rate measured at any position five (5) centimeters from the tube housing assembly shall not exceed 1 mGy (100 mrad) in any one hour.

(b) **>50 and <500 kV Systems.** The leakage air kerma rate measured at a distance of one (1) meter from the target in any direction shall not exceed 1 cGy (1 rad) in any one (1) hour. This air kerma rate measurement may be averaged over areas no larger than ~~100~~ one hundred square centimeters (100 cm^2). In addition, the air kerma rate at a distance of five (5) centimeters from the surface of the tube housing assembly shall not exceed 30 cGy (30 rad) per hour.

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H.6.4 **Filter System.** The filter system shall be so designed that:

[39] Electronic brachytherapy devices are subject to the requirements of H.11, and are exempt for the requirements of H.6.

(a) Filters can not be accidentally displaced at any possible tube orientation;

(b) For equipment installed after 1 August 1978, an interlock system prevents irradiation if the proper filter is not in place;

(c) The air kerma rate escaping from the filter slot shall not exceed 1 cGy (1 rad) per hour at one (1) meter under any operating conditions; and

(d) Each filter shall be marked as to its material of construction and its thickness.

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H.6.6 **Source Marking.** The tube housing assembly shall be so marked that it is possible to determine the location of the source to within five (5) millimeters, and such marking shall be readily accessible for use during calibration procedures.

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H.6.8 **Timer.** A suitable irradiation control device shall be provided to terminate the irradiation after a pre-set time interval.

(c) The timer shall terminate irradiation when a pre-selected time has elapsed, if any dose monitoring system present has not previously terminated irradiation.

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(d) The timer shall permit accurate pre-setting and determination of exposure times as short as one (1) second.

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H.6.11 **Target-to-Skin Distance (TSD).** There shall be a means of determining the central axis TSD to within one (1) centimeter and of reproducing this measurement to within two (2) millimeters thereafter.

H.6.12 **Shutters.** Unless it is possible to bring the X-ray output to the prescribed exposure parameters within five (5) seconds after the X-ray "ON" switch is energized, the beam shall be attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly. In addition, after the unit is at operating parameters, the shutter shall be controlled by the operator from the control panel. An indication of shutter position shall appear at the control panel.

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H.6.15 **Additional Requirements.** Treatment rooms which contain a therapeutic radiation machine capable of operating above 150 kV shall meet the following additional requirements:

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(d) When any door referred to in H.6.15(c) is opened while the X-ray tube is activated, the air kerma rate at a distance of one (1) meter from the source shall be reduced to less than 1 mGy (100 mrad) per hour.

H.6.16 **Full Calibration Measurements.**

(a) Full calibration of a therapeutic radiation machine subject to H.6 shall be performed by, or under the

direct supervision of, a ~~Radiotherapy~~ Qualified Medical Physicist:

(1) Before the first medical use following installation or reinstallation of the therapeutic radiation machine; and

(2) At intervals not exceeding twelve (12) calendar months ~~1 year~~; and

(3) Before medical use under the following conditions:

(i) Whenever quality assurance check measurements indicate that the radiation output differs by more than five percent (5%) from the value obtained at the last full calibration and the difference cannot be reconciled; and

(ii) Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam.

(4) Notwithstanding the requirements of H.6.16(a)(3):

(i) Full calibration of therapeutic radiation machines with multi-energy capabilities is required only for those modes and/or energies that are not within their acceptable range; and

(ii) 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 H.6.16(a)(3)(i).

(b) ~~The Radiotherapy Physicist shall perform or directly supervise all elements of a full calibration necessary to determine that all parameters are within acceptable limits:~~

~~(1) Whenever quality assurance check measurements indicate that the radiation output differs by more than 5 percent from the value obtained at the last full calibration and the difference cannot be reconciled. Therapeutic radiation machines with multi-energy capabilities shall only require measurements for those modes and/or energies that are not within their acceptable range; and~~

~~(2) 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 energies, measurements shall be performed on the effected 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 H.6.16(b)(1).~~

~~(c)~~ To satisfy the requirement of H.6.16(a) ~~and H.6.16(b)~~, full calibration shall include all measurements recommended for annual calibration by "AAPM Protocol for 40-300 kV X-ray Beam Dosimetry in Radiotherapy and Radiobiology": AAPM Report No. 76, prepared by AAPM Radiation Therapy Committee Task Group #61. ~~NCRP Report 69, "Dosimetry of X-Ray and Gamma Ray Beams for Radiation Therapy in the Energy Range 10 keV to 50 MeV" (1981).~~

(~~d~~ c)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 both the therapeutic radiation machine and the X-ray tube, the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine, and the signature of the ~~Radiotherapy~~ Qualified Medical Physicist responsible for ~~performance of~~ performing the calibration.

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H.6.17 **Periodic Quality Assurance Checks.**

(a) Periodic quality assurance checks shall be performed on therapeutic radiation machines subject to H.6, which are capable of operation at greater than or equal to 50 kV.

(b) To satisfy the requirement of H.6.17(a), quality assurance checks shall meet the following requirements:

(1) The registrant shall perform quality assurance checks in accordance with written procedures established by the ~~Radiotherapy~~ Qualified Medical Physicist; and

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(c) The cause for a parameter exceeding a tolerance set by the ~~Radiotherapy~~ Qualified Medical Physicist shall be investigated and corrected before the system is used for patient/human research subject irradiation.

(d) Whenever a quality assurance check indicates a significant change in the operating characteristics of a system, as specified in the ~~Radiotherapy~~ Qualified Medical Physicist's quality assurance check procedures, those elements of a full calibration shall be performed, as required in H.6.16(a), that are necessary to determine that all affected parameters are within acceptable limits. Other quality assurance check procedures should be repeated, as necessary, to ensure that all system parameters are within acceptable limits.

(e) The registrant shall use the dosimetry system described in H.4.3(b) to make the quality assurance check required in H.6.17(b).

(f) The registrant shall have the ~~Radiotherapy~~ Qualified Medical Physicist review and sign the results of each radiation output quality assurance check within ~~1 month~~ thirty (30) days of the date that the check was performed.

(g) The registrant shall ensure that safety quality assurance checks of therapeutic radiation machines subject to H.6 are performed at intervals not to exceed ~~1 month~~ thirty (30) days.

(h) Notwithstanding the requirements of H.6.17(f) and H.6.17(g), the registrant shall ensure that no therapeutic radiation machine is used to administer radiation to humans unless the quality assurance checks required by H.6.17(f) and H.6.17(g) have been performed within the thirty (30) day period immediately prior to said administration.

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(j) The registrant shall maintain a record of each quality assurance check required by H.6.17(a) and H.6.17(g) for three (3) years. The record shall include the date of the quality assurance check, the manufacturer's name, model number, and serial number for the therapeutic radiation machine, the manufacturer's name, model number and serial number of the instrument(s) used to measure the radiation output of the therapeutic radiation machine, and the signature of the individual who performed the periodic quality assurance check.

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H.7 THERAPEUTIC RADIATION MACHINES - PHOTON THERAPY SYSTEMS (500 kV AND ABOVE) AND ELECTRON THERAPY SYSTEMS (500 keV AND ABOVE)

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H.7.2 **Leakage Radiation Outside the Maximum Useful Beam in Photon and Electron Modes.**

(a) 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 (2) meters which is perpendicular to and centered on the central axis of the useful beam at the nominal treatment distance (i.e. patient/human research subject plane), shall not exceed a maximum of 0.2 percent and an average of 0.1 percent 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~~ one hundred square centimeters (100 cm^2) at a minimum of sixteen (16) points uniformly distributed in the plane.

(b) Except for the area defined in H.7.2(a), the absorbed dose due to leakage radiation (excluding neutrons) at one (1) meter from the electron path between the electron source and the target or electron window shall not exceed 0.5 percent 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~~ one hundred square centimeters (100 cm^2).

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H.7.3 **Leakage Radiation Through Beam Limiting Devices.**

(a) **Photon Radiation.** All adjustable or interchangeable beam limiting devices shall attenuate the useful beam such that at the nominal treatment distance, the maximum absorbed dose anywhere in the area shielded by the beam limiting device(s) shall not exceed ~~2~~ two percent (2%) of the maximum absorbed dose on the central axis of the useful beam measured in a ~~10 centimeters by 10 centimeters~~ one hundred square centimeter (100 cm^2) radiation field, or maximum available field size if less than one hundred square centimeters (100 cm^2).

(b) **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:

(1) A maximum of ~~2~~ two percent (2%) and average of 0.5 percent 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 (7) centimeters outside the periphery of the useful beam; and

(2) A maximum of ~~10~~ ten percent (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 (2) centimeters outside the periphery of the useful beam.

(c) **Measurement of Leakage Radiation.**

(1) **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 (2) 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~~ ten square centimeters (10 cm^2);

(2) **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 ~~1~~ one square centimeter (1 cm^2) suitably protected against radiation which has been scattered from material beyond the radiation detector. Measurements shall be made using one (1) centimeter of water equivalent build up material.

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H.7.6 **Beam Monitors.** All therapeutic radiation machines subject to H.7 shall be provided with redundant beam monitoring systems. The detectors for these systems shall be fixed in the useful beam during treatment to indicate the dose monitor unit rate.

(a) Equipment manufactured after 1 January 1985 shall be provided with at least two (2) independently powered integrating dose meters. Alternatively, common elements may be used if the production of radiation

is terminated upon failure of any common element.

(b) Equipment manufactured on or before 1 January 1985 shall be provided with at least one (1) radiation detector. This detector shall be incorporated into a useful beam monitoring system.

(c) The detector and the system into which that detector is incorporated shall meet the following requirements:

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(5) Each beam monitoring system shall have a legible display at the treatment control panel. For equipment manufactured after 1 January 1985, each display shall:

(i) Maintain a reading until intentionally reset;

(ii) Have only one scale and no electrical or mechanical scale multiplying factors;

(iii) Utilize a design such that increasing dose is displayed by increasing numbers; and

(iv) In the event of power failure, the beam monitoring information required in H.7.6(c)(5)(iii) displayed at the control panel at the time of failure shall be retrievable in at least one system for a twenty (20) minute period of time.

H.7.7 **Beam Symmetry.**

(a) A bent-beam linear accelerator with beam flattening filter(s) subject to H.7 shall be provided with auxiliary device(s) to monitor beam symmetry.

(b) The device(s) referenced in H.7.7(a) shall be able to detect field asymmetry greater than ~~10~~ ten percent (10%). and

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H.7.10 **Termination of Irradiation by the Beam Monitoring System or Systems During Stationary Beam Radiation Therapy.**

(a) Each primary system shall terminate irradiation when the pre-selected number of dose monitor units has been detected by the system.

(b) 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~~ fifteen percent (15%) or forty (40) dose monitor units above the pre-selected number of dose monitor units set at the control panel has been detected by the secondary dose monitoring system. and

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H.7.16 **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:

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(e) Moving beam radiation therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental movement.

(1) For equipment manufactured after 1 January 1985:

(i) Where angle terminates the irradiation in moving beam radiation therapy, the dose monitor

units delivered shall differ by less than ~~5~~ five percent (5%) from the dose monitor unit value selected;

(ii) An interlock shall be provided to prevent motion of more than five (5) degrees or one (1) cm beyond the selected limits during moving beam radiation therapy;

(iii) An interlock shall be provided to require that a selection of direction be made at the treatment control panel in all units which are capable of both clockwise and counter-clockwise moving beam radiation therapy.

(2) For equipment manufactured after 1 July 1999:

(i) An interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any ten (10) degrees of rotation or one (1) cm of linear motion differs by more than ~~20~~ twenty percent (20%) from the selected value;

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H.7.18 **~~Radiotherapy~~ Qualified Medical Physicist Support.**

(a) The services of a ~~Radiotherapy~~ Qualified Medical Physicist shall be required in facilities having therapeutic radiation machines with energies of 500 kV and above. The ~~Radiotherapy~~ Qualified Medical Physicist shall be responsible for:

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(b) If the ~~Radiotherapy~~ Qualified Medical Physicist is not a full-time employee of the registrant, the operating procedures required by H.7.19 shall also specifically address how the ~~Radiotherapy~~ Qualified Medical Physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the ~~Radiotherapy~~ Qualified Medical Physicist can be contacted.

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H.7.20 **Acceptance Testing, Commissioning and Full Calibration Measurements.**

(a) Acceptance testing, commissioning and full calibration of a therapeutic radiation machine subject to H.7 shall be performed by, or under the direct supervision of, a ~~Radiotherapy~~ Qualified Medical Physicist.

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(c) Full calibration shall include measurement of all applicable parameters required by "Quality Assurance of Medical Accelerators: AAPM Report No. 142"[40] ~~Table II of "Comprehensive QA for Radiation Oncology: AAPM Report No. 46", prepared by AAPM Radiation Therapy Task Group 40~~, and shall be performed in accordance with "AAPM Code of Practice for Radiotherapy Accelerators: AAPM Report No. 47", prepared by AAPM Radiation Therapy Task Group 45. Although it shall not be necessary to complete all elements of a full calibration at the same time, all applicable parameters (for all energies) shall be completed at intervals not exceeding twelve (12) calendar months, unless a more frequent interval is required in Table II.

(d) The ~~Radiotherapy~~ Qualified Medical Physicist shall perform or directly supervise all elements of a full calibration necessary to determine that all parameters are within acceptable limits:

(1) Whenever quality assurance check measurements indicate that the radiation output differs by more than ~~5~~ five percent (5%) from the value obtained at the last full calibration and the difference cannot

[40] AAPM Report 142 supersedes Table II of "Comprehensive QA for Radiation Oncology: AAPM Report No. 46", prepared by AAPM Radiation Therapy Task Group 40.

be reconciled. Therapeutic radiation machines with multi-energy and/or multi-mode capabilities shall only require measurements for those modes and/or energies that are not within their acceptable range; and

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(f) 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 ~~Radiotherapy~~ Qualified Medical Physicist responsible for performance of the calibration.

(g) **Therapy-Related Computer Systems.** The registrant shall perform acceptance testing on the treatment planning system of therapeutic radiation machine -related computer systems in accordance with current published recommendations from a recognized national professional association (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:

(i) The source-specific input parameters required by the dose calculation algorithm;

(ii) The accuracy of dose calculations at representative points;

(iii) The accuracy of isodose plots and graphic displays;

(iv) The accuracy of the software used to determine radiation source positions from radiographic images; and

(v) 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) 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.

H.7.21 **Periodic Quality Assurance Checks.**

(a) Periodic quality assurance checks shall be performed on all therapeutic radiation machines subject to H.7 at intervals not to exceed those specified in "Comprehensive QA for Radiation Oncology: AAPM Report No. 46, prepared by AAPM Radiation Therapy Committee Task Group 40. All periodic quality assurance checks with an annual frequency do not have to be performed at the same time, but shall be completed during an interval not to exceed twelve (12) consecutive calendar months.

(b) The registrant shall use a dosimetry system which has been inter-compared within the previous twelve (12) months with the dosimetry system described in H.4.3(a) to make the periodic quality assurance checks required in H.7.21(a).

(c) The registrant shall perform periodic quality assurance checks required by H.7.21(a) in accordance with procedures established by the ~~Radiotherapy~~ Qualified Medical Physicist.

(d) The registrant shall review the results of each periodic radiation output check according to the following procedures:

(1) The Authorized User or ~~Radiotherapy~~ 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 ~~Radiotherapy~~ Qualified Medical Physicist has determined that all parameters are within their acceptable tolerances;

(2) If all radiation output quality assurance check parameters appear to be within their acceptable range, the quality assurance check shall be reviewed and signed by either the Authorized User or ~~Radiotherapy~~ Qualified Medical Physicist within ~~14 calendar~~ three (3) treatment days; and

(3) The ~~Radiotherapy~~ Qualified Medical Physicist shall review and sign the results of each radiation output quality assurance check at intervals not to exceed ~~1 month~~ thirty (30) days.

(e) Therapeutic radiation machines subject to H.7 shall have the following safety quality assurance checks performed at intervals not to exceed one (1) week:

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(g) The registrant shall maintain a record of each quality assurance check required by H.7.21(a) and H.7.21(e) for three (3) years. The record shall include the date of the quality assurance check, the manufacturer's name, model number, and serial number for the therapeutic radiation machine, the manufacturer's name, model number and serial number of the instrument(s) used to measure the radiation output of the therapeutic radiation machine, and the signature of the individual who performed the periodic quality assurance check.

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H.8 CALIBRATION OF SURVEY INSTRUMENTS

H.8.1 The registrant shall ensure that the survey instruments used to show compliance with Part H have been calibrated before first use, at intervals not to exceed twelve (12) months, and following repair.

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H.8.4 The registrant shall retain a record of each calibration required in H.8.1 for three (3) years. The record shall include:

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H.8.5 The registrant may obtain the services of individuals licensed by the Agency, the U.S. Nuclear Regulatory Commission~~,~~ or another Agreement State~~, or a Licensing State~~ to perform calibrations of survey instruments. Records of calibrations which contain information required by H.8.4 shall be maintained by the registrant.

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H.11 ELECTRONIC BRACHYTHERAPY

H.11.1 **Applicability**. Electronic brachytherapy devices shall be subject to the requirements of H.11, and shall be exempt for the requirements of H.6.

(a) An electronic brachytherapy device that does not meet the requirements of H.11 shall not be used for irradiation of patients; and

(b) 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).

H.11.2 **Possession of Survey Instrument(s).** Each facility location authorized to use an electronic brachytherapy device in accordance with H.11 shall possess appropriately calibrated portable monitoring equipment. As a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 μSv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. The survey instrument(s) shall be operable and calibrated in accordance with H.8 for the applicable electronic brachytherapy source energy.

H.11.3 **Facility Design Requirements for Electronic Brachytherapy Devices**. In addition to shielding adequate to meet requirements of H.9, the treatment room shall meet the following design requirements:

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

(b) Access to the treatment room shall be controlled by a door at each entrance.

(c) 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.

(d) 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 and/or as localized shielded material around the treatment site.

(e) For electronic brachytherapy devices capable of operating at greater than 150 kV:[41]

(1) The control panel shall be located outside the treatment room;

(2) Interlocks shall be provided such that all entrance doors 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 electronic brachytherapy device to operation without closing the door and reinitiating irradiation by manual action at the control panel; and

(3) When any door referred to in H.11.3(e(2)) is opened while the X-ray tube is activated, the air kerma rate at a distance of one (1) meter from the source shall be reduced to less than 1 mGy (100 mrad) per hour.

H.11.4. **Electrical Safety for Electronic Brachytherapy Devices**.

(a) The high voltage transformer shall be electrically isolated to prevent electrical and magnetic interference with the surrounding environment and ancillary equipment.

(b) The high voltage transformer shall be isolated from personnel (e.g., 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.

(c) The high voltage transformer shall have appropriate safety labels warning personnel of potential electrical shock and/or heat related injuries.

(d) Equipment manufactured after 1 January 2006 shall be in compliance with the most current revision of the following International Electrotechnical Commission (IEC) Documents:

[41] Facility design requirements for electronic bracytherapy devices which would operate in the 50-150 kV range have intentionally been omitted because an evaluation of this technology, as it existed at the time this subpart was finalized, appears to indicate that such devices are not likely to be produced.

(1) IEC 60601-1:1998+A1+A2:1995;

(2) IEC 60601-1-2:2001;

(3) IEC 60601-2-8:1999; and

(4) IEC 60601-2-17:2004.

H.11.5 **Control Panel Functions.** The control panel, in addition to the displays required by other provisions in H.11, shall:

(a) Provide an indication of whether electrical power is available at the control panel and if activation of the electronic brachytherapy source is possible;

(b) Provide an indication of whether x-rays are being produced;

(c) Provide a means for indicating electronic brachytherapy source potential and current;

(d) Provide the means for terminating an exposure at any time; and

(e) Include an access control (locking) device that will prevent unauthorized use of the electronic brachytherapy device.

H.11.6 **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.

(a) A timer shall be provided at the treatment control panel. The timer shall indicate the planned setting and the time elapsed or remaining;

(b) The timer shall not permit an exposure if set at zero;

(c) 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;

(d) The timer shall terminate irradiation when a pre-selected time has elapsed, if any dose monitoring system has not previously terminated irradiation.

(e) The timer shall permit setting of exposure times as short as 0.1 second; and

(f) The timer shall be accurate to within one percent (1%) of the selected value or 0.1 second, whichever is greater.

H.11.7 **Qualified Medical Physicist Support.**

(a) The services of a Qualified Medical Physicist shall be required in facilities having electronic brachytherapy devices. The Qualified Medical Physicist shall be responsible for:

(1) Evaluation of the output from the electronic brachytherapy source;

(2) Generation of the necessary dosimetric information;

(3) Supervision and review of treatment calculations prior to initial treatment of any treatment site;

(4) Establishing the periodic and day-of-use quality assurance checks and reviewing the data from those checks as required in H.11.11;

(5) Consultation with the Authorized User in treatment planning, as needed; and

(6) Performing calculations/assessments regarding patient treatments that may constitute a misadministration.

(b) If the Qualified Medical Physicist is not a full-time employee of the registrant, the operating procedures required by H.11.8 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.11.8. **Operating Procedures.**

(a) Only individuals approved by the Authorized User, Radiation Safety Officer, or Qualified Medical Physicist shall be present in the treatment room during treatment;

(b) Electronic brachytherapy devices shall not be made available for medical use unless the requirements of H.4.1, H.11.9 and H.11.10 have been met;

(c) The electronic brachytherapy device shall be rendered inoperable, either by hardware or password, when unattended by qualified staff or service personnel;

(d) 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 unshielded exposure from the treatment beam;

(e) If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used;

(f) Written procedures shall be developed, implemented, and maintained for responding to an abnormal situation. These procedures shall include:

(1) Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions; and

(2) 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.

(g) A copy of the current operating and emergency procedures shall be physically located at the electronic brachytherapy device control console[42];

(h). Instructions shall be posted at the electronic brachytherapy device control console[30] 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

(i) The Radiation Safety Officer, or his/her 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.

H.11.9 **Safety Precautions for Electronic Brachytherapy Devices.**

(a) A Qualified Medical Physicist shall determine which persons in the treatment room require monitoring when the beam is energized;

(b) An Authorized User and a Qualified Medical Physicist shall be physically present during the initiation of all patient treatments involving the electronic brachytherapy device;

(c) A Qualified Medical Physicist and either an Authorized User or a 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;

[42] 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.

(d) When shielding is required by H.11.3(d), 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 A.2.3 of these Regulations for any individual, other than the patient, in the treatment room; and

(e) All personnel in the treatment room are required to 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.

H.11.10 **Electronic Brachytherapy Source Calibration Measurements.**

(a) Calibration of the electronic brachytherapy source output for an electronic brachytherapy device subject to H.11 shall be performed by, or under the direct supervision of, a Qualified Medical Physicist;

(b) Calibration of the electronic brachytherapy source output shall be made for each electronic brachytherapy source, or after any repair affecting the x-ray beam generation, or when indicated by the electronic brachytherapy source quality assurance checks;

(c) Calibration of the electronic brachytherapy source output shall utilize a dosimetry system as described in H.4.3;

(d) Calibration of the electronic brachytherapy source output shall include, as applicable, determination of:

(1) The output within two percent (2%) of the expected value, if applicable, or determination of the output if there is no expected value;

(2) Timer accuracy and linearity over the typical range of use;

(3) Proper operation of back-up exposure control devices;

(4) Evaluation that the relative dose distribution about the source is within five percent (5%) of that expected; and

(5) Source positioning accuracy to within one (1) millimeter within the applicator;

(e) Calibration of the x-ray source output required by H.11.10(a) through (d) 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.

(f) 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 it's electronic brachytherapy source; the model numbers and serial numbers of the instrument(s) used to calibrate the electronic brachytherapy device; and the name and signature of the Qualified Medical Physicist responsible for performing the calibration.

H.11.11 **Periodic and Day-of-Use Quality Assurance Checks for Electronic Brachytherapy Devices.**

(a) Quality assurance checks shall be performed on each electronic brachytherapy device subject to H.11:

(1) At the beginning of each day of use;

(2) Each time the device is moved to a new room or site[43]; and

(3) After each x-ray tube installation.

[43] *Site* is intended to include each day of use at each operating location for a self-contained electronic brachytherapy unit transported in a van or trailer. See H.11.14 for additional clarification.

(b) The registrant shall perform periodic quality assurance checks required by H.11.11(a) in accordance with procedures established by the Qualified Medical Physicist;

(c) To satisfy the requirements of H.11.11(a), radiation output quality assurance checks shall include as a minimum:

(1) Verification that output of the electronic brachytherapy source falls within three percent (3%) of expected values, as appropriate for the device, as determined by:

(i) Output as a function of time, or

(ii) Output as a function of setting on a monitor chamber.

(2) Verification of the consistency of the dose distribution to within three percent (3%) of that found during calibration required by X.11.10; and

(3) Validation of the operation of positioning methods to ensure that the treatment dose exposes the intended location within one (1) mm; and

(d) The registrant shall use a dosimetry system that has been intercompared within the previous twelve (12) months with the dosimetry system described in H.4.3(a) to make the quality assurance checks required in H.11.11(c);

(e) The registrant shall review the results of each radiation output quality assurance check according to the following procedures:

(1) 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 their acceptable tolerances;

(2) If all radiation output quality assurance check parameters appear to be within their acceptable range, the quality assurance check shall be reviewed and signed by either the Authorized User or Qualified Medical Physicist within two (2) days; and

(3) The Qualified Medical Physicist shall review and sign the results of each radiation output quality assurance check at intervals not to exceed thirty (30) days.

(f) To satisfy the requirements of H.11.11(a), safety device quality assurance checks shall, at a minimum, assure:

(1) Proper operation of radiation exposure indicator lights on the electronic brachytherapy device and on the control console;

(2) Proper operation of viewing and intercom systems in each electronic brachytherapy facility, if applicable;

(3) Proper operation of radiation monitors, if applicable;

(4) The integrity of all cables, catheters or parts of the device that carry high voltages; and

(5) Connecting guide tubes, transfer tubes, transfer-tube-applicator interfaces, and treatment spacers are free from any defects that interfere with proper operation.

(g) If the results of the safety device quality assurance checks required in H.11.11(f) indicate any malfunction, 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 items.

(h) The registrant shall maintain a record of each quality assurance check required by H.11.11(c). and H.11.11(g) in an auditable form for three (3) years.

(1) 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;

(2) For radiation output quality assurance checks required by H.11.11(c)., 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(s) used to measure the radiation output of the electronic brachytherapy device.

H.11.12 **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.

(a) 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:

(1) The source-specific input parameters required by the dose calculation algorithm;

(2) The accuracy of dose, dwell time, and treatment time calculations at representative points;

(3) The accuracy of isodose plots and graphic displays;

(4) The accuracy of the software used to determine radiation source positions from radiographic images; and

(5) 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.

(b) 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.

(c) 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.

H.11.13 **Training.**

(a) 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 H.11.8. If the interval between patients exceeds one year, retraining of the individuals shall be provided before the next treatment is administered.

(b) In addition to the requirements of H.3.3 for therapeutic radiation machine Authorized Users and H.3.4 for Qualified Medical Physicists, these individuals 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 nor be limited to:

(1) Device-specific radiation safety requirements;

(2) Device operation;

(3) Clinical use for the types of use approved by the FDA;

(4) Emergency procedures, including an emergency drill; and

(5) The registrant's Quality Assurance Program.

(c) A registrant shall retain a record of individuals receiving instruction required by H.11.13(a) and (b) for three (3) years. The record shall include a list of the topics covered, the date of the instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

H.11.14 **Mobile Electronic Brachytherapy Service.** A registrant providing mobile electronic brachytherapy service shall, as a minimum:

(a) Check each survey instrument for consistent response with a dedicated check source before medical use at each address of use or on each day of use, whichever is more restrictive. The registrant is not required to keep records of these checks.

(b) Account for the electronic brachytherapy source in the electronic brachytherapy device before departure from the client's address.

(c) Perform, at each location on each day of use, all of the required quality assurance checks specified in H.11.11 to assure proper operation of the device.

H.12 OTHER USE OF ELECTRONICALLY-PRODUCED RADIATION TO DELIVER THERAPEUTIC RADIATION DOSAGE.

H.12.1 A person shall not utilize any device which is designed to electrically generate a source of ionizing radiation to deliver therapeutic radiation dosage, and which is not appropriately regulated under any existing category of therapeutic radiation machine, until:

(a) The applicant or registrant has, at a minimum, provided the Agency with:

(1) A detailed description of the device and its intended application(s);

(2) Facility design requirements, including shielding and access control;

(3) Documentation of appropriate training for Authorized User physician(s) and qualified medical physicist(s)

(4) Methodology for measurement of dosages to be administered to patients or human research subjects;

(5) Documentation regarding calibration, maintenance, and repair of the device, as well as instruments and equipment necessary for radiation safety;

(6) Radiation safety precautions and instructions; and

(7) Other information requested by the Agency in its review of the application; and

(b) 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.

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PART I
X-RAY AND RADIOACTIVE MATERIALS FEES

I.1 GENERAL PROVISIONS

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I.1.2 **Fee Exempt.** Notwithstanding the requirement of ~~Section~~ §I.1.1 of these Regulations ~~above~~, no fees shall be required for radioactive materials licenses authorizing the use of source material as shielding only in devices and containers, provided, however, that all other licensed radioactive material in the device or container will be subject to the fees required by Subpart I.3 of these Regulations.

I.1.3 **Payment of Fees.** All fees specified in the *Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health* ~~shall be payable by check or money order to the General Treasurer, State of Rhode Island, and~~ shall be submitted to the Agency.

I.1.4 **Inquiries.** Any inquiry regarding Agency fees should be addressed to:

Rhode Island Department of Health
Radiation Control ~~Agency~~
3 Capitol Hill - Room ~~206~~ 305
Providence, RI 02908-5097
Telephone: (401) 222-~~2438~~ 2566

I.2 X-RAY FEES

I.2.1 **Submission of Initial Fee.** ~~Upon approval of an application for registration, the Agency shall notify the applicant and shall stipulate the amount of the registration fee.~~ (a) Each initial application for a Registration Certificate in a category for which a fee has been established in *Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health* shall be accompanied by a fee in the amount of the Annual Fee specified for that registration category. A registration application shall not be considered prior to payment of the full amount specified. Registration applications for which no remittance is received shall be returned to the applicant.

(b) Initial applications, accompanied by the appropriate registration fee and which are received by the Agency during the period 1 July through 31 August of a calendar year, shall also constitute a renewal application for the period ending 31 August of the following calendar year, without payment of an additional annual registration fee. ~~Said registration fee shall be submitted to the Agency as follows:~~

~~(a) **For Existing X-ray Equipment Facilities:** The registration fee shall be submitted prior to the expiration date of the registrant's current Registration Certificate.~~

~~(b) **For New X-ray Equipment Facilities:** The registration fee shall be submitted prior to ownership or possession of X-ray equipment.~~

~~(c) **For New Servicing or Services:** The registration fee shall be submitted prior to furnishing or offering to provide servicing or services.~~

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I.2.5 **Annual Fees**. The Agency shall issue an annual fee invoice to each registrant, based on the applicable annual fee established in the *Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory*

and Administrative Services Provided by the Department of Health. Fees shall be payable prior to the expiration date of the registrant's current Registration Certificate.

I.3 RADIOACTIVE MATERIALS FEES

I.3.1 **Application Fee.** Each initial application for a license in a category for which a fee has been established in ~~Appendix A to this Part~~ the *Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health* shall be accompanied by a non-refundable fee in the amount of the Annual Fee specified for that license category. A license application shall not be considered prior to payment of the full amount specified. License applications for which no ~~remittance~~ fee is received shall be returned to the applicant.

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~~**PART I**~~

~~**APPENDIX B**~~

~~**X-RAY REGISTRATION FEE SCHEDULE**~~

~~**CATEGORY I**~~

~~Facilities and/or individuals in Category I, as listed below, shall be subject to an annual registration fee established in the *Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health*.~~

~~(a) **Facilities:**~~

~~1. Facilities performing diagnostic radiography limited to podiatric procedures.~~

~~2. Facilities performing diagnostic radiography limited to veterinary procedures.~~

~~3. Facilities limited to storage of X-ray equipment, excluding X-ray equipment exempt from registration under the regulations.~~

~~(b) **Individuals or Facilities Providing the Following Services:**~~

~~1. Installation and/or servicing of X-ray equipment and associated components for Agency registrants.~~

~~2. NVLAP certified personnel dosimetry services for Agency registrants and/or radioactive materials licensees.~~

~~**CATEGORY II**~~

~~Facilities and/or individuals in Category II, as listed below, shall be subject to an annual registration fee established in the *Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health*.~~

~~(a) **Facilities:**~~

~~1. Facilities performing diagnostic radiography limited to chiropractic procedures;~~

~~2. Facilities performing diagnostic radiography limited to intra-oral dental procedures and/or extra-oral dental procedures, including panoramic and cephalometric procedures.~~

~~3. Facilities performing superficial radiation therapy procedures [<1 MeV].~~

~~4. Facilities utilizing specialized diagnostic radiography equipment including, but not limited to, therapy simulators, CT scanners, and dedicated mammography units.~~

~~5. Facilities performing only limited diagnostic radiographic procedures (i.e.: chest/extremities) and/or specific diagnostic radiographic procedures which are not included in any other human use registration category.~~

~~6. Facilities utilizing cabinet X-ray systems and/or X-ray units which are not included in any other non-human use registration category.~~

~~(b) **Individuals: [RESERVED].**~~

~~CATEGORY III~~

~~Facilities and/or individuals in Category III, listed below, shall be subject to an annual registration fee established in the *Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health*.~~

(a) ~~**Facilities:**~~

1. ~~Facilities performing industrial radiographic procedures.~~
2. ~~Facilities performing radiation therapy procedures [> 1 MeV].~~
3. ~~Facilities operating particle accelerators not authorized for human use.~~
4. ~~Facilities utilizing analytical X-ray equipment with an "open-beam" configuration.~~

(b) ~~**Individuals:**~~

1. ~~Calibration of health physics instrumentation for Agency registrants and/or radioactive materials licensees.~~
2. ~~General radiation physics services for Agency registrants and/or radioactive materials licensees.~~
3. ~~Diagnostic Medical Physicist services for Agency registrants. [Calibration and surveys of diagnostic X-ray equipment]~~
4. ~~Diagnostic Medical Physicist services for Agency registrants. [Calibration and surveys of computed tomography (CT) X-ray systems]~~
5. ~~Radiotherapy Physicist services for Agency registrants. [Calibration and surveys of therapeutic X-ray equipment and/or medical accelerators]~~
6. ~~Radiotherapy Physicist services for Agency materials licensees. [Calibration and surveys of teletherapy units utilizing sealed radioactive sources]~~

~~CATEGORY IV~~

~~Facilities and/or individuals in Category IV, listed below, shall be subject to an annual registration fee established in the *Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health*.~~

(a) ~~**Facilities:**~~

1. ~~Facilities performing general purpose diagnostic radiographic procedures outside of an institution licensed by the State of Rhode Island as a hospital.~~

(b) ~~**Individuals: [RESERVED].**~~

~~CATEGORY V~~

~~Facilities and/or individuals in Category V, listed below, shall be subject to an annual registration fee established in the *Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health*.~~

(a) ~~**Facilities:**~~

1. ~~Facilities performing general purpose diagnostic radiographic procedures in an institution licensed by the State of Rhode Island as a hospital.~~

(b) ~~**Individuals: [RESERVED].**~~

~~**MULTIPLE X-RAY FACILITIES/SERVICES AT ONE LOCATION**~~

~~Persons registering multiple X-ray facilities and/or services at one location or address may elect to pay a combined annual registration fee. The maximum annual registration fee for X-ray facilities and/or services shall be as established in the *Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health*.~~

PART I

APPENDIX B

X-RAY REGISTRATION CATEGORIES

HEALING ARTS REGISTRATION CATEGORIES

DEF ⏄ Facilities performing diagnostic radiography limited to intra-oral dental procedures and/ or extra-oral dental procedures, including panoramic procedures and cephalometric procedures.

HRF ⏄ Facilities performing general purpose diagnostic radiographic procedures (including fluoroscopy) in an institution licensed by the State of Rhode Island as a hospital.

RAD ⏄ Facilities performing general purpose diagnostic radiographic procedures (including fluoroscopy) outside of an institution licensed by the State of Rhode Island as a hospital.

RTF ⏄ Facilities utilizing one or more therapeutic radiation machines, including dedicated therapy simulator(s).

SRF ⏄ Facilities performing diagnostic radiography (excluding fluoroscopy) limited to a single category of specific radiographic procedures, as specified on the facility's application. The category shall also include facilities performing only chiropractic or podiatric procedures.

SRM ⏄ Facilities performing two (2) or more categories of specific diagnostic radiography procedures (excluding fluoroscopy), as specified on the facility's application.

VEF ⏄ Facilities performing diagnostic radiography limited to veterinary procedures.

SERVICES REGISTRATION CATEGORIES

PXS ⏄ Individuals or facilities providing installation and/or servicing of X-ray equipment and associated components for Agency registrants.

⏄ Individuals or facilities providing NVLAP certified personnel dosimetry services for Agency registrants and/or radioactive materials licensees.

RPS ⏄ Calibration of health physics instrumentation for Agency registrants and/or radioactive materials licensees.

⏄ General radiation physics services for Agency registrants and/or radioactive materials licensees.

⏄ Diagnostic X-ray Physics services for Agency registrants. [Calibration and surveys of diagnostic X-ray equipment]

⏄ Diagnostic X-ray Physics services for Agency registrants. [Calibration and surveys of computed tomography (CT) X-ray systems]

⏄ Radiotherapy Physics services for Agency registrants. [Calibration and surveys of therapeutic radiation machines]

⏄ Radiotherapy Physics services for Agency materials licensees. [Calibration and surveys of remote afterloader units, teletherapy units, and/or gamma stereotactic radiosurgery units]

STO ⏄ Facilities limited to storage of X-ray equipment, excluding X-ray equipment exempt from registration under these Regulations.

NON-HEALING ARTS REGISTRATION CATEGORIES

- **IRF** – Facilities utilizing X-ray equipment to perform industrial radiographic procedures.
- **IRA** – Facilities utilizing a Category A industrial radiation machines as defined in Subpart E.3.
- **IRB** – Facilities utilizing a Category B industrial radiation machines as defined in Subpart E.3.
- **OTH** – Facilities utilizing X-ray equipment for non-healing arts applications not otherwise defined in these Regulations.
- **PAF** – Facilities utilizing particle accelerators not authorized for human use.

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