Connecticut Department of
ENERGY &
ENVIRONMENTAL
PROTECTION

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Notice of Intent Repeal and Adopt Ionizing Radiation Regulations

In accordance with the provisions of section 4-168(a) of the Connecticut General Statutes (CGS), the Commissioner of the Department of Energy and Environmental Protection (DEEP) hereby gives notice that it proposes to repeal and adopt regulations concerning the control and evaluation of ionizing radiation, under the authority of CGS sections 22a-6 and 22a-153.

Description.
The purpose of this proposal is to update DEEP's ionizing radiation regulations. These regulations have not been substantially updated since the early 1970's and as a result, evolving standards have become more protective of human health. These new regulations address the revised standards for exposure to ionizing radiation, as well as changing trends in diagnostic, and radiation therapy technologies. Additionally, these new regulations will be more consistent with other state and federal regulations.

The following sections of the Regulations of Connecticut State Agencies (RCSA) will be repealed: 19-24-1 to 19-24-14 inclusive, and 19-25a-1 to 19-25d-11 inclusive. DEEP is proposing to adopt new regulatory sections for the control of ionizing radiation, as RCSA sections 22a-153-1 to 22a-153-9, inclusive. The new regulatory sections address the following areas: decommissioning criteria for license termination; the use of diagnostic and therapeutic quantities of radionuclide's; computed tomography x-ray systems; external beam radiation therapy machines; instructions and reports to workers; use of diagnostic x-ray imaging systems; industrial radiographic operations; and definitions appropriate to the new requirements.

Written comments. All interested persons are invited to comment on the proposal. Comments should be submitted no later than April 16, 2014 to Denny Galloway, DEEP, Bureau of Air Management, Radiation Division, 79 Elm Street, Hartford, Connecticut 06106-5127. Comments may be submitted by U.S. Mail to the address below or by electronic mail to Denny.Galloway@ct.gov.

Public hearing. In addition to accepting written comments, DEEP will also hold the public hearing described below. Any person giving oral comment at the hearing will be asked to submit a written copy of such comments.

PUBLIC HEARING
April 16, 2014
Time 10:30 AM
DEEP, 5th Floor, Holcombe Room
79 Elm Street, Hartford, CT

The proposal described above, a fiscal impact analysis, a small business impact analysis and a statement required by section 22a-6(h) of the Connecticut General Statutes (CGS) are available for public inspection during normal business hours from Denny Galloway at the Bureau of Air Management, Radiation Division, 79 Elm Street, Hartford, CT. The same documents are posted on DEEP's website. For further information, contact Denny Galloway of the Bureau of Air Management at (860) 424-3029 or by electronic mail to Denny.Galloway@ct.gov

DEEP is an Affirmative Action/Equal Opportunity Employer that is committed to complying with the requirements of the Americans with Disabilities Act. Any person with a disability who may need a communication aid or service may contact DEEP's ADA Coordinator at 860-424-3194 or at deep.hrmed@ct.gov. Any person needing a hearing accommodation may call the State of Connecticut relay number - 711. Any person with limited proficiency in English, who may need information in another language, may contact DEEP's Title VI Coordinator at 860-424-3035 or at deep.aaoffice@ct.gov. ADA or Title VI discrimination complaints may be filed with DEEP's EEO Manager at 860-424-3035 or at deep.aaoffice@ct.gov. Requests for accommodations must be made at least two weeks prior to any agency hearing, program or event.

_____ _____

Date

Robert J. Klee
Interim Commissioner

Connecticut Department of
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Submission of Notice of Intent for Website Publication

TO: Office of the Secretary of the State (regulations.sots@ct.gov)
FROM: Denny A. Galloway, Supervising Radiation Control Physicist
DATE: 10 March 2014
SUBJECT: Notice of Intent to Repeal and Adopt Radiation Regulations

Pursuant to CGS section 4-168, please find attached a notice of the Department of Energy and Environmental Protection's intent to take an action to amend and adopt regulations. Please post this notice at your earliest convenience on the website of the Office of the Secretary of the State.

To assist you, I provide the following information about the notice and proposal:

Notice type: Notice of intent

Agency: Department of Energy & Environmental Protection

Subject matter: Radiation Regulations

Sections affected: RCSA sections 19-24-1 to 19-24-14 and 19-25a-1 to 19-25d-11

Public comments close: 16 April 2014

This notice and associated documents will be posted on DEEP's website. The documents have been provided to the web master and should be posted within 48 hours.

Please get in touch with me at 860-424-3525 or denny.galloway@ct.gov if you have questions concerning this notice.

The Regulations of Connecticut State Agencies are amended by adding section 22a-153-1, as follows:

(NEW)

Sec. 22a-153-1. General provisions for sources of ionizing radiation.

(a) Definitions. For purposes of sections 22a-153-1 through 22a-153-9, the following definitions shall apply:

(1) "AAPM" means American Association of Physicists in Medicine.

(2) "Absorbed dose" or "D" means the mean energy imparted by ionizing radiation to matter. Absorbed dose is determined as the quotient of dE by dM, where dE is the mean energy imparted by ionizing radiation to matter of mass dM. The SI unit of absorbed dose is joule per kilogram, and the special name of the unit of absorbed dose is the gray (Gy).

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

(4) "Act" means chapter 446a of the Connecticut General Statutes.

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

(6) "Added filtration" means any filtration that is in addition to inherent filtration.

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

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

(9) "Airborne radioactivity area" means a room, enclosure or area in which airborne radioactive materials exist in concentrations:

(A) In excess of the derived air concentrations (DACs) specified in Appendix B, Table I of 22a-153-2 of these regulations; or

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

(10) "ALARA" or "as low as is reasonably achievable" means making every reasonable effort to maintain exposures to radiation as far below the applicable dose limits as is practical, consistent with the purpose for which the registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in

relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and registered sources of radiation in the public interest.

(11) “ANSI” means the American National Standards Institute.

(12) "Authorized medical physicist" means a person who:

(A) Is identified as an authorized medical physicist on a specific medical use license or equivalent permit or registration issued by the Commissioner, NRC or an Agreement State; or

(B) Is identified as an authorized medical physicist on a permit or registration pursuant to a specific medical use license of broad scope issued by the Commissioner, NRC or an Agreement State.

(13) "Automatic exposure control” or "AEC" means a device, including a phototimer and an ion chamber, that automatically controls one or more technique factors in order to obtain a required quantity of radiation at a preselected location or locations.

(14) "Background radiation" means radiation from cosmic sources and naturally occurring radioactive materials, including radon, except as a decay product of source or special nuclear material, and including global fallout as it exists in the environment from the testing of nuclear explosive devices. Background radiation does not include sources of radiation from radioactive materials regulated by the Department.

(15) "Beam axis" means the axis of rotation of the beam limiting device.

(16) "Becquerel" or "Bq" means the SI unit of activity. One becquerel is equal to 1 disintegration or transformation per second (dps or tps).

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

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

(19) "Brachytherapy source" means a radioactive source or a manufacturer-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.

(20) "Byproduct material" means:

(A) 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

(B) 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.

(21) "Calendar quarter" means not less than twelve (12) consecutive weeks nor more than fourteen (14) consecutive weeks. The first calendar quarter of each year shall begin in January and subsequent calendar quarters shall be so arranged such that no day is included in more than one calendar quarter and no day in any one year is omitted from inclusion within a calendar quarter.

(22) "Calibration" means the determination of (1) the response or reading of an instrument relative to a series of known radiation values over the range of the instrument, or (2) the strength of a source of radiation relative to a standard.

(23) "CFR" means Code of Federal Regulations.

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

(25) "Collimator" means a radiation shield that is placed on the end of the guide tube or directly onto a radiographic exposure device to restrict the size of the radiation beam when the sealed source is cranked into position to make a radiographic exposure.

(26) "Commissioner" means the Commissioner of the Connecticut Department of Energy and Environmental Protection, or any member of the Department or any local air pollution control official or agency authorized by the Commissioner, acting singly or jointly, to whom the Commissioner assigns any functions arising under the provisions of these regulations.

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

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

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

(30) "Curie" or "Ci" means a unit of quantity of activity. One curie is that quantity of radioactive material which decays at the rate of 3.7E+10 disintegrations or transformations per second (dps or tps).

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

(32) "Department" means the Connecticut Department of Energy and Environmental Protection.

(33) "Department of Energy" means the Department of Energy established by Public Law 95-91, August 4, 1977, 42 U.S.C. 7101 et seq., to the extent that the Department exercises functions formerly vested in the Atomic Energy Commission, its Chairman, members, officers and components and transferred to the Energy Research and Development Administration and to the Administrator thereof pursuant to sections 104(b), (c) and (d) of the Energy Reorganization Act of 1974 (Public Law 93-438, October 11, 1974, 42 U.S.C. 5814, effective January 19, 1975) and re-transferred to the Secretary of Energy pursuant to section 301(a) of the Department of Energy Organization Act (Public Law 95-91, August 4, 1977, 42 U.S.C. 7151, effective October 1, 1977.)

(34) "Depleted uranium" or "DU" means the source material uranium in which the isotope uranium-235 is less than 0.711 weight percent of the total uranium present. “Depleted uranium” does not include special nuclear material.

(35) "Dose" or "radiation dose" means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, total organ dose equivalent or total effective dose equivalent.

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

(37) "Dose limits" or "limits" means the permissible upper bounds of radiation doses established in accordance with these regulations.

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

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

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

(41) "Exposure" means being exposed to ionizing radiation or to radioactive material. The SI unit of exposure is the coulomb per kilogram (C/kg).

(42) "Exposure rate" means the exposure per unit of time, expressed in units of roentgen per minute or milliroentgen per hour.

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

(44) "Facility" means the location within one building, vehicle and under the same administrative control (1) at which the possession, use, processing or storage of radioactive material is or was authorized or (2) at which one or more radiation-producing machines or radioactivity-inducing machines are installed or located. "Facility" may also mean multiple such locations at a site or part of a site.

(45) "Filter" means material placed in the useful beam to preferentially absorb selected radiations.

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

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

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

(49) "Healing arts" means "the practice of healing arts" as defined in section 20-1 of the Connecticut General Statutes.

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

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

(52) "Individual monitoring" means the assessment of:

(A) Dose equivalent by the use of either individual monitoring devices or survey data; or

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

(53) "Individual monitoring devices" or "personnel monitoring equipment" means devices designed to be worn by a single individual for the assessment of dose equivalent. For purposes of these regulations, "personnel dosimeter" and "dosimeter" are equivalent terms. Individual monitoring devices ~~are~~ include, but are not limited to, film badges, thermoluminescent dosimeters (TLDs), pocket ionization chambers and personal air sampling devices.

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

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

(56) "Interlock" means a device, electrical or mechanical, that either prevents activation of equipment until a preliminary condition has been met or prevents hazardous operation.

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

(58) "Irradiation" means the exposure of a living being or matter to ionizing radiation.

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

(60) "Kilovolt," "kV" or "keV" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one thousand volts in a vacuum, where the abbreviation "kV" applies for photons and the abbreviation "keV" for electrons.

(61) "Lead equivalent" means the thickness of the material in question affords the same attenuation, under specified conditions, as lead.

(62) "Leakage radiation" means radiation emanating from the radiation therapy system or diagnostic source assembly except for the useful beam or radiation produced when the exposure switch or timer is not activated.

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

(64) "Licensee" means any person who is licensed by the Department.

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

(66) "Management" means the chief executive officer or other individual having the authority to manage, control, direct or administer a registrant or licensee's activities, or such persons' delegate or delegates.

(67) "Medical event" means "medical event" as defined in 10 CFR 35.3045(a).

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

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

(70) "Month" means a calendar month.

(71) "NARM" means any naturally occurring or accelerator-produced radioactive material. “NARM” does not include byproduct, source or special nuclear material.

(72) "Natural radioactivity" means radioactivity of naturally occurring nuclides.

(73) "NIOSH" means the National Institute for Occupational Safety and Health.

(74) "NIST" means the National Institute for Standards and Technology.

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

(76) "NVLAP" means the National Voluntary Laboratory Accreditation Program.

(77) "Occupational dose" means the dose received by an individual in the course of employment in which the individual's assigned duties for the registrant involve exposure to sources of radiation, whether or not the sources of radiation are in the possession of the registrant or another person. "Occupational dose" does not include dose received: from background radiation; as a patient from medical practices; from voluntary participation in medical research programs; or as a member of the public.

(78) "Particle accelerator" or "accelerator" means any machine capable of accelerating electrons, protons, deuterons or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 MeV, excluding the following: an orthovoltage x-ray machine, a diagnostic x-ray machine, a therapeutic x-ray machine and an electron microscope.

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

(80) "Peak tube potential," "kilovolts peak" or "kVp" means the maximum value of the potential difference across the x-ray tube during an exposure.

(81) "Phantom" means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation. Both the atomic number (Z) and the density of "phantom" material are similar to that of tissue.

(82) "Person" means "person" as defined in section 22a-151 of the Connecticut General Statutes.

(83) "Pharmacist" means "pharmacist" as defined in section 20-571 of the Connecticut General Statutes.

(84) "Physician" means "physician" as defined in section 20-13a of the Connecticut General Statutes.

(85) "Primary protective barrier" means the material, excluding filters, placed in the useful beam.

(86) "Protective apron" means an apron made of radiation absorbing materials used to reduce radiation exposure.

(87) "Protective barrier" or "barrier" means a barrier of radiation absorbing material used to reduce radiation exposure. A "protective barrier" may be either primary or secondary.

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

(89) "Public dose" means the dose received by a member of the public from sources of radiation from registered operations. “Public dose” does not include occupational dose, a dose received from background radiation, a dose received as a patient from medical practices or a dose received from voluntary participation in medical research programs.

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

(91) "Qualified expert" means an individual having the knowledge and training to measure ionizing radiation, to evaluate safety techniques and to advise regarding radiation protection needs, including, but not limited to: individuals certified in the appropriate field by a specialty board with a certification process recognized by the Commissioner; an "authorized medical physicist" pursuant to 10 CFR 35.51; or those having equivalent qualifications. With reference to the calibration of radiation therapy equipment, an individual having, in addition to the above qualifications, training and experience in the clinical applications of radiation physics to radiation therapy, including, but not limited to: individuals certified in radiological physics by a specialty board with a certification process recognized by the Commissioner; or those having equivalent qualifications.

(92) "Quality factor" or "Q" means the modifying factor listed in Tables 1-1 and 1-2 of this section that is used to derive dose equivalent from absorbed dose.

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

(94) "Radiation" or "ionizing radiation" means alpha particles, beta particles, gamma rays, x-rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of directly or indirectly producing ions. “Radiation” does not include non-ionizing radiation, such as radiowaves or microwaves, visible, infrared or ultraviolet light.

(95) "Radiation area" means any area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.05 mSv (0.005 rem) in one (1) hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates.

(96) "Radiation detector" or "detector" means a device that in the presence of radiation provides a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

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

(98) "Radiation safety officer" or “RSO” means an individual who has the knowledge and responsibility to apply appropriate radiation protection regulations.

(99) "Radioactive drug" means a drug that contains a radioactive substance that is used to diagnose or treat disease, including but not limited to cancer,

(100) "Radioactive material" means any solid, liquid or gas that emits radiation spontaneously.

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

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

(103) "Registrant" means any person who holds a valid registration.

(104) "Registration" means "registration" as defined in section 22a-151 pursuant to the Connecticut General Statutes.

(105) "Regulations of the Department of Transportation" means the regulations in 49 CFR 100-189.

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

(107) "Research and development" means:

(A) Theoretical analysis, exploration or experimentation; or

(B) The extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials and processes. Research and development does not include the internal or external administration of radiation or radioactive material to human beings.

(108) "Restricted area" means an area, access to which is limited by the registrant for the purpose of protecting individuals against undue risks from exposure to sources of radiation. A "restricted area" does not include an area used as a residential quarter, but separate rooms in a residential building may be set apart as a restricted area.

(109) "Roentgen" or "R" means the special unit of exposure. One roentgen equals 2.58E-4 coulombs per kilogram of air.

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

(111) "Shallow dose equivalent" or "H_s", as applied to the external exposure of the skin or an extremity, means the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm^2) averaged over an area of 10 square centimeters.

(112) "Shutter" means a device that:

(A) Is attached to the tube housing assembly;

(B) Is able to intercept the entire cross-sectional area of the useful beam; and

(C) Has a lead equivalency not less than that of the tube housing assembly.

(113) "SI" means the abbreviation for the International System of Units.

(114) "Sievert" or “Sv” means the SI unit of dose equivalent measured in units of joules per kilogram.

(115) "Simulator" or "radiation therapy simulation system" means any X-ray system exclusively used to localize the volume to be exposed during radiation therapy and reproduce the position and size of the therapeutic irradiation field.

(116) "Site" means the area contained within the boundary of a location under the control of persons generating or storing radioactive materials; or using ionizing radiation.

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

(118) "Source material" means:

(A) Uranium or thorium, or any combination thereof, in any physical or chemical form; or

(B) Ores that contain by weight one-twentieth of 1 percent (0.05 percent) or more of uranium, thorium or any combination of uranium and thorium.

“Source material” does not include special nuclear material.

(119) "Source material milling" means any activity resulting in the production of byproduct material as defined by subparagraph (B) of subdivision 14 of this section.

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

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

(122) "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 inch); and

(C) It satisfies the test requirements specified by the Nuclear Regulatory Commission. A special form encapsulation designed in accordance with the Nuclear Regulatory Commission requirements in effect on June 30, 1983, and constructed prior to July 1, 1985, may continue to be used. A special form encapsulation either designed or constructed after June 30, 1985 shall meet requirements of this definition applicable at the time of its design or construction.

(123) "Special nuclear material" means:

(A) Plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material that the Nuclear Regulatory Commission, pursuant to the provisions of section 51 of the Atomic Energy Act of 1954, as amended, determines to be special nuclear material, but does not include source material; or

(B) Any material artificially enriched by any of the foregoing but does not include source material.

(124) "Special nuclear material in quantities not sufficient to form a critical mass" means the sum of the ratios of uranium-235 (U-235); uranium-233 (U-233) or plutonium (Pu) is equal to or less than one when determined according to the following formula:

$$\frac{\text{U-235 (grams)}}{350} + \frac{\text{U-233 (grams)}}{200} + \frac{\text{Pu (grams)}}{200} \leq 1$$

(125) “Specific license” means “specific license” as defined in section 22a-151 of the Connecticut General Statutes.

(126) “Standard temperature and pressure” means a dry gas temperature of 68 degrees Fahrenheit and a gas pressure of 14.7 pounds per square inch absolute (20 degrees C, 760 mmHg).

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

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

(129) "Survey" means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal or presence of sources of radiation. When appropriate, such evaluation includes, but is not limited to, tests, physical examinations and measurements of levels of radiation or concentrations of radioactive material present.

(130) "Target-to-skin distance," "TSD," "source-to-skin distance" or "SSD" means the distance measured along the beam axis from the center of the front surface of the x-ray target or electron-beam focus point to the surface of the irradiated patient.

(131) "Technique factors" means the following conditions of operation:

(A) For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;

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

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

(D) For CT x-ray systems not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan time in seconds, or the product of tube current and exposure time in mAs and the scan time when the scan time and exposure time are equivalent; and

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

(132) "Temporary job site" means a location where mobile medical services are conducted in addition to the location(s) of use authorized on a registration or license. OR "Temporary job site" means a location where radiographic operations are performed and where sources of radiation may be stored other than the location of use authorized on the registration.

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

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

(135) "Total organ dose equivalent" or "TODE" means the sum of the deep dose equivalent and the committed dose equivalent to the organ receiving the highest dose.

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

(137) "Tube housing assembly" means the tube housing with tube installed, including high-voltage or filament transformers and other appropriate elements when such are contained within the tube housing.

(138) “Type A package” means “Type A package,” as defined in 49 CFR 173.403.

(139) “Type B package” means “Type B package,” as defined in 49 CFR 173.403.

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

(141) "Unrestricted area" or "uncontrolled area" means an area, access to which is neither limited nor controlled by the licensee or registrant for the purposes of limiting exposure to radiation.

(142) "Useful beam" or "radiation field" means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam limiting device when the exposure controls are in a mode to cause the imaging system or therapeutic radiation machine to produce radiation.

(143) "Waste" or "low-level waste" means radioactive waste that is:

(A) Neither high-level waste nor transuranic waste, nor spent nuclear fuel, nor by-product material, as defined in Section 11e(2) of the Atomic Energy Act of 1954, as amended; and

(B) Classified by the federal government as low-level waste, consistent with existing law, but does not include waste generated as a result of atomic energy defense activities of the federal government, as defined in P.L. 96-573, or federal research and development activities.

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

(145) "Week" means seven consecutive days starting on Sunday.

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

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

(148) "Working level month" or "WLM" means an exposure to one working level for one hundred seventy (170) hours.

(149) "X-ray equipment," "equipment" or "stationary x-ray equipment" means an x-ray system, subsystem or component thereof, inclusive of the following types:

(A) "Mobile x-ray equipment" means x-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled;

(B) "Portable x-ray equipment" means x-ray equipment designed to be hand-carried; and

(C) "Stationary x-ray equipment" means x-ray equipment installed in a fixed location.

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

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

(152) "Year" means the twelve-month period beginning January 1, unless the starting date is otherwise specified in a regulation, license or registration.

(b) Applicability.

(1) Except as otherwise specifically provided, this section applies, as specified in sections 22a-153-2 through 22a-153-9 of the Regulations of Connecticut State Agencies, to all persons who receive, possess, use, transfer, own or acquire any source of radiation.

(2) No sources of ionizing radiation shall be used unless registered with the Department.

(c) Records and reports.

(1) Each registrant shall make and maintain records showing the receipt, transfer and disposal of all sources of radiation, and any other records necessary to determine compliance with sections 22a-153-2 through 22a-153-9 of the Regulations of Connecticut State Agencies.

(2) Copies of all records required by subdivision (1) of this subsection and all reports submitted to the Commissioner shall be:

(A) Made available to the Commissioner to inspect and copy upon request; and

(B) Maintained on-site for five years from the date such record or report is created.

(3) All reports required to be submitted to the Commissioner pursuant to sections 22a-153-2 through 22a-153-9 of the Regulations of Connecticut State Agencies shall be directed to the Division of Radiation, Bureau of Air Management.

(d) Inspections.

Each registrant shall, at all reasonable times, allow the Commissioner opportunity to inspect sources of radiation and the premises and facilities wherein such sources of radiation are used or stored.

(e) Tests. Each registrant shall perform, upon instructions from the Commissioner, or shall permit the Commissioner to perform, such reasonable tests as the Commissioner deems appropriate or necessary including, but not limited to, tests of:

(1) Sources of radiation;

(2) Facilities wherein sources of radiation are used or stored;

(3) Radiation detection and monitoring instruments; and

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

(f) Enforcement and prohibitions.

(1) The Commissioner may, by regulation, permit or order, impose upon any registrant such requirements in addition to those established in sections 22a-153-1 through 22a-153-9 of the Regulations of Connecticut State Agencies, including impoundment of sources of radiation, as it deems appropriate or necessary to minimize danger to public health and safety or property.

(2) The following activities are prohibited:

(A) Use of a hand-held fluoroscopic screen with x-ray equipment unless it has been listed in the Registry of Sealed Source and Devices or accepted for certification by the Food and Drug Administration, Center for Devices and Radiological Health; and

(B) Use of a shoe-fitting fluoroscopic device.

(g) Units of exposure and dose.

(1) For the purposes of sections 22a-153-1 through 22a-153-9 of the Regulations of Connecticut State Agencies, the unit of exposure shall be the coulomb per kilogram (C/kg) of air, and one roentgen shall be equal to 2.58E-4 coulomb per kilogram of air at standard temperature and pressure.

(2) Except as provided in subdivision (4) of this subsection, for the purposes of sections 22a-153-1 through 22a-153-9 of the Regulations of Connecticut State Agencies, the units of dose shall be the following:

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

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

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

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

(3) Except as provided in subdivision (4) of this subsection, for the purposes of sections 22a-153-2 through 22a-153-9 of the Regulations of Connecticut State Agencies, the quality factors for converting absorbed dose to dose equivalent shall be as indicated in Table 1-1.

TABLE 1-1
QUALITY FACTORS AND ABSORBED DOSE EQUIVALENCIES

Type of radiation	***Quality factor***	***Absorbed dose equal to a unit dose equivalent[a]***
X-, gamma, or beta radiation and high-speed electrons	1	1
Alpha particles, multiple-charged particles, fission fragments and heavy particles of unknown charge	20	0.05
Neutrons of unknown energy	10	0.1
High-energy protons	10	0.1

[a] Absorbed dose in gray equal to 1 Sv or the absorbed dose in rad equal to 1 rem.

(4) For the purposes of sections 22a-153-2 through 22a-153-9 of the Regulations of Connecticut State Agencies, a registrant may measure the neutron fluence rate rather than determine the neutron dose equivalent rate in sievert per hour or rem per hour, according to one of the following:

(A) 0.01 Sv (1 rem) of neutron radiation of unknown energies may be assumed to result from a total fluence of 25 million neutrons per square centimeter incident upon the body; or

(C) If sufficient information exists to estimate the approximate energy distribution of the neutrons, the registrant may use the fluence rate per unit dose equivalent or the appropriate Q value from Table 1-2 to convert a measured tissue dose in gray or rad to dose equivalent in sievert or rem.

TABLE 1-2

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

	Neutron Energy (MeV)	Quality Factor[a/] (Q)	Fluence per Unit Dose Equivalent[b/] (Neutrons cm^{-2} rem^{-1})	Fluence per Unit Dose Equivalent[b/] (Neutrons cm^{-2} Sv^{-1})
(thermal)				
	2.5E-8	2	980E+6	980E+8
	1E-7	2	980E+6	980E+8
	1E-6	2	810E+6	810E+8
	1E-5	2	810E+6	810E+8
	1E-4	2	840E+6	840E+8
	1E-3	2	980E+6	980E+8
	1E-2	2.5	1010E+6	1010E+8
	1E-1	7.5	170E+6	170E+8
	5E-1	11	39E+6	39E+8
	1	11	27E+6	27E+8
	2.5	9	29E+6	29E+8
	5	8	23E+6	23E+8
	7	7	24E+6	24E+8
	10	6.5	24E+6	24E+8
	14	7.5	17E+6	17E+8
	20	8	16E+6	16E+8
	40	7	14E+6	14E+8
	60	5.5	16E+6	16E+8
	1E+2	4	20E+6	20E+8
	2E+2	3.5	19E+6	19E+8
	3E+2	3.5	16E+6	16E+8
	4E+2	3.5	14E+6	14E+8

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

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

(h) Units of Activity. For the purposes of sections 22a-153-2 through 22a-153-9 of the Regulations of Connecticut State Agencies, activity shall be expressed in the SI unit of becquerel (Bq) or in the special unit of curie (Ci), or their multiples, or disintegrations or transformations per unit of time, where:

(1) One becquerel (Bq) = 1 disintegration or transformation per second (dps or tps); and

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

The Regulations of Connecticut State Agencies are amended by adding section 22a-153-2, as follows:

(NEW)

Sec. 22a-153-2. Standards for protection against radiation.

(a) Definitions. For the purposes of this section the following definitions apply. Terms that are used in this section and not defined in this section are as provided in section 22a-153-1 of the Regulations of Connecticut State Agencies.

(1) "ALI" or “annual limit on intake” means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. “ALI” is the smaller value of intake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent of 0.05 Sv (5 rem) or a committed dose equivalent of 0.5 Sv (50 rem) to any individual organ or tissue.

(2) "Class” means an assignment under a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W or Y, according to the clearance half times as follows: for Class D, less than ten (10) days; for Class W, ten (10) to one hundred (100) days; and for Class Y, greater than one hundred (100)days.

(3) "Declared pregnant woman" means a woman who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception. The term applies until such woman withdraws the declaration in writing or is no longer pregnant.

(4) "Derived air concentration" or "DAC" means the concentration of a given radionuclide in air which, if breathed by the reference man for a working year of two thousand (2,000) hours under conditions of light work, results in an intake of one ALI. As used in this section, the condition of light work is an inhalation rate of 1.2 cubic meters of air per hour for two thousand (2,000) hours in a year.

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

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

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

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

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

(10) "Remainder" means the five other organs or tissues with the highest dose e.g., liver, kidney, pancreas, stomach, small intestine and upper large intestine.

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

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

(13) "Stochastic effect" means a health effect that occurs randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects.

(14) "Very high radiation area" means an area, accessible to individuals, in which radiation levels could result in an individual receiving an absorbed dose in excess of five Gy (500 rad) in one hour at one meter from a source of radiation or from any surface that the radiation penetrates.

(15) "Weighting factor" or "w_T" for an organ or tissue (T) means the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of w_T are as defined in Table 2-1:

Table 2-1. Organ Dose Weighting Factors

Organ or Tissue (T)	w_T
Gonads	0.25
Breast	0.15
Red bone marrow	0.12
Lung	0.12
Thyroid	0.03
Bone surfaces	0.03
Remainder	0.30[a/]
Whole Body	1.00[b/]

[a/] 0.30 results from 0.06 for each of 5 "remainder" organs, excluding the skin and the lens of the eye, that receive the highest doses.

[b/] For the purpose of weighting the external whole body dose, for adding it to the internal dose, a single weighting factor, $w_T = 1.0$, has been specified. The use of other weighting factors for external exposure will be approved on a case-by-case basis until such time as specific guidance is issued.

(b) Applicability.

(1) This section applies to persons registered by the Commissioner to receive, possess, use, transfer or dispose of sources of radiation.

(2) The exposure and dose limits in this section do not apply to doses resulting from:

(A) Background radiation;

(B) Exposure of patients to radiation for the purpose of medical diagnosis or therapy; or

(C) Exposure from voluntary participation in medical research programs.

(c) More restrictive limit.

Any condition in a registration issued prior to ***the effective date of this section*** that is more restrictive than this section shall remain in force until there is an amendment or renewal of such registration.

(d) Radiation protection programs.

(1) No later than one year from ***the effective date of this section***, each registrant shall develop a site-specific radiation protection program sufficient to meet the requirements of this section.

(2) In its radiation protection program, the registrant shall use, to the extent practicable, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and public doses that are as low as is reasonably achievable.

(3) The radiation protection program shall be described in a manual with an index. Such manual shall be updated on an annual basis. The manual shall include, but not be limited to, the following information:

(A) A summary of the applicable occupation and public dose limits;

(B) Procedures for operating the facility within the dose limits established under this section;

(C) Procedures for monitoring exposure;

(D) Procedures for recordkeeping consistent with subsection (n) of this section; and

(E) Procedures for reporting consistent with subsection (o) of this section.

(4) The registrant shall, at intervals not to exceed 13 months, review the radiation protection program content and implementation and update the manual as necessary to meet the requirements of this section.

(5) The radiation protection program manual shall be maintained in a location readily accessible to all workers and shall be available for inspection by the Commissioner upon request.

(e) Occupational dose limits.

(1) Occupational dose limits for adults. A registrant shall restrict the occupational dose to individual adults according to the limits in this subdivision, calculated according to this subsection:

(A) An annual limit, which is the more limiting of:

(i) The total effective dose equivalent equal to 0.05 Sv (5 rem), or

(ii) The sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 0.5 Sv (50 rem); and

(B) The annual limits to the lens of the eye, to the skin, and to the extremities, which are:

(i) A lens dose equivalent of 0.15 Sv (15 rem), and

(ii) A shallow dose equivalent of 0.5 Sv (50 rem) to the skin or to any extremity.

(2) Each registrant shall calculate doses received in excess of the annual limits, by subtracting doses received during accidents, emergencies and planned special exposures, from the limits for planned special exposures that the individual may receive during the current year and during the individual's lifetime.

(3) A registrant shall calculate the assigned deep dose equivalent and shallow dose equivalent for the portion of the body receiving the highest exposure, as follows:

(A) 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; or

(B) When a protective apron is worn while working with medical fluoroscopic equipment and monitoring is conducted as specified in subsection (i)(2)(A)(iv) of this section, the effective dose equivalent for external radiation shall be determined as follows:

(i) When only one individual monitoring device is used and such device is located at the neck outside the protective apron, the reported deep dose equivalent shall be the effective dose equivalent for external radiation, and

(ii) When individual monitoring devices are worn, both under the protective apron at the waist and outside the protective apron at the neck, the effective dose equivalent calculation shall be calculated using the ANSI procedure for performing multiple dosimetry, provided the following are addressed:

(I) A statement that the weighting factors will be used only for physicians performing cardiology or interventional radiology using fluoroscopy,

(II) The date the weighting factors will be implemented. Weighting factors may not be used retroactively, and

(III) A statement that personnel who have their doses calculated using this method will be informed annually of the original dosimeter measurements and the process used to determine their doses of record.

(4) DAC and ALI values may be used to determine the individual's dose and to demonstrate compliance with the occupational dose limits.

(5) Notwithstanding the annual dose limits of subdivision (1) of this subsection, a registrant shall limit the soluble uranium intake by an individual to 10 milligrams in a week in consideration of chemical toxicity.

(6) A registrant shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person during the current year.

(7) Compliance with requirements for summation of external and internal doses. If a registrant is required to monitor pursuant to both subsections (i)(2)(A) and (i)(2)(B) of this section, such registrant shall demonstrate compliance with the dose limits by summing external and internal doses. If the registrant is required to monitor only pursuant to subsection (i)(2)(A) of this section or only pursuant to subsection (i)(2)(B) of this section, then summation is not required to demonstrate compliance with the dose limits. The registrant may demonstrate compliance with the requirements for summation of external and internal doses pursuant to subparagraphs (A) through (C) of this subdivision. The dose equivalents for the lens of the eye, the skin and the extremities are not included in the summation, but are subject to separate limits.

(A) Intake by inhalation. If the only intake of radionuclides is by inhalation, the total effective dose equivalent limit is not exceeded if the sum of the deep dose equivalent divided by the total effective dose equivalent limit, and one of the following, does not exceed unity:

(i) The sum of the fractions of the inhalation ALI for each radionuclide;

(ii) The total number of derived air concentration-hours (DAC-hours) for all radionuclides divided by two thousand (2,000); or

(iii) The sum of the calculated committed effective dose equivalents to all significantly irradiated organs or tissues (T) calculated from bioassay data using appropriate biological models and expressed as a fraction of the annual limit. For purposes of this requirement, an organ or tissue is deemed to be significantly irradiated if, for that organ or tissue, the product of the weighting factors, w_T, and the committed dose equivalent, $H_{T,50}$, per unit intake is greater than 10 percent of the maximum weighted value of $H_{T,50}$, that is, $w_T H_{T,50}$, per unit intake for any organ or tissue.

(B) Intake by oral ingestion. If the occupationally exposed individual receives an intake of radionuclides by oral ingestion greater than 10 percent of the applicable oral ALI, the registrant shall account for this intake and include it in demonstrating compliance with the limits.

(C) Intake through wounds or absorption through skin. A registrant shall evaluate and, to the extent practical, account for intakes through wounds or skin absorption. The intake through intact skin has been included in the calculation of DAC for hydrogen-3 and does not need to be evaluated or accounted for pursuant to this subparagraph.

(8) Determination of external dose. Each registrant shall determine the external dose from airborne radioactive material as follows:

(A) Include the contribution to the deep dose equivalent, lens dose equivalent and shallow dose equivalent from external exposure to the radioactive cloud; and

(B) When the airborne radioactive material includes radionuclides other than noble gases or if the cloud of airborne radioactive material is not relatively uniform, airborne radioactivity measurements and DAC values shall not be used as the primary means to assess the deep dose equivalent. The determination of the deep dose equivalent to an individual shall be based upon measurements using instruments or individual monitoring devices.

(9) Determination of internal dose. A registrant shall determine internal exposure according to subparagraphs (A) through (H) of this subdivision, as follows:

(A) For purposes of assessing dose used to determine compliance with occupational dose equivalent limits, a registrant shall, as required pursuant to subsection (i)(2) of this section, take suitable and timely measurements of:

(i) Concentrations of radioactive materials in air in work areas,

(ii) Quantities of radionuclides in the body,

(iii) Quantities of radionuclides excreted from the body, or

(iv) Combinations of these measurements;

(B) Unless respiratory protective equipment is used**,** as provided in subsection (j)(6) of this section, or the assessment of intake is based on bioassays, the licensee shall assume that an individual inhales radioactive material at the airborne concentration in which the individual is present;

(C) When specific information on the physical and biochemical properties of the radionuclides taken into the body or the behavior of the material in an individual is known, the registrant may:

(i) Use that information to calculate the committed effective dose equivalent, and, if used, the registrant shall document that information in the individual's record;

(ii) Upon prior approval of the Commissioner, adjust the DAC or ALI values to reflect the actual physical and chemical characteristics of airborne radioactive material, for example, aerosol size distribution or density; and

(iii) Separately assess the contribution of fractional intakes of Class D, W or Y compounds of a given radionuclide to the committed effective dose equivalent;

(D) If the registrant chooses to assess intakes of Class Y material using the measurements given in subsections (e)(9)(A)(ii) or (e)(9)(A)(iii) of this section, the registrant may delay the recording and reporting of the assessments for periods up to seven months, unless otherwise required by subsections (o)(2) or (o)(3) of this section. This delay enables the registrant to make additional measurements basic to the assessments;

(E) If the identity and concentration of each radionuclide in a mixture are known, the fraction of the DAC applicable to the mixture for use in calculating DAC-hours shall be either:

(i) The sum of the ratios of the concentration to the appropriate DAC value, that is, D, W, or Y from Appendix B of 10 CFR 20 for each radionuclide in the mixture, or

(ii) The ratio of the total concentration for all radionuclides in the mixture to the most restrictive DAC value for any radionuclide in the mixture;

(F) If the identity of each radionuclide in a mixture is known, but the concentration of one or more of the radionuclides in the mixture is not known, the DAC for the mixture shall be the most restrictive DAC of any radionuclide in the mixture;

(G) When a mixture of radionuclides in air exists, a registrant may disregard certain radionuclides in the mixture if:

(i) The registrant uses the total activity of the mixture in demonstrating compliance with the dose limits in subdivision (e) of this section and in complying with the monitoring requirements in, subsection (i)(2)(B) of this section,

(ii) The concentration of any radionuclide disregarded is less than 10 percent of its DAC, and

(iii) The sum of these percentages for all of the radionuclides disregarded in the mixture does not exceed 30 percent; and

(H) When determining the committed effective dose equivalent, the following information may be considered:

(i) To calculate the committed effective dose equivalent, the registrant may assume that the inhalation of one ALI, or an exposure of two thousand (2,000) DAC-hours, results in a committed effective dose equivalent of 0.05 Sv (5 rem) for radionuclides that have their ALIs or DACs based on the committed effective dose equivalent, and

(ii) For an ALI and the associated DAC determined by the non-stochastic organ dose limit of 0.5 Sv (50 rem), the intake of radionuclides that would result in a committed effective dose equivalent of 0.05 Sv (5 rem), that is, the stochastic ALI, is listed in parentheses in Table I of Appendix B of 10 CFR 20. The registrant may, as a simplifying assumption, use the stochastic ALI to determine committed effective dose equivalent. However, if the registrant uses the stochastic ALI, the registrant shall also demonstrate that the limit in subdivision (1)(A)(ii) of this subsection is met.

(10) Determination of prior occupational dose. A registrant shall determine the prior occupational dose as follows:

(A) For each individual who may enter the registrant's restricted area and is likely to receive, in a year, an occupational dose requiring monitoring pursuant to subsection (i)(2) of this section, the registrant shall make the following determinations according to the requirements of this subdivision:

(i) Determine the occupational radiation dose received during the current year, and

(ii) Attempt to obtain the records of lifetime cumulative occupational radiation dose.

(B) Prior to permitting an individual to participate in a planned special exposure, a registrant shall determine:

(i) The internal and external doses from all previous planned special exposures, and

(ii) All doses in excess of the limits, including doses received during accidents and emergencies, received during the lifetime of the individual.

(C) In complying with the requirements of subparagraph (A) of this subdivision, a registrant may:

(i) Accept, as a record of the occupational dose that the individual received during the current year, a written signed statement from the individual or from the individual's most recent employer for work involving radiation exposure that discloses the nature and the amount of any occupational dose that the individual received during the current year,

(ii) Accept, as the record of lifetime cumulative radiation dose, an up-to-date **Agency Form Y** or equivalent, signed by the individual and countersigned by an appropriate official of the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the registrant, and

(iii) Obtain reports of the individual's dose equivalent from the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the registrant, by telephone, telegram, facsimile, or letter. The registrant shall request a written verification of the dose data if the authenticity of the transmitted report cannot be established.

(D) The registrant shall record the exposure history as required by subparagraph (A) of this subdivision**,** as follows:

(i) On **Agency Form Y**, or other clear and legible record, of all the information required on that form. The form or record shall show each period in which the individual received occupational exposure to radiation or radioactive material and shall be signed by the individual who received the exposure. For each period for which the registrant obtains reports, the licensee or registrant shall use the dose shown in the report in preparing **Agency Form Y** or equivalent. For any period in which the registrant does not obtain a report, the licensee or registrant shall place a notation on **Agency Form Y** or equivalent indicating the periods of time for which data are not available, and

(ii) Registrants are not required to partition historical dose between external dose equivalent(s) and internal committed dose equivalent(s). Occupational exposure histories obtained and recorded on **Agency Form Y** or equivalent before the effective date of this section that do not include effective dose equivalent may be used in the absence of specific information on the intake of radionuclides by the individual.

(E) If the registrant is unable to obtain a complete record of an individual's current and previously accumulated occupational dose, the registrant shall assume:

(i) In establishing administrative controls pursuant to subsection (e)(6) of this section for the current year, that the allowable dose limit for the individual is reduced by 12.5 mSv (1.25 rem) for each calendar quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure, and

(ii) That the individual is not available for planned special exposures.

(F) The registrant shall retain the records on **Agency Form Y** or equivalent until the department terminates each pertinent registration requiring this record. The registrant shall retain records used in preparing **Agency Form Y** or equivalent for five (5) years after the record is made.

(11) Planned special exposures. A registrant may authorize an adult worker to receive doses in addition to and accounted for separately from the doses received under the limits specified subdivisions (1) through (6) of this subsection provided that each of the following conditions is satisfied:

(A) The registrant authorizes a planned special exposure only in an exceptional situation when alternatives that might avoid the higher exposure are unavailable or impractical;

(B) The registrant and employer, if the employer is not the registrant, specifically authorizes the planned special exposure, in writing, before the exposure occurs;

(C) Before a planned special exposure, the registrant ensures that each individual involved is:

(i) Informed of the purpose of the planned operation,

(ii) Informed of the estimated doses and associated potential risks and specific radiation levels or other conditions that might be involved in performing the task, and

(iii) Instructed in the measures to be taken to keep the dose ALARA considering other risks that may be present;

(D) Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant ascertains prior doses as required by subdivision (10)(B) of this subsection during the lifetime of the individual for each individual involved;

(E) Subject to subdivision (2) of this subsection, the registrant shall not authorize a planned special exposure that would cause an individual to receive a dose from all planned special exposures and all doses in excess of the limits to exceed:

(i) The numerical values of any of the dose limits in subdivision (1) of this subsection in any year, and

(ii) Five times the annual dose limits in subdivision (1) of this subsection during the individual's lifetime.

(F) The registrant maintains records of the conduct of a planned special exposure in accordance with subsection (n)(6) of this section and submits a written report in accordance with subsection (o)(4) of this section;

(G) The registrant records the best estimate of the dose resulting from the planned special exposure in the individual's record and informs the individual, in writing, of the dose within 30 days from the date of the planned special exposure. The dose from planned special exposures shall not be considered in controlling future occupational dose of the individual pursuant to subdivision (1) of this subsection but shall be included in evaluations required by subparagraphs (D) and (E) of this subdivision.

(12) Occupational dose limits for minors. The annual occupational dose limits for minors are 10% of the annual occupational dose limits specified for adult workers *in* subdivisions (1) through (6) of this subsection.

(13) Dose to an embryo or fetus. A registrant shall ensure that the dose to an embryo or fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 5 mSv (0.5 rem), calculated as follows:

(A) The registrant shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the occupational exposure limit of this subdivision;

(B) The dose to an embryo or fetus shall be taken as the sum of:

(i) The dose to the embryo or fetus from radionuclides in the embryo or fetus and radionuclides in the declared pregnant woman, and

(ii) The dose that is most representative of the dose to the embryo or fetus from external radiation, that is, in the mother's lower torso region**,** as follows:

(I) If multiple measurements have not been made, assignment of the highest deep dose equivalent for the declared pregnant woman shall be the dose to the embryo or fetus, in accordance with subdivision (10)(C) of this subsection; or

(II) If multiple measurements have been made, assignment of the deep dose equivalent for the declared pregnant woman from the individual monitoring device that is most representative of the dose to the embryo or fetus shall be the dose to the embryo or fetus. Assignment of the highest deep dose equivalent for the declared

pregnant woman to the embryo or fetus is not required unless that dose is also the most representative deep dose equivalent for the region of the embryo or fetus.

(C) When the woman declares pregnancy to the registrant, the dose to the embryo or fetus has exceeded 4.5 mSv (0.45 rem), the registrant shall be deemed to be in compliance with occupational exposure limit of this subdivision if the additional dose to the embryo or fetus does not exceed 0.5 mSv (0.05 rem) during the remainder of the pregnancy.

(f) Emergency worker dose limits. Emergency worker exposure control limits shall be determined on a case by case basis. Justification beyond occupational limits specified in subsection (e) of this section shall be for protecting valuable property, life saving activities or the protection of large populations.

(g) Radiation dose limits for individual members of the public.

(1) Each registrant shall conduct operations to limit the dose received by individual members of the public as follows:

(A) Except as provided in subdivision (2)(D) of this subsection, the total effective dose equivalent to individual members of the public from the registered operation shall not exceed 1 mSv (0.1 rem) in a year, exclusive of the dose contribution from the registrant's disposal of radioactive material into sanitary sewerage;

(B) The dose in any unrestricted area from external sources shall not exceed 0.02 mSv (0.002 rem) in any one hour; and

(C) The total effective dose equivalent to individual members of the public from infrequent exposure to radiation from radiation machines shall not exceed 5 mSv (0.5 rem).

(2) The dose limits of subdivision (1) of this subsection shall be determined as follows:

(A) If the registrant permits members of the public to have access to restricted areas, the limits for members of the public continue to apply to those individuals;

(B) A registrant or an applicant may apply for prior Commissioner’s authorization to operate up to an annual dose limit for an individual member of the public of 5 mSv (0.5 rem). Such application shall be submitted one hundred twenty (120) days prior to operation in question in writing on a form provided by the Commissioner and shall include the following information:

(i) Demonstration of the need for and the expected duration of operations in excess of the limit in subdivision (1) of this subsection,

(ii) The registrant's program to assess and control dose within the 5 mSv (0.5 rem) annual limit, and

(iii) The procedures to be followed to maintain the dose ALARA;

(C) In addition to the requirements of this section, a registrant subject to the provisions of EPA's generally applicable environmental radiation standards in 40 CFR 190 shall comply with those standards;

(D) The Commissioner may impose additional restrictions on radiation levels in unrestricted areas and on the total quantity of radionuclides that a registrant may release in effluents in order to restrict the collective dose;

(E) The registrant shall make surveys of radiation levels in unrestricted areas and radioactive materials in effluents released to unrestricted areas to demonstrate compliance with the dose limits for individual members of the public in subdivision (1) of this subsection;

(F) A registrant shall show compliance with the annual dose limit in subdivision (1) of this subsection by:

(i) Demonstrating by measurement or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from the registered operation does not exceed the annual dose limit, or

(ii) Demonstrating that:

(I) The annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in Table II of Appendix B of 10 CFR 20, and

(II) If an individual were continuously present in an unrestricted area, the dose from external sources would not exceed 0.02 mSv (0.002 rem) in an hour and 0.5 mSv (0.05 rem) in a year; and

(G) Upon approval from the Commissioner, the registrant may adjust the effluent concentration values in Appendix B of 10 CFR 20 , Table II, for members of the public, to take into account the actual physical and chemical characteristics of the effluents, such as aerosol size distribution, solubility, density, radioactive decay equilibrium and chemical form.

(h) Testing for leakage or contamination of sealed sources.

(1) The registrant in possession of any sealed source shall test such source for leaking or contamination according to the following requirements:

(A) Except as specified in subdivision (2) of this subsection, each sealed source shall be tested for leakage or contamination and the test results received before the sealed source is put into use unless the registrant has a certificate from the transferor indicating that the sealed source was tested within six months before transfer to the registrant;

(B) Each sealed source that is not designed to emit alpha particles shall be tested for leakage or contamination at intervals not to exceed six (6) months or at alternative intervals approved by the Commissioner, an Agreement State or the Nuclear Regulatory Commission:

(i) 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, the applicant shall include in 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

(ii) In determining the acceptable interval for test of leakage of radioactive material, the Commissioner will consider information that includes, but is not limited to:

(I) primary containment or source capsule,

(II) protection of primary containment,

(III) method of sealing containment,

(IV) containment construction materials,

(V) form of contained radioactive material,

(VI) maximum temperature withstood during prototype tests,

(VII) maximum pressure withstood during prototype tests,

(VIII) maximum quantity of contained radioactive material,

(IX) radiotoxicity of contained radioactive material, and

(X) operating experience with identical sources or devices, or similarly designed and constructed sources or devices.

(C) Each sealed source that is designed to emit alpha particles shall be tested for leakage or contamination at intervals not to exceed three (3) months or at alternative intervals approved by the Commissioner, an Agreement State or the Nuclear Regulatory Commission as follows:

(i) 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 shall include in his application sufficient information to demonstrate that such longer interval is justified by performance

characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source, and

(ii) In determining the acceptable interval for test of leakage of radioactive material, the Commissioner will consider information that includes, but is not limited to:

(I) primary containment or source capsule,

(II) protection of primary containment,

(III) method of sealing containment,

(IV) containment construction materials,

(V) form of contained radioactive material,

(VI) maximum temperature withstood during prototype tests,

(VII) maximum pressure withstood during prototype tests,

(VIII) maximum quantity of contained radioactive material,

(IX) radiotoxicity of contained radioactive material, and

(X) operating experience with identical sources or devices or similarly designed and constructed sources or devices;

(D) For each sealed source that is required to be tested for leakage or contamination, at any other time there is reason to suspect that the sealed source might have been damaged or might be leaking, the licensee or registrant shall assure that the sealed source is tested for leakage or contamination before further use;

(E) Tests for leakage for all sealed sources, except brachytherapy sources manufactured to contain radium, shall be capable of detecting the presence of 185 Bq (0.005 μCi) of radioactive material on a test sample. Test samples shall be taken from the sealed source or from the surfaces of the container in which the sealed source is stored or mounted on which one might expect contamination to accumulate. For a sealed source contained in a device, test samples are obtained when the source is in the "off" position;

(F) The test for leakage for brachytherapy sources manufactured to contain radium shall be capable of detecting an absolute leakage rate of 37 Bq (0.001 μCi) of radon-222 in a twenty four (24) hour period when the collection efficiency for radon-222 and its daughters has been determined with respect to collection method, volume and time; and

(G) Tests for contamination from radium daughters shall be taken on the interior surface of brachytherapy source storage containers and shall be capable of detecting the presence of 185 Bq (0.005 μCi) of a radium daughter which has a half-life greater than four days.

(2) Notwithstanding subsection (b)(1) of this section**,** a licensee or registrant is not required to perform testing for leakage or contamination on the following sealed sources:

(A) Sealed sources containing only radioactive material with a half-life of less than thirty (30) days;

(B) Sealed sources containing only radioactive material as a gas;

(C) Sealed sources containing 3.7 MBq (100 μCi) or less of beta or photon-emitting material or 370 kBq (10 μCi) or less of alpha-emitting material;

(D) Sealed sources containing only hydrogen-3;

(E) Seeds of iridium-192 encased in nylon ribbon; and

(F) Sealed sources, except teletherapy and brachytherapy sources, which are stored, not being used and identified as in storage. The registrant shall test each such sealed source for leakage or contamination and receive the test results before any use or transfer unless it has been tested for leakage or contamination within six (6) months before the date of use or transfer.

(3) Tests for leakage or contamination from sealed sources shall be performed by persons specifically authorized by the Commissioner, an Agreement State or the Nuclear Regulatory Commission to perform such services.

(4) Test results shall be recorded in units of becquerel or microcurie and maintained for inspection by the Commissioner. Records of test results for sealed sources shall be made pursuant to subsection (n)(4) of this section.

(5) The following shall be considered evidence that a sealed source is leaking:

(A) The presence of 185 Bq (0.005 μCi) or more of removable contamination on any test sample;

(B) Leakage of 37 Bq (0.001 μCi) of radon-222 per twenty four (24) hours for brachytherapy sources manufactured to contain radium; and

(C) The presence of removable contamination resulting from the decay of 185 Bq (0.005 μCi) or more of radium.

(6) The registrant shall immediately withdraw a leaking sealed source from use and shall take action to prevent the spread of contamination. The leaking sealed source shall be repaired or disposed of in accordance with this section.

(7) Reports of test results for leaking or contaminated sealed sources shall be made pursuant to subsection (o)(7) of this section.

(i) Surveys and monitoring.

(1) General requirements.

(A) Each registrant shall make, or cause to be made, surveys that:

(i) Are necessary for the registrant to comply with this section, and

(ii) Are necessary under the circumstances to evaluate:

(I) Radiation levels,

(II) Concentrations or quantities of radioactive material, and

(III) The potential radiological hazards that could be present;

(B) The registrant shall ensure that instruments and equipment used for quantitative radiation measurements, such as dose rate and effluent monitoring, are calibrated at intervals not to exceed thirteen (13) months for the radiation measured, except when a more frequent interval is specified in another applicable part of these regulations or a registration;

(C) All personnel dosimeters, except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to any extremity, that require processing to determine the radiation dose and that are used by registrants to comply with subsections (e)(1) through (e)(6) of this section, other applicable provisions of the Regulations of Connecticut State Agencies or conditions specified in a registration shall be processed and evaluated by a dosimetry processor who:

(i) Holds current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program of the National Institute of Standards and Technology, and

(ii) Is approved in this accreditation process for the type of radiation or in the National Voluntary Laboratory Accreditation Program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

(2) Conditions requiring individual monitoring of external and internal occupational dose. Each registrant shall monitor exposures from sources of radiation at levels sufficient to demonstrate compliance with the occupational dose limits of this section. As a minimum:

(A) Each registrant shall monitor occupational exposure to radiation and shall supply and require the use of individual monitoring devices by the following individuals:

(i) Adults likely to receive, in one year from sources external to the body, a dose in excess of 10 percent of the limits in subsection (e)(1) of this section,

(ii) Minors and declared pregnant women likely to receive, in one year from sources external to the body, a dose in excess of 10 percent of any of the applicable limits in subsections (e)(12) and (e)(13) of this section,

(iii) Individuals entering a high or very high radiation area, and

(iv) Individuals working with medical fluoroscopic equipment.

(B) Each registrant shall monitor to determine compliance with subsection (e)(9) of this section, the occupational intake of radioactive material by and assess the committed effective dose equivalent to:

(i) Adults likely to receive, in one year, an intake in excess of 10 percent of the applicable ALI in Table I, Columns 1 and 2, of Appendix B of 10 CFR 20, and

(ii) Minors and declared pregnant women likely to receive, in one year, a committed effective dose equivalent in excess of 0.5 mSv (0.05 rem).

(3) Location of individual monitoring devices. Each registrant shall ensure that individuals who are required to monitor occupational doses in accordance with subdivision (2)(A) of this subsection wear individual monitoring devices as follows:

(A) An individual monitoring device used for monitoring the dose to the whole body shall be worn at the unshielded location of the whole body likely to receive the highest exposure. When a protective apron is worn, the location of the individual monitoring device is typically at neck level;

(B) An individual monitoring device used for monitoring the dose to an embryo/fetus of a declared pregnant woman, pursuant to subsection (e)(13) of this section, shall be located at the waist under any protective apron being worn by the woman;

(C) An individual monitoring device used for monitoring the lens dose equivalent, to demonstrate compliance with subsection (e)(1)(B)(i) of this section, shall be located at neck level, outside any protective apron being worn by the monitored individual, or at an unshielded location closer to the eye;

(D) An individual monitoring device used for monitoring the dose to the extremities, to demonstrate compliance with subsection (e)(1)(B)(ii) of this section, shall be worn on the extremity likely to receive the highest exposure. Each individual monitoring device shall be oriented to measure the highest dose to the extremity being monitored, as appropriate to the use of the device; and

(E) When only one individual monitoring device is used to determine the effective dose equivalent for external radiation pursuant to subsection (e)(3)(B) of this

section, it shall be located at the neck outside the protective apron. When a second individual monitoring device is used, for the same purpose, it shall be located under the protective apron at the waist. The second individual monitoring device is required for a declared pregnant woman.

(j) Control of exposure from external sources in restricted areas.

(1) Control of access to high radiation areas.

(A) Each registrant shall install and use at least one of the following measures at each entrance or access point to a high radiation area:

(i) A control device that, upon entry into the area, causes the level of radiation to be reduced below that level at which an individual might receive a deep dose equivalent of 1 mSv (0.1 rem) in one hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates,

(ii) A control device that energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry, or

(iii) Entryways that are locked, except during periods when access to the areas is required, with positive control over each individual entry;

(B) In place of the controls required by subparagraph (A) of this subdivision for a high radiation area, the registrant may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry;

(C) The registrant may apply to the Commissioner for approval of alternative methods for controlling access to high radiation areas pursuant to subparagraphs (A) and (B) of this subdivision;

(D) The registrant shall establish controls such as an emergency exit door required by subparagraphs (A) and (C) of this subdivision in a way that does not prevent individuals from leaving a high radiation area;

(E) The registrant is not required to control each entrance or access point to a room or other area that is a high radiation area solely because of the presence of radioactive materials prepared for transport and packaged and labeled in accordance with the regulations of the Department of Transportation provided that:

(i) The packages do not remain in the area longer than three days, and

(ii) The dose rate at one meter from the external surface of any package does not exceed 0.1 mSv (0.01 rem) per hour;

(F) The registrant is not required to control entrance or access to rooms or other areas in hospitals solely because of the presence of patients containing radioactive material, provided that there are personnel in attendance who are taking the necessary precautions to prevent the exposure of individuals to radiation or radioactive material in excess of the established limits in this section and to operate within the ALARA provisions of the registrant's radiation protection program; and

(G) The registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a high radiation area as described in subdivision (1) of this subsection if the registrant has met all the specific requirements for access and control specified in other applicable sections of the Regulations of Connecticut State Agencies established under section 22a-153 of the Connecticut General Statutes.

(2) Control of access to very high radiation areas.

(A) In addition to implementing the requirements in subdivision (1) of this subsection, the registrant shall institute measures to ensure that an individual is not able to gain unauthorized or inadvertent access to areas in which radiation levels could be encountered at five (5) Gy (500 rad) or more in one hour at one meter from a source of radiation or any surface through which the radiation penetrates. This requirement does not apply to rooms or areas in which diagnostic x-ray systems are the only source of radiation, or to non-self-shielded irradiators;

(B) The registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a very high radiation area as described in subparagraph (A) of this subdivision if the registrant has met all the specific requirements for access and control specified in other applicable sections of the Regulations of Connecticut State Agencies established under section 22a-153 of the Connecticut General Statutes.

(3) Control of access to very high radiation areas with non-self shielded irradiators. This subdivision applies to any registrant with a source of radiation in a non-self shielded irradiator.

(A) In each area in which radiation levels may exceed five Gy (500 rad) in one hour at one meter from a source of radiation used to irradiate materials, the registrant shall:

(i) Equip each entrance or access point with entry control devices that:

(I) Function automatically to prevent any individual from inadvertently entering a very high radiation area,

(II) Permit deliberate entry into the area only after a control device is actuated that causes the radiation level within the area, from the source of radiation, to be reduced below a level at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 mSv (0.1 rem) in one hour, and

(III) Prevent operation of the source of radiation if it would produce radiation levels in the area that could result in a deep dose equivalent to an individual in excess of 1 mSv (0.1 rem) in one (1) hour,

(ii) Provide control devices in addition to those required by subparagraph (A)(i) of this subdivision so that, upon failure of the entry control devices to function as required by subparagraph (A)(i) of this subdivision:

(I) The radiation level within the area, from the source of radiation, is reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 mSv (0.1 rem) in one (1) hour, and

(II) Conspicuous visible and audible alarm signals are generated to make an individual attempting to enter the area aware of the hazard and at least one other authorized individual, who is physically present, familiar with the activity and prepared to render or summon assistance, aware of the failure of the entry control devices,

(iii) Provide control devices so that, upon failure or removal of physical radiation barriers other than the sealed source's shielded storage container:

(I) The radiation level from the source of radiation is reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 mSv (0.1 rem) in one hour, and

(II) Conspicuous visible and audible alarm signals are generated to make potentially affected individuals aware of the hazard and the registrant or at least one other individual, who is familiar with the activity and prepared to render or summon assistance, aware of the failure or removal of the physical barrier,

(iv) When the shield for stored sealed sources is a liquid, provide means to monitor the integrity of the shield and to signal, automatically, loss of adequate shielding,

(v) Equip each area with devices that will automatically generate conspicuous visible and audible alarm signals to alert personnel in the area before the source of radiation can be put into operation and in time for any individual in the area to operate a clearly identified control device, which must be installed in the area and which can prevent the source of radiation from being put into operation,

(vi) Control each area with administrative procedures and devices sufficient to ensure that the area is cleared of personnel prior to each use of the source of radiation,

(vii) Check each area by a radiation measurement to ensure that, prior to the first entry of a person into the area after any use of the source of radiation, the radiation level from the source of radiation in the area is below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 mSv (0.1 rem) in one (1) hour,

(viii) Test the entry control devices required in subparagraph (A)(i) of this subdivision for proper functioning as follows:

(I) Conduct tests prior to initial operation with the source of radiation on any day, unless operations were continued uninterrupted from the previous day,

(II) Conduct tests prior to resumption of operation of the source of radiation after any unintentional interruption, and

(III) Submit and adhere to a schedule for periodic tests of the entry control and warning systems,

(ix) Refrain from conducting operations, other than those necessary to place the source of radiation in safe condition or to effect repairs on controls, unless control devices are functioning properly, and

(x) Control entry and exit portals that are not intended for use by individuals and that are used in transporting materials to and from the irradiation area by providing devices and administrative procedures that automatically warn against inadvertent entry by any individual through such portals. Exit portals for irradiated materials shall be equipped to detect and signal the presence of any loose radioactive material that is carried toward such an exit and to use automatic controls to prevent loose radioactive material from being carried out of the area;

(B) Registrants for sources of radiation that are subject to subparagraph (A) of this subdivision where compliance with subparagraph (A) is impracticable due to position or location of use may apply to the Commissioner for approval of alternative safety measures. Alternative safety measures shall provide personnel protection at least equivalent to those specified in subparagraph (A) of this subdivision. At least one of the alternative measures shall include an entry-preventing interlock control based on a measurement of the radiation that ensures no individual can gain access to the area where such sources of radiation are used until high radiation levels are absent;

(C) The entry control devices required by subparagraphs (A) and (B) of this subdivision shall be established in such a way that no individual will be prevented from leaving the area;

(D) This subdivision shall not apply to a self-shielded irradiator that is used in teletherapy or industrial radiography where:

(i) The source of radiation is both stored and operated within the same shielding radiation barrier, and

(ii) The design makes the source physically inaccessible to any individual and prevents high levels of radiation in an area that is accessible to any individual; and

(E) The requirements of subparagraphs (A)(iii) and (A)(iv) of this subdivision shall not apply to physical radiation barriers that are permanent structural components, such as walls, and that have no credible probability of failure or removal in ordinary circumstances.

(4) Use of process or other engineering controls. Each registrant shall use, to the extent practical, process or other engineering controls, including but not limited to, containment, decontamination or ventilation, to control the concentration of radioactive material in air.

(5) Use of other controls.

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

(i) Control of access,

(ii) Limitation of exposure times,

(iii) Use of respiratory protection equipment, or

(iv) Other controls; and

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

(6) Use of individual respiratory protection equipment. If a registrant assigns or permits the use of respiratory protection equipment to limit the intake of radioactive material, such registrant shall meet the requirements of this subdivision, as follows:

(A) Use only respiratory protection equipment that is tested and certified by NIOSH, except as otherwise provided in this subdivision;

(B) Use equipment that has not been tested or certified by NIOSH, or for which there is no schedule for testing or certification extended by NIOSH, only with approval of the Commissioner. A request for such use shall include evidence that the material and performance characteristics of the equipment are capable of

providing the proposed degree of protection under anticipated conditions of use, such as manufacturer testing;

(C) Implement and maintain a respiratory protection program that includes:

(i) Air sampling sufficient to identify the potential hazard, permit proper equipment selection and estimate doses,

(ii) Surveys and bioassays, as necessary, to evaluate actual intakes,

(iii) Testing of respirators for operability by performing a user seal check for face sealing devices and functional check for other devices immediately prior to each use;

(iv) Written procedures regarding the following:

(I) Monitoring, including air sampling and bioassays,

(II) Supervision and training of respirator users,

(III) Fit testing,

(IV) Respirator selection,

(V) Breathing air quality,

(VI) Inventory and control,

(VII) Storage, issuance, maintenance, repair, testing, and quality assurance of respiratory protection equipment,

(VIII) Record keeping, and

(IX) Limitations on periods of respirator use and relief from respirator use,

(v) Determination by a physician that an individual user is medically fit to use respiratory protection equipment prior to:

(I) The initial fitting of a face sealing respirator,

(II) The first field use of non-face sealing respirators, and

(III) Either every twelve (12) months thereafter, or periodically at a frequency determined by a physician, and

(vi) Fit testing, with fit factor ten times the assigned protection factor for negative pressure devices, and a fit factor of 500 for any positive pressure, continuous flow and pressure-demand devices, before the first field use of

tight fitting, face-sealing respirators and periodically thereafter at a frequency not to exceed one (1) year. Fit testing must be performed with the face piece operating in the negative pressure mode;

(D) Advise each respirator user that the user may leave the area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions or any other conditions that might require such relief;

(E) Consider limitations on respiratory device use appropriate to the type and mode of use. When selecting respiratory devices the registrant shall provide for vision correction, adequate communication, low temperature work environments and the concurrent use of other safety or radiological protection equipment. The registrant shall use equipment in such a way as not to interfere with the proper operation of the respirator;

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

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

(H) Ensure that no objects, materials or substances, such as facial hair, or any conditions that interfere with the face-to-face piece seal or valve function, and that are under the control of the respirator wearer, are present between the skin of the wearer's face and the sealing surface of a tight-fitting respirator face piece; and

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

(7) The Commissioner may impose additional restrictions necessary to:

(A) Ensure that the respiratory protection program of a registrant is adequate to limit doses to individual from airborne radioactive material consistent with maintaining total effective dose equivalent ALARA; and

(B) Limit the extent to which a registrant may use respiratory protection equipment instead of process or other engineering controls.

(8) The registrant shall obtain authorization from the Commissioner before using assigned protection factors in excess of those specified in Appendix A to 10 CFR 20. The Commissioner may authorize a registrant to use higher assigned protection factors on receipt of an application that includes:

(A) A description of the situation for which a need exists for higher protection factors; and

(B) A demonstration that the respiratory protection equipment provides these higher protection factors under the proposed conditions of use.

(k) Storage and control of registered sources of radiation. Each registrant shall:

(1) Secure registered radioactive material from unauthorized removal or access;

(2) Maintain constant surveillance, or use devices or administrative procedures, to prevent unauthorized use of registered radioactive material in an unrestricted area; and

(3) Use devices or administrative procedures to prevent unauthorized use of registered radiation machines.

(*l*) Precautionary procedures.

(1) Caution signs. Each registrant:

(A) Shall use the three-bladed design in Figure 2-1 to label a source of radiation:

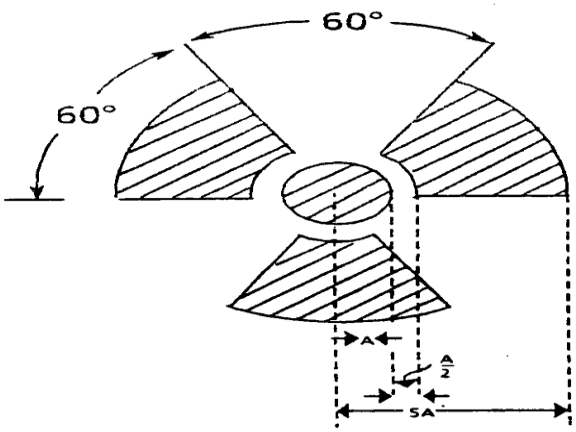

Figure 2-1. Radiation Symbol.

(B) Use magenta, purple or black to color the cross-hatched area in Figure 2-1, and use yellow for the symbol background, except that a registrant may label sources, source holders or device components containing sources of radiation that are subject to high temperatures with conspicuously etched or stamped radiation caution symbols without a color requirement;

(C) May provide, on or near signs and labels required by this section, additional information, as appropriate, to make individuals aware of potential radiation exposures and to minimize the exposures.

(2) Posting requirements. Each registrant shall post areas and rooms, as follows:

(A) For each radiation area, with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIATION AREA" or "CAUTION, X-RAY," as appropriate;

(B) For each high radiation area, with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, HIGH RADIATION AREA" or "DANGER, HIGH RADIATION AREA;"

(C) For each very high radiation area:

(i) Except as provided in subdivision (2)(C)(ii) of this subsection, with a conspicuous sign or signs bearing the radiation symbol and words "GRAVE DANGER, VERY HIGH RADIATION AREA," and

(ii) For areas in use in a medical facility where patient care is provided, with a conspicuous sign or signs bearing the radiation symbol and words "CAUTION, VERY HIGH RADIATION AREA" or "DANGER, VERY HIGH RADIATION AREA;"

(D) For each airborne radioactivity area, with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, AIRBORNE RADIOACTIVITY AREA" or "DANGER, AIRBORNE RADIOACTIVITY AREA;"

(E) For each area or room in which there is used or stored a source of radiation or an amount of radioactive material exceeding ten times the quantity of such material specified in Appendix C of 10 CFR 20 with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S);"

(3) Exceptions to posting requirements. Notwithstanding subsection (*l*)(2) of this section, a registrant is not required to post caution signs in the following areas or rooms:

(A) Containing sources of radiation for periods of less than eight (8) hours, if each of the following conditions is met:

(i) The sources of radiation are constantly attended during such periods by an individual who takes the precautions necessary to prevent the exposure of individuals to sources of radiation in excess of the limits established in this section, and

(ii) The area or room is subject to the registrant's control;

(B) That are occupied by patients in hospitals, provided that the requirements of sections 22a-153-8(z) of the Regulations of Connecticut State Agencies are met:

(i) A patient being treated with a permanent implant could be released from confinement pursuant to section 22a-153- 8(z) of the Regulations of Connecticut State Agencies, or

(ii) A patient being treated with a therapeutic radiopharmaceutical could be released from confinement pursuant to section 22a-153- 8(z) of the Regulations of Connecticut State Agencies;

(C) Where a sealed source is present, provided the radiation level at 30 centimeters from the surface of the sealed source container or housing, or material equivalent to a sealed source, does not exceed 0.05 mSv (0.005 rem) per hour;

(D) Because of the presence of radiation machines used solely for diagnosis in the healing arts; and

(E) Used for teletherapy in a hospital or clinic, provided that:

(i) Access to the room is controlled pursuant to 10 CFR 35.615, and

(ii) Personnel in attendance take necessary precautions to prevent the inadvertent exposure of workers, other patients and members of the public to radiation in excess of the limits established in this section.

(4) Labeling containers and radiation machines. Each registrant shall ensure that:

(A) Each container of registered material bears a durable, clearly visible label bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL." The label shall also provide information that may include the radionuclides present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels and mass enrichment, to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures;

(B) Prior to removal or disposal of empty uncontaminated containers to unrestricted areas, the radioactive material label is removed or defaced, or the registrant

otherwise clearly indicates that the container no longer contains radioactive materials;

(C) Each radiation machine is labeled in a conspicuous manner, which cautions individuals that radiation is produced when it is energized.

(5) Exemptions to labeling requirements. A registrant is not required to label installed manufacturing or process equipment, such as piping and tanks, or any of the following containers:

(A) Holding registered material in quantities less than the quantities listed in Appendix C of 10 CFR 20;

(B) Holding registered material in concentrations less than those specified in Table III of Appendix B of 10 CFR 20;

(C) Attended by an individual who takes the precautions necessary to prevent the exposure of individuals in excess of the limits established by this section;

(D) When in transport and packaged and labeled in accordance with 40 CFR 173.403(m) and (w) and 40 CFR 173.421 through 173.424;

(E) That are accessible only to individuals authorized to handle or use them, or to work in the vicinity of the containers, if the contents are identified to these individuals by a readily available written record. The record shall be retained as long as the containers are in use for the purpose indicated on the record.

(6) Procedures for receiving and opening packages. Each registrant shall:

(A) When expecting delivery of a package containing quantities of radioactive material in excess of a Type A quantity, make arrangements to receive:

(i) The package when the carrier offers it for delivery, or

(ii) The notification of the arrival of the package at the carrier's terminal and to take possession of the package expeditiously;

(B) Monitor:

(i) The external surfaces of a package labeled as specified in 49 CFR 172.403 and 49 CFR 172.436 through 172.440 for radioactive contamination unless:

(I) The package contains only radioactive material in the form of gas or in special form, or

(II) Special form sources are transferred in a vehicle owned or operated by the registrant,

(ii) The external surfaces of a package labeled as specified in 49 CFR 172.403 and 172.436-440 for radiation levels unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, and

(iii) All packages known to contain radioactive material for radioactive contamination and radiation levels if there is evidence of degradation of package integrity, such as packages that are crushed, wet or damaged;

(C) Perform the monitoring required by subsection (*l*)(6)(B) of this section as soon as practicable after receipt of the package, but not later than three (3) hours after the package is received at the licensee's or registrant's facility if it is received during the licensee's or registrant's normal working hours, or not later than three (3) hours from the beginning of the next working day if it is received after working hours;

(D) Immediately notify the final delivery carrier and, by telephone, telegram, mailgram or facsimile, the Commissioner when:

(i) Removable radioactive surface contamination exceeds the limits of 10 CFR 71.87(i), or

(ii) External radiation levels exceed the limits of 10 CFR 71.47; and

(E) Establish, maintain and retain written procedures for safely opening packages in which radioactive material is received, and ensure that the procedures are followed and that due consideration is given to special instructions for the type of package being opened.

(m) Waste disposal.

(1) General requirements.

(A) Each registrant shall dispose of radioactive licensed or registered material only as follows:

(i) By transfer to an authorized recipient as provided in subsection (m)(6) of this section or 10 CFR 30, 40, 60, 61, 63, 70 and 72,

(ii) By decay in storage,

(iii) By release in effluents within the limits in subsection (g) of this section, or

(iv) As authorized pursuant to subdivisions (2) through (5) of this subsection.

(B) A person shall be specifically registered to receive waste containing radioactive material from other persons for:

(i) Treatment prior to disposal,

(ii) Treatment or disposal by incineration,

(iii) Decay in storage,

(iv) Disposal at a land disposal facility licensed pursuant to 10 CFR 61,

(v) Disposal at a geologic repository under 10 CFR 60 or 63, or

(vi) Storage until transferred to a storage or disposal facility authorized to receive the waste.

(2) A registrant or applicant for a registration may apply to the Commissioner for approval of proposed procedures, not otherwise authorized in this section, to dispose of registered material generated in the registrant's operations. Each application shall include:

(A) A description of the waste containing registered material to be disposed of, including the physical and chemical properties that have an impact on risk evaluation, and the proposed manner and conditions of waste disposal;

(B) An analysis and evaluation of pertinent information on the nature of the environment;

(C) The nature and location of other potentially affected facilities under the control of the licensee or registrant; and

(D) Analyses and procedures to ensure that doses are maintained ALARA and within the dose limits in this section.

(3) Disposal by release into sanitary sewerage.

(A) A registrant may discharge registered material into sanitary sewerage if each of the following conditions is satisfied:

(i) The material is readily soluble, or is readily dispersible biological material, in water,

(ii) The quantity of registered material that the registrant releases into the sewer in one month divided by the average monthly volume of water released into the sewer by the licensee or registrant does not exceed the concentration listed in Table III of Appendix B of 10 CFR 20, and

(iii) If more than one radionuclide is released, the following conditions must also be satisfied:

(I) The licensee or registrant shall determine the fraction of the limit in Table III of Appendix B of 10 CFR 20 represented by discharges into sanitary sewerage by dividing the actual monthly average concentration of each radionuclide released by the licensee

or registrant into the sewer by the concentration of that radionuclide listed in Table III of Appendix B of 10 CFR 20, and

(II) The sum of the fractions for each radionuclide required by subdivision (3)(A)(iii)(a) of this section does not exceed unity,

(iv) The total quantity of radioactive material that the registrant releases into the sanitary sewerage in a year does not exceed 185 GBq (5 Ci) of hydrogen-3, 37 GBq (1 Ci) of carbon-14 and 37 GBq (1 Ci) of all other radioactive materials combined; and

(B) Excreta from individuals undergoing medical diagnosis or therapy with radioactive material are not subject to the limitations contained in subdivision (3)(A) of this section.

(4) Treatment or disposal by incineration. A registrant may treat or dispose of registered radioactive material by incineration only in the form and concentration specified in subsection (m)(5) of this section or as specifically approved by the Commissioner pursuant to subsection (m)(2) of this section.

(5) Disposal of specific wastes.

(A) A registrant may dispose of registered radioactive material as if it were not radioactive if the registered radioactive material is:

(i) 1.85 kBq (0.05 μCi), or less, of hydrogen-3 or carbon-14 per gram of medium used for liquid scintillation counting, and

(ii) 1.85 kBq (0.05 μCi), or less, of hydrogen-3 or carbon-14 per gram of animal tissue, averaged over the weight of the entire animal;

(B) A registrant shall not dispose of tissue pursuant to subsection (m)(5)(A)(ii) of this section in a manner that would permit its use either as food for humans or as animal feed; and

(C) The registrant shall maintain records in accordance with subsection (n)(9) of this section.

(6) Transfer for disposal and manifests.

(A) The requirements of this subdivision are designed to control transfers of low-level radioactive waste intended for disposal at a licensed low-level radioactive waste disposal facility, establish a manifest tracking system and supplement existing requirements concerning transfers and recordkeeping for those wastes;

(B) Each shipment of radioactive waste designated for disposal at a licensed low-level radioactive waste disposal facility shall be accompanied by a shipment manifest as specified in Appendix G.I of 10 CFR 20;

(C) Each shipment manifest shall include a certification by the waste generator as specified in Appendix G.II of 10 CFR 20; and

(D) Each person involved in the transfer of waste for disposal or in the disposal of waste, including the waste generator, waste collector, waste processor and disposal facility operator, shall comply with the requirements specified in Appendix G.III of 10 CFR 20.

(7) Compliance with environmental and health protection regulations. Nothing in subsections (m)(1) through (m)(6) inclusive of this section shall relieve the registrant from the duty to comply with all other applicable federal, state and local regulations governing any other toxic or hazardous properties of disposed materials.

(n) Records.

(1) General provisions. Each registrant shall:

(A) Use the SI units becquerel, gray, sievert and coulomb per kilogram, or the special units curie, rad, rem and roentgen, including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by this section; and

(B) Distinguish among the quantities entered on the records required by this section, such as, total effective dose equivalent, total organ dose equivalent, shallow dose equivalent, lens dose equivalent, deep dose equivalent or committed effective dose equivalent.

(2) Records of radiation protection programs. Each registrant shall:

(A) Maintain records of the radiation protection program, including:

(i) The provisions of the program, and

(ii) Audits and other reviews of program content and implementation;

(B) Retain the records required by subsection (n)(2)(A)(i) of this section until the Commissioner terminates the registration requiring the record. The registrant shall retain the records required by subsection (n)(2)(A)(ii) of this section for five (5) years after the record is made.

(3) Records of surveys. Each registrant shall:

(A) Maintain records showing the results of surveys and calibrations required by subsections (i)(1) and (*l*)(6)(B) of this section for a period of five (5) years after the record is made;

(B) Retain each of the following records until the Commissioner terminates each pertinent registration requiring the record:

(i) Results of surveys made to determine the dose from external sources of radiation used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents,

(ii) Results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose,

(iii) Results of air sampling, surveys and bioassays required pursuant to subsection (i) of this section, and

(iv) Results of measurements and calculations used to evaluate the release of radioactive effluents to the environment; and

(C) Upon termination of a registration, the registrant shall permanently store records on **Agency Form Y** or equivalent.

(4) Records of tests for leakage or contamination of sealed sources. Records of tests for leakage or contamination of sealed sources required by this section shall be kept in units of becquerel or microcurie and maintained for inspection by the Commissioner for five (5) years after the records are made.

(5) Records of prior occupational dose. Each registrant shall:

(A) Retain, for a period of five (5) years from the date of creation, records of prior occupational dose and exposure history as specified in subsection (e)(10) of this section on **Agency Form Y** or equivalent until the Commissioner terminates each pertinent registration requiring this record; and

(B) Upon termination of a registration, permanently store records on **Agency Form Y** or equivalent;

(6) Records of planned special exposures. Each registrant shall:

(A) For each use of the provisions of subsection (e)(11) of this section for planned special exposures, maintain records that describe:

(i) The exceptional circumstances requiring the use of a planned special exposure,

(ii) The name of the management official who authorized the planned special exposure and a copy of the signed authorization,

(iii) What actions were necessary,

(iv) Why the actions were necessary,

(v) What precautions were taken to ensure that doses were maintained ALARA,

(vi) What individual and collective doses were expected to result, and

(vii) The doses actually received in the planned special exposure;

(B) Retain the records until the Commissioner terminates each pertinent license or registration requiring these records; and

(C) Upon termination of the registration, permanently store records on **Agency Form Y** or equivalent.

(7) Records of individual monitoring results. Each registrant shall:

(A) Maintain records of doses received by all individuals for whom monitoring was required pursuant to subsection (i)(2) of this section, and records of doses received during planned special exposures, accidents and emergency conditions. These records shall include, as applicable:

(i) The deep dose equivalent to the whole body, lens dose equivalent, shallow dose equivalent to the skin and shallow dose equivalent to the extremities,

(ii) The estimated intake of radionuclides,

(iii) The committed effective dose equivalent assigned to the intake of radionuclides,

(iv) The specific information used to calculate the committed effective dose equivalent pursuant to subsection (e)(9)(C) of this section,

(v) The total effective dose equivalent when required by subsection (e)(7) of this section, and

(vi) The total of the deep dose equivalent and the committed dose to the organ receiving the highest total dose;

(B) Make the records specified in subsection (n)(7)(A) of this section annually at intervals not to exceed thirteen months;

(C) Maintain the records specified in subsection (n)(7)(A) of this section on **Agency Form Z**, in accordance with the instructions for **Agency Form Z**, or in clear and legible records containing all the information required by **Agency Form Z;**

(D) Maintain the records of dose to an embryo/fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy, including the estimated date of conception, shall also be kept on file, but may be maintained separately from the dose records; and

(E) Retain each required form or record until the Commissioner terminates each pertinent registration requiring the record.

(8) Records of dose to individual members of the public. Each registrant shall:

(A) Maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public; and

(B) Retain the records required by subsection (n)(8)(A) of this section until the Commissioner terminates the registration requiring the record.

(9) Records of waste disposal. Each registrant shall:

(A) Maintain records of the disposal of registered materials made pursuant to section 22a-165d of the Connecticut General Statutes or subsections (m)(1) through (m)(5) of this section; and

(B) Retain the records required by subsection (n)(9)(A) of this section until the Commissioner terminates each registration requiring the record;

(10) Records of testing of entry control devices for very high radiation areas. Each registrant shall:

(A) Maintain records of tests made pursuant to subsection (j)(3)(A)(viii) of this section on entry control devices for very high radiation areas. Such records shall include the date, time and results of each such test of function; and

(B) Retain the records required by subsection (n)(10)(A) of this section for five (5) years after the record is made.

(11) Form of records. Each registrant shall:

(A) Maintain records in a form that is legible throughout the specified retention period;

(B) Include all pertinent information, including stamps, initials and signatures on all records;

(C) Maintain records in the form of the paper original or a reproduced copy; a microform copy, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period; or an electronic copy capable of producing accurate and complete records during the required retention period; and

(D) Apply adequate safeguards against tampering with and loss of records.

(o) Reporting.

(1) Reports of stolen, lost or missing sources of radiation. Each registrant shall:

(A) Report to the Commissioner by telephone the following occurrences in the designated times:

(i) Lost, stolen or missing radioactive material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in Appendix C of 10 CFR 20 under such circumstances that it appears to the licensee or registrant that an exposure could result to individuals in unrestricted areas, immediately after the occurrence of the loss becomes known to the licensee or registrant, or

(ii) Lost, stolen or missing radioactive material in an aggregate quantity greater than ten times the quantity specified in Appendix C of 10 CFR 20, within thirty days after the occurrence of the loss becomes known to the licensee or registrant if such material is still missing, and

(iii) A lost, stolen or missing radiation machine, immediately after its occurrence becomes known to the registrant;

(B) Make a report pursuant to subsection (o)(1)(A) of this section shall, within thirty (30) days after making the telephone report, submit to the Commissioner a written report including the following information:

(i) A description of the source of radiation involved, including, for radioactive material, the kind, quantity and chemical and physical form; and, for radiation machines, the manufacturer, model and serial number, type and maximum energy of radiation emitted,

(ii) A description of the circumstances under which the loss or theft occurred,

(iii) A statement of disposition, or probable disposition, of the source of radiation involved,

(iv) Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas,

(v) Actions that have been taken, or will be taken, to recover the source of radiation, and

(vi) Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of sources of radiation;

(C) Subsequent to filing the written report, report additional substantive information as required by the Commissioner on a loss or theft within thirty (30) days after the licensee or registrant learns of such information; and

(D) In each report required by this subdivision, include names of individuals who may have received exposure to radiation in a separate and detachable portion of the report.

(2) Notification of incidents.

(A) Immediate notification. Notwithstanding other requirements for notification pursuant to this section, each licensee or registrant shall immediately report each event involving a source of radiation possessed by the licensee or registrant that may have caused or threatens to cause any of the following conditions:

(i) An individual to receive:

(I) A total effective dose equivalent of 0.25 Sv (25 rem) or more,

(II) A lens dose equivalent of 0.75 Sv (75 rem) or more, or

(III) A shallow dose equivalent to the skin or extremities or a total organ dose equivalent of 2.5 Gy (250 rad) or more; or

(ii) The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake five times the occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.

(B) Twenty-four hour notification. Each licensee or registrant shall, within 24 hours of discovery of the event, report to the Commissioner each event involving loss of control of a licensed or registered source of radiation possessed by the licensee or registrant that may have caused, or threatens to cause, any of the following conditions:

(i) An individual to receive, in a period of 24 hours:

(a) A total effective dose equivalent exceeding 0.05 Sv (5 rem);

(b) A lens dose equivalent exceeding 0.15 Sv (15 rem); or

(c) A shallow dose equivalent to the skin or extremities or a total organ dose equivalent exceeding 0.5 Sv (50 rem); or

(ii) The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake in excess of one occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.

(C) Licensees or registrants shall make the reports required by subsections (o)(2)(A) and (o)(2)(B) of this section by initial contact by telephone to the Commissioner and shall confirm the initial contact by telegram, mailgram or facsimile to the Commissioner;

(D) The licensee or registrant shall prepare each report filed with the Commissioner pursuant to subsection (o)(2) of this section so that names of individuals who have

received exposure to sources of radiation are stated in a separate and detachable portion of the report; and

(E) The provisions of subsection (o)(2) of this section do not apply to doses that result from planned special exposures, provided such doses are within the limits for planned special exposures and are reported pursuant to subsection (o)(4) of this section.

(3) Reports of exposures, radiation levels and concentrations of radioactive material exceeding the limits.

(A) Reportable events. In addition to the notification required by subsection (o)(2) of this section, each licensee or registrant shall submit a written report within thirty (30) days after learning of any of the following occurrences:

(i) Incidents for which notification is required by subsection (o)(2) of this section,

(ii) Doses in excess of any of the following:

(I) The occupational dose limits for adults in subsections (c)(1) through (e)(6) of this section,

(II) The occupational dose limits for a minor in subsection (e)(12) of this section,

(III) The limits for an embryo/fetus of a declared pregnant woman in subsection (e)(13) of this section,

(IV) The limits for an individual member of the public in subsection (g)(1) of this section, or

(V) Any applicable limit in the license or registration;

(iii) Levels of radiation or concentrations of radioactive material in:

(I) A restricted area in excess of applicable limits in the license or registration, or

(II) An unrestricted area in excess of ten times the applicable limit set forth in this section or in the license or registration, whether or not involving exposure of any individual in excess of the limits in subsection (g)(1) of this section; or

(iv) For licensees subject to the provisions of the Environmental Protection Commissioner's generally applicable environmental radiation standards in 40 CFR 190, levels of radiation or releases of radioactive material in excess of those standards, or of license conditions related to those standards.

(B) Contents of reports.

(i) Each report required by subsection (3)(A) of this section shall describe the extent of exposure of individuals to radiation or radioactive material, including, as appropriate:

(I) Estimates of each individual's dose,

(II) The levels of radiation and concentrations of radioactive material involved,

(III) The cause of the elevated exposures, dose rates or concentrations; and

(IV) Corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, generally applicable environmental standards, and associated license or registration conditions.

(ii) Each report filed pursuant to subsection (o)(3)(A) of this section shall include for each individual exposed: the name, Social Security account number and date of birth. With respect to the limit for the embryo/fetus in subsection (e)(13) of this section, the identifiers should be those of the declared pregnant woman. The report shall be prepared so that this information is stated in a separate and detachable portion of the report.

(C) All licensees or registrants who make reports pursuant to subsection (o)(3)(A) of this section shall submit the report in writing to the Commissioner.

(4) Reports of planned special exposures. The licensee or registrant shall submit a written report to the Commissioner within thirty (30) days following any planned special exposure conducted in accordance with subsection (e)(11) of this section, informing the Commissioner that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by subsection (n)(6) of this section.

(5) Reports of Individual Monitoring.

(A) This section applies to each person licensed or registered by the Commissioner to:

(i) Possess or use sources of radiation for purposes of industrial radiography pursuant to section 22a-153-3 of the Regulations of Connecticut State Agencies, or

(ii) Possess or use at any time, for processing or manufacturing for distribution pursuant to section 22a-153-8 of the Regulations of Connecticut State Agencies, radioactive material in quantities exceeding any one of the quantities in Table 2(o):

Table 2(o)

Radionuclide	Activity	
	Ci	GBq
Cesium-137	1	37
Cobalt-60	1	37
Gold-198	100	3,700
Iodine-131	1	37
Iridium-192	10	370
Krypton-85	1,000	37,000
Promethium-147	10	370
Technetium-99m	1,000	37,000

(B) Each licensee or registrant in a category listed in subparagraph (A) of this subdivision shall submit an annual report of the results of individual monitoring carried out by the licensee or registrant for each individual for whom monitoring was required by subsection (i)(2) of this section during that year. The licensee or registrant may include additional data for individuals for whom monitoring was provided but not required. The licensee or registrant shall use **Agency Form Z** or equivalent or electronic media containing all the information required by **Agency Form Z**; and

(C) The licensee or registrant shall file the report required by subparagraph (B) of this subdivision, covering the preceding year, on or before April 30 of each year. The licensee or registrant shall submit the report to the Commissioner.

(6) Notifications and reports to individuals.

(A) Requirements for notification and reports to individuals of exposure to radiation or radioactive material are specified in 22a-153-6(c);

(B) When a licensee or registrant is required pursuant to subsection (o)(3) of this section to report to the Commissioner any exposure of an individual to radiation or radioactive material, the licensee or registrant shall also notify the individual. Such notice shall be transmitted at a time not later than the transmittal to the Commissioner, and shall comply with the provisions of 22a-153-6(c)(1).

(7) Reports of leaking or contaminated sealed sources. The licensee or registrant shall file a report within five (5) days with the Commissioner if the test for leakage or contamination required pursuant to subsection (h) of this section indicates a sealed source is leaking or

contaminated. The report shall include the equipment involved, the test results and the corrective action taken.

(p) Vacating premises.

Each registrant shall, no less than ninety (90) days before vacating or relinquishing possession or control of premises that may have been contaminated with radioactive material as a result of his activities, notify the Commissioner in writing of intent to vacate. When deemed necessary by the Commissioner, the registrant shall decontaminate the premises in such a manner as the Commissioner may specify.

(q) Protection factors for respirators.

(1) The protection factors assigned in Table 2(q)-A shall apply only in a respiratory protection program for use in the selection of respiratory protective equipment where the contaminants are identified and the possible concentrations of contaminants are known.

(2) The protection factors of Table 2(q)-A are applicable only to airborne radiological hazards and may not be appropriate to circumstances when chemical or other respiratory hazards exist instead of, or in addition to, radioactive hazards.

Table 2(q)-A. Protection factors for respirators.

	Operating Mode	Assigned Protection Factors
I. Air purifying respirators (Particulate[a] only)		
Filtering faceplate disposable[b]	Negative Pressure	([b])
Facepiece, half[c]	Negative Pressure	10
Facepiece, full	Negative Pressure	100
Facepiece	Powered air-purifying respirators	50
Facepiece, full	Powered air-purifying respirators	1000
Helmet/hood	Powered air-purifying respirators	1000
Facepiece, loosefitting	Powered air-purifying respirators	25

II. Atmosphere suppling respirators (Particulate, gases, and vapors[d])		
1: Airline Respirator:		
Facepiece, half	Demand	10
Facepiece, half	Continuous Flow	50
Facepiece, half	Pressure Demand	50
Facepiece, full	Demand	100
Facepiece, full	Continuous Flow	1000
Facepiece, full	Pressure Demand	1000
Helmet/hood	Continuous Flow	1000
Facepiece, loose-fitting	Continuous Flow	25
Suit	Continuous Flow	([e])
2: Self-contained breathing apparatus (SCBA):		
Facepiece, full	Demand	[f]100
Facepiece, full	Pressure Demand	[g]10,000
Facepiece, full	Demand, Recirculating	[f]100
Facepiece, full	Positive Pressure Recirculating	[g]10,000
III. Combination Respirators:		
Any combination of air-purifying and atmosphere-supplying respirators	Assigned protection factor for type and mode of operations as listed above	

FOOTNOTES

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

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

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

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

e. No NIOSH approval schedule is currently available for atmospheric supplying units. This equipment may be used in an acceptable respiratory protection program as long as all the other minimum program requirements, with the exception of fit testing, are met.

f. The licensee should implement institutional controls to assure that these devices are not used in areas immediately dangerous to life or health.

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

Appendix A
Quantities of Radioactive Materials Exempted from Registration Requirements

Materials in Sealed Sources

Radioactive materials in sealed sources not exceeding 1 millicurie for a given installation.

Materials Not in Sealed Sources

1. Not more than 1 microcurie total quantity of any one or any combination of the following:

Pb^{210}, Ra^{226}, Ac^{227}, Pu^{239}, Am^{241}, Cm^{242}, Po^{210}, At^{211}, U^{233}.

2. Not more than 10 microcuries total quantity of any one or any combination of the following:

Sc^{46}, Co^{60}, Sr^{90}, Ag^{105}, Ru^{106}, Te^{129}, I^{131}, Cs^{137}, Ce^{144}, Eu^{154}, W^{181}, Re^{183}, Ir^{192}.

3. Not more than 100 microcuries total quantity of any one or any combination of the following:

P^{32}, Cl^{36}, Ca^{45}, Sc^{47}, Sc^{48}, V^{48}, Fe^{59}, Zn^{65}, Ga^{72}, As^{76}, Rb^{86}, Sr^{89}, Y^{91}, Nb^{95}, Tc^{96}, Rh^{105}, Cd^{109}, Ag^{111}, Sn^{113}, Te^{127}, Ba^{140}, La^{140}, Pr^{143}, Sm^{151}, Ho^{166}, Tm^{170}, Lu^{177}, Ta^{182}, Pt^{191}, Pt^{193}, Au^{198}, Au^{199}, Tl^{200}, Pb^{203}, Tl^{204}, Th^{234}.

4. Not more than 1,000 microcuries total quantity of any one or any combination of the following:

H^3, Be^7, C^{14}, Na^{24}, S^{35}, K^{42}, Cr^{51}, Fe^{55}, Mn^{56}, Ni^{59}, Gu^{64}, Ge^{71}, Mo^{99}, Pd^{103}, Pm^{147}, Ir^{190}, Au^{196}, Tl^{201}, Tl^{202}, natural uranium, natural thorium.

5. Not more than 10 microcuries of any one or any combination of any radioactive materials not specified above.

The Regulations of Connecticut State Agencies are amended by adding section 22a-153-3, as follows:

(NEW)

Sec. 22a-153-3. Industrial radiographic operations.

(a) Definitions. For the purposes of this section:

(1) "Associated equipment" means equipment that is used in conjunction with a radiographic exposure device to make radiographic exposures that drives, guides, or comes in contact with the source, including, but not limited to, guide tubes, control tubes, control (drive) cables, removable source stops, "J" tubes and collimators when used as an exposure head.

(2) "Cabinet radiography" means industrial radiography conducted in an enclosure or cabinet so shielded that every location on the exterior meets the dose limits for individual members of the public as specified in section 22a-153-2(g) of the Regulations of Connecticut State Agencies.

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

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

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

(6) "Coefficient of variation" or "C" means the ratio of the standard deviation to the mean value of a set of observations, estimated using the following equation:

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

where:

s = Standard deviation of the observed values;

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

x_i = i_{th} observation in sample;

n = Number of observations in sample.

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

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

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

(10) "Exposure head" or "source stop" means a device that locates the gamma radiography sealed source in the selected working position.

(11) "Field station" means a facility from which sources of radiation may be stored or used and from which equipment is dispatched.

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

(13) "Industrial radiography" or "radiography" means an examination of the structure of materials by the nondestructive utilization of ionizing radiation to make radiographic images.

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

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

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

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

(18) "Radiographer certification" means written approval received from a certifying entity stating that an individual has satisfactorily met the radiation safety, testing and experience criteria subsection (m)(2)(A)(ii) of this section.

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

(20) "Radiographic exposure device," "camera" or "projector" means any instrument containing a sealed source fastened or contained therein, in which the sealed source or shielding thereof may be

moved, or otherwise changed, from a shielded to unshielded position for purposes of making a radiographic exposure.

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

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

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

(24) "Source changer" means a device designed and used for replacement of sealed sources in radiographic exposure devices, or for transporting and storing sealed sources.

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

(b) Applicability. This section applies to all owners and operators of sources of radiation used in industrial radiography, inclusive of radiation machines and sealed radioactive sources, except that this section shall not apply to:

(1) Medical uses of sources of radiation subject to sections 22a-153-7 and 22a-153-8 of the Regulations of Connecticut State Agencies;

(2) Industrial uses of hand-held light intensified imaging devices if the dose rate eighteen inches from the source of radiation to any individual does not exceed two millirem per hour. Devices that exceed this limit shall meet the applicable requirements of this section; and

(3) Use of certified and certifiable cabinet x-ray systems, except that a registrant of cabinet x-ray system shall:

(A) Prevent any individual from operating 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 inspection by the Commissioner until disposal is authorized by the Commissioner;

(B) Conduct tests for proper operation of interlocks at intervals not to exceed six (6) months. Records of test data shall be maintained for inspection by the Commissioner until disposal of such records is authorized by the Commissioner;

(C) Perform an evaluation of the radiation dose rates to determine compliance with section 22a-153(g) of the Regulations of Connecticut State Agencies and 21 CFR 1020.40, at intervals not to exceed one year. Records of these evaluations shall be maintained for inspection by the Commissioner for five (5) years after the date of the evaluation; and

(D) Certified cabinet x-ray systems shall be maintained in compliance with 21 CFR 1020.40, and no modification shall be made to such systems unless prior approval has been granted by the Commissioner.

(c) Licensing and registration requirements for industrial radiography operations. The owner or operator of an industrial radiography operation subject to this section shall apply for a specific license for the use of radioactive material or to register the use of radiation machine on forms prescribed by the Commissioner. All such applications shall include:

(1) A proposed radiographer and radiographer assistant training program that meets the requirements of subsection (m)(3) of this section. For two (2) years from the effective date of this section, the owner or operator may affirm that all individuals acting as industrial radiographers will be certified in radiation safety by a certifying entity before commencing duty as radiographers. Such affirmation substitutes for a description of its initial training and examination program for radiographers in the subjects outlined in subsection (m) (3) (F) of this section;

(2) Procedures for verifying and documenting the certification status of radiographers and for ensuring that the certification of individuals acting as radiographers remains valid;

(3) Written operating and emergency procedures as described in subsection (m)(4) of this section;

(4) 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 subsection (m)(3)(E) of this section;

(5) A description of the owner or operator's overall organizational structure as it applies to the radiation safety responsibilities in industrial radiography, including specified delegation of authority and responsibility;

(6) The qualifications of the individual or individuals designated as the radiation safety officer as described in subsection (m)(2)(A) of this section;

(7) Procedures for performing leak testing of sealed sources or exposure devices containing DU shielding, if applicable, which include the following:

(A) Methods of collecting the samples;

(B) Qualifications of each individual analyzing the samples;

(C) Instruments to be used; and

(D) Methods of analyzing the samples.

(8) Methods for calibrating survey instruments and alarming rate meters, if applicable, and descriptions of the experience of individuals performing such calibrations. All calibrations shall be performed according to the procedures described and at the intervals prescribed in subsections (h) and (m)(6)(G)(iv) of this section;

(9) Identification and description of the location or locations of all field stations and permanent radiographic installations;

(10) Identification of the location or locations where all records required by this section will be maintained;

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

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

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

(C) Methods for gas-tight encapsulation of equipment.

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

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

(B) Storage facilities for radioactive material; and

(C) Methods for restricting access to radiation areas.

(13) The Commissioner will issue a written license or registration to the applicant who submits the applicable information required by this subsection. The Commissioner will contact an applicant in writing if the Commissioner requires additional information, specifying a date for submission of such additional information, before the Commissioner may issue a registration or license pursuant to this subsection.

(d) Performance requirements for industrial radiography equipment. Equipment used in industrial radiographic operations shall meet the following minimum criteria:

(1) Each radiographic exposure device, source assembly or sealed source, and all associated equipment shall meet the requirements specified in ANSI, N432-1980 "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography," (NBS Handbook 136, January 1981).

(2) In addition to the requirements specified in subdivision (1) of this subsection, the following requirements apply to radiographic exposure devices, source changers, source assemblies and sealed sources:

(A) The licensee or registrant shall ensure that each radiographic exposure device has attached to it a durable, legible, clearly visible label bearing the:

(i) Chemical symbol and mass number of the radionuclide in the device,

(ii) Activity and the date on which this activity was last measured,

(iii) Model or product code and serial number of the sealed source,

(iv) Name of the manufacturer of the sealed source, and

(v) Licensee or registrant's name, address, and telephone number;

(B) Radiographic exposure devices intended for use as Type B packages shall meet the applicable transportation requirements of 49 CFR 100 through 189 and 390 through 397 and 10 CFR 71; and

(C) Modification of radiographic exposure devices, source changers, and source assemblies and associated equipment is prohibited, unless approved by the Commissioner.

(3) In addition to the requirements specified in subsections (d)(1) and (d)(2) of this section, the following requirements apply to radiographic exposure devices, source assemblies and associated equipment that allow the source to be moved out of the device for radiographic operations or to source changers:

(A) The coupling between the source assembly and the control cable shall be designed in such a manner that the source assembly will not become disconnected if cranked outside the guide tube. The coupling shall be such that it cannot be unintentionally disconnected under normal and reasonably foreseeable abnormal conditions;

(B) The device shall automatically secure the source assembly when it is cranked back into the fully shielded position within the device. This securing system may only be released by means of a deliberate operation on the exposure device;

(C) The outlet fittings, lock box and drive cable fittings on each radiographic exposure device shall be equipped with safety plugs or covers, which shall be installed during storage and transportation to protect the source assembly from water, mud, sand or other foreign matter;

(D) Each sealed source or source assembly shall have attached to it or engraved on it, a durable, legible, visible label that does not interfere with the safe operation of the exposure device or associated equipment and includes the words:

"DANGER -- RADIOACTIVE"
or
"CAUTION -- RADIOACTIVE"

(E) The guide tube shall be able to withstand a crushing test that closely approximates the crushing forces that are likely to be encountered during use and be able to withstand a kinking resistance test that closely approximates the kinking forces that are likely to be encountered during use;

(F) Guide tubes shall be used when moving the source out of the device;

(G) An exposure head or similar device designed to prevent the source assembly from passing out of the end of the guide tube shall be attached to the outermost end of the guide tube during industrial radiography operations;

(H) The guide tube exposure head connection shall be able to withstand the tensile test for control units specified in ANSI N432-1980; and

(I) Source changers shall provide a system for ensuring that the source will not be accidentally withdrawn from the changer when connecting or disconnecting the drive cable to or from a source assembly.

(4) All radiographic exposure devices and associated equipment in use after the effective date of this section, shall comply with the requirements of this section.

(5) Notwithstanding subsection (d)(1) of this section, equipment used in industrial radiographic operations need not comply with § 8.9.2(c) of the Endurance Test in ANSI N432-1980, if the prototype equipment has been tested using a torque value representative of the torque that an individual using the radiography equipment can reasonably exert on the lever or crankshaft of the drive mechanism.

(e) Limits on external radiation levels from storage containers and source changers.

The maximum exposure rate limits for storage containers and source changers are two millisieverts (200 mrem) per hour at any exterior surface, and 0.1 millisieverts (10 mrem) per hour at one meter from any exterior surface with the sealed source in the shielded position.

(f) Locking of sources of radiation, storage containers and source changers.

(1) Each radiographic exposure device shall have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. The exposure device or its container shall be kept locked when not under the direct surveillance of a radiographer or a radiographer's assistant except at permanent radiographic installations as stated in subsection (m)(8) of this section. If the lock is keyed, the key shall be removed after opening and closing the lock mechanism. In addition, during radiographic operations the sealed source assembly shall be secured in the shielded position each time the source is returned to that position.

(2) Each sealed source storage container and source changer shall have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. Storage containers and source changers shall be kept locked when containing sealed sources except when under the direct surveillance of a radiographer or a radiographer's assistant. If the lock is keyed, the key shall be removed after opening and closing the lock mechanism.

(3) The control panel of each radiation machine shall be equipped with a lock that will prevent the unauthorized use of an x-ray system or the accidental production of radiation. The radiation machine shall be kept locked and the key removed at all times except when under the direct visual surveillance of a radiographer or a radiographer’s assistant.

(g) Labeling, storage and transportation.

(1) The licensee or registrant shall not use a source changer or a container to store radioactive material unless the source changer or the storage container has securely attached to it a durable, legible and clearly visible label bearing the standard radiation symbol described in section 22a-153-2(*l*)(1) of the Regulations of Connecticut State Agencies and the wording:

CAUTION [or DANGER]
RADIOACTIVE MATERIAL
NOTIFY CIVIL AUTHORITIES [or NOTIFY NAME OF LICENSEE OR REGISTRANT]

(2) The licensee or registrant shall not transport radioactive material unless the material is packaged, and the package is labeled, marked and accompanied with appropriate shipping papers in accordance with 49 CFR 100 through 189 and 390 through 397 and 10 CFR 71.

(3) Radiographic exposure devices, source changers, storage containers and radiation machines shall be physically secured to prevent tampering or removal by unauthorized personnel. The licensee or registrant shall store radioactive material in a manner that will minimize danger from explosion or fire.

(4) The licensee or registrant shall lock and physically secure the transport package containing radioactive material in the transporting vehicle to prevent accidental loss, tampering or unauthorized removal.

(5) The licensee's or registrant's name and city or town where the main business office is located shall be prominently displayed with a durable, clearly visible label or labels on both sides of all vehicles used to transport radioactive material or radiation machines for temporary job site use.

(h) Radiation survey instruments.

(1) The licensee or registrant shall keep sufficient calibrated and operable radiation survey instruments at each location where sources of radiation are present to make the radiation surveys required by this section and section 22a-153-2 of the Regulations of Connecticut State Agencies. Instrumentation required by this section shall be capable of measuring a range from 0.02 millisieverts (two mrem) per hour through 0.01 sievert (one rem) per hour.

(2) The licensee or registrant shall have each radiation survey instrument required pursuant to subsection (h)(1) of this section calibrated as follows:

(A) At energies appropriate for use and at intervals not to exceed six (6) months or after instrument servicing, except for battery changes;

(B) For linear scale instruments, at two points located approximately one-third and two-thirds of full-scale on each scale; for logarithmic scale instruments, at mid-range of each decade, and at two points of at least one decade; and for digital instruments, at three points between 0.02 and 10 millisieverts (two and 1000 mrem) per hour; and

(C) To achieve an accuracy within plus or minus 20% of the true radiation dose rate at each point checked.

(3) The licensee or registrant shall maintain records of the results of the instrument calibrations in accordance with subsection (n)(3) of this section.

(i) Leak testing and replacement of sealed sources.

(1) The replacement of any sealed source fastened to or contained in a radiographic exposure device and leak testing of any sealed source shall be performed by a person authorized to do so by the department, NRC or another Agreement State.

(2) The opening, repair or modification of any sealed source shall be performed by a person specifically authorized to do so by the department, NRC or another Agreement State.

(3) Testing and recordkeeping requirements. Each licensee or registrant who uses a sealed source shall:

(A) Have the source tested for leakage at intervals not to exceed six (6) months. The leak testing of the source shall be performed using a method approved by the department, NRC or by another Agreement State. The wipe sample shall be taken from the nearest accessible point to the sealed source where contamination might accumulate and shall be analyzed for radioactive contamination. The analysis shall be capable of detecting the presence of 185 bequerel (0.005 μCi) of radioactive material on the test sample and shall be performed by a person specifically authorized by department, NRC or another Agreement State to perform the analysis;

(B) Maintain records of the leak tests in accordance with subsection (n)(4) of this section; and

(C) Unless a sealed source is accompanied by a certificate from the transferor that shows that it has been leak tested within six (6) months before the transfer, it shall not be used by the licensee until tested for leakage. Sealed sources that are in storage and not in use do not require leak testing, but shall be tested before use or transfer to another person if the interval of storage exceeds six (6) months.

(4) Any test conducted pursuant to subsections (i)(2) and (i)(3) of this section that reveals the presence of 185 becquerel (0.005 μCi) or more of removable radioactive material shall be considered evidence that the sealed source is leaking. The licensee or registrant shall:

(A) Immediately withdraw the equipment involved from use and decontaminate and repair or disposed of such equipment; and

(B) File a report with the Commissioner within five (5) days of any test results that equal or exceed 185 becquerel (0.005 μCi), describing the equipment involved, the test results and the corrective action taken.

(5) Each exposure device using DU shielding and an "S- tube" configuration shall be tested for DU contamination at intervals not to exceed thirteen (13) months. Such test shall be:

(A) Capable of detecting the presence of 185 becquerel (0.005 μCi) of radioactive material on the test sample; and

(B) Performed by a person specifically authorized by the department, NRC or another Agreement State to perform the analysis.

(6) Should such DU contamination testing reveal the presence of DU contamination:

(A) The exposure device shall be removed from use until an evaluation of the wear of the S-tube has been made; and

(B) The S-tube may not be used again if the evaluation reveals that the S-tube is worn through.

(7) DU shielded devices do not have to be tested for DU contamination while not in use or in storage but the licensee or registrant shall:

(A) Before using or transferring a DU shielded device, test the device for DU contamination if the interval of storage exceeds twelve (12) months; and

(B) Make a record of the DU leak-test in accordance with subsection (n)(4) of this section.

(j) Quarterly inventory. Each licensee or registrant shall:

(1) Conduct a quarterly physical inventory to account for all sources of radiation and for devices containing DU that are received and possessed under the license; and

(2) Maintain records of the quarterly inventory in accordance with subsection (n)(5) of this section.

(k) Inspection and maintenance of radiation machines and survey instruments.

(1) The licensee or registrant shall perform visual and operability checks on survey meters, radiation machines, radiographic exposure devices, transport and storage containers, associated equipment and source changers before each day's use, or work shift, to ensure that:

(A) The equipment is in good working condition;

(B) The sources are adequately shielded; and

(C) Required labeling is present.

(2) Survey instrument operability shall be performed using check sources or other appropriate means.

(3) If equipment problems are found, the equipment shall be removed from service until repaired.

(4) Each licensee or registrant shall have written procedures for and perform inspection and routine maintenance of radiation machines, radiographic exposure devices, source changers, associated equipment, transport and storage containers, and survey instruments at intervals not to exceed three (3) months or before the first use thereafter to ensure the proper functioning of

components important to safety. If equipment problems are found, the equipment shall be removed from service until repaired.

(5) The licensee's or registrant's inspection and maintenance program shall include procedures to assure that Type B packages are shipped and maintained in accordance with the certificate of compliance or other approval.

(6) Records of equipment problems and of any maintenance performed under this subsection shall be made in accordance with subsection (n)(7) of this section.

(*l*) Permanent radiographic installations.

(1) The licensee or registrant shall equip each entrance that is used for personnel access to a high radiation area in a permanent radiographic installation with either:

(A) An entrance control of the type described in section 22a-153-2(i) of the Regulations of Connecticut State Agencies that causes the radiation level upon entry into the area to be reduced; or

(B) Both conspicuous visible and audible warning signals to warn of the presence of radiation. The visible signal shall be actuated by radiation whenever the source is exposed or the machine is energized. The audible signal shall be actuated when an attempt is made to enter the installation while the source is exposed or the machine is energized.

(2) The system installed pursuant to subdivision (1) of this subsection shall include a check of both visible and audible signals and be tested for proper operation with a radiation source each day before the installation is used for radiographic operations.

(3) Entrance control devices that reduce the radiation level upon entry as designated in subdivision (1)(A) of this subsection shall be tested monthly and as follows:

(A) If an entrance control device or an alarm is operating improperly, the licensee or registrant shall label the equipment as defective and shall make repairs within seven (7) calendar days, and

(B) The facility may continue to be used during this seven (7) day period, provided the licensee or registrant implements the continuous surveillance requirements of subsection (m)(8) of this section and uses an alarming ratemeter.

(4) Test records for entrance controls and audible and visual alarms shall be maintained in accordance with subsection (n)(8) of this section.

(m) Radiation safety requirements.

(1) Industrial radiographic operations shall be conducted according to the following requirements:

(A) Whenever radiography is performed at a location other than a permanent radiographic installation, the radiographer shall be accompanied by at least one other qualified radiographer or an individual who has at a minimum met the requirements of

subsection (m)(3)(C). The additional qualified individual shall observe the operations and be capable of providing immediate assistance to prevent unauthorized entry. Radiography may not be performed if only one qualified individual is present;

(B) All radiographic operations shall be conducted in a permanent radiographic installation unless otherwise specifically authorized by the Commissioner;

(C) Except when physically impossible, collimators shall be used in industrial radiographic operations that use radiographic exposure devices that allow the source to be moved out of the device; and

(D) A licensee or registrant may conduct lay-barge, offshore platform or underwater radiography only if procedures have been approved by the Commissioner, the NRC or by another Agreement State.

(2) Radiation safety officer. To ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's or registrant's program, each registrant or licensee shall employ a radiation safety officer as follows:

(A) The minimum qualifications, training and experience for radiation safety officers for industrial radiography shall include:

(i) Completion of the training and testing requirements of subsection (m)(3)(A) of this section,

(ii) 2000 hours of hands-on experience as a qualified radiographer in industrial radiographic operations. Excessive hours spent in a single area of the radiation process shall not be included in the 2000 hours, and

(iii) Formal training in the establishment and maintenance of a radiation protection program.

(B) The Commissioner may consider alternatives to the requirements of subparagraph (A) of this subdivision when the radiation safety officer has appropriate training and experience in the field of ionizing radiation, and has adequate formal training with respect to the establishment and maintenance of a radiation safety protection program.

(C) The specific duties and authorities of the radiation safety officer shall include:

(i) Establishing and overseeing all operating, emergency and ALARA procedures as required by section 22a-153-2 of the Regulations of Connecticut State Agencies and reviewing such procedures regularly to ensure that they conform to the department's regulations and license or registration conditions,

(ii) Overseeing and approving the training program for radiographic personnel to ensure that appropriate and effective radiation protection practices are taught,

(iii) Ensuring that required radiation surveys and leak tests are performed and documented in accordance with this section, including any corrective measures when levels of radiation exceed established limits,

(iv) Ensuring that personnel monitoring devices are calibrated, if applicable, and used properly; that records are kept of the monitoring results; and that timely notifications are made as required by section 22a-153-2 of the Regulations of Connecticut State Agencies, and

(v) Ensuring that operations are conducted safely and for implementing corrective actions including terminating operations.

(D) Each licensee or registrant shall meet the requirements of subsections (m)(2)(A) and (m)(2)(B) of this section no later than two (2) years from the effective date of this section.

(3) Training. Each licensee or registrant shall:

(A) Not permit any person to act as a radiographer until such person has:

(i) Received at least forty (40) hours of training in the subjects outlined in subsection (m)(3)(F) of this section in addition to on-the-job training consisting of hands-on experience under the supervision of a radiographer and is certified through a radiographer certification program by a certifying entity in accordance with the criteria specified in subsection (q) of this section. The on-the-job training shall include a minimum of two (2) months (320 hours) of active participation in the performance of industrial radiography utilizing radioactive material or one (1) month (160 hours) of active participation in the performance of industrial radiography utilizing radiation machines. Individuals performing industrial radiography utilizing radioactive materials and radiation machines shall complete both segments of the on-the-job training (three (3) months or 480 hours),

(ii) Received copies of and instruction in the requirements described in this section and other applicable laws and regulations cited in the license or registration under which the radiographer will perform industrial radiography, and the licensee's or registrant’s operating and emergency procedures,

(iii) Demonstrated an understanding of items in subparagraph (A)(ii) of this subdivision by successful completion of a written or oral examination,

(iv) Received training in the use of the registrant’s radiation machines, or the licensee's radiographic exposure devices, sealed sources, in the daily inspection of devices and associated equipment and in the use of radiation survey instruments,

(v) Demonstrated understanding of the use of the equipment described in subparagraph (A)(iv) of this subdivision by successful completion of a practical examination; and

(iv) For the two (2) years following the effective date of this section, an individual who has not met the requirements of subdivision (3)(A)(i) of this subsection, may act as a radiographer if the individual has received at least forty (40) hours of training in the subjects outlined in subdivision (3)(F) of this subsection and demonstrated an understanding of these subjects by successful completion of a written examination that was previously submitted to and approved by the department, NRC or another Agreement State, in addition to on-the-job training consisting of hands-on experience under the supervision of a radiographer. Excessive hours spent in a single area of the radiation process shall not be included as hours of hands-on experience. The on-the-job training shall include a minimum of two (2) months (320 hours) of active participation in the performance of industrial radiography utilizing radioactive material or one (1) month (160 hours) of active participation in the performance of industrial radiography utilizing radiation machines. Individuals performing industrial radiography utilizing radioactive materials and radiation machines shall complete both segments of the on-the-job training (three (3) months or 480 hours).

(B) Not permit any individual to act as a radiographer's assistant until the individual has:

(i) Received copies of and instruction in the requirements described in the regulations contained in this section, and other applicable sections of the laws and regulations cited in the license or registration under which the radiographer's assistant will perform industrial radiography, and the licensee's or registrant’s operating and emergency procedures,

(ii) Demonstrated an understanding of items in subparagraph (B)(i) of this subdivision by successful completion of a written or oral examination,

(iii) Under the personal supervision of a radiographer, received training in the use of the registrant’s radiation machines, or the licensee's radiographic exposure devices and sealed sources, in the daily inspection of devices and associated equipment, and in the use of radiation survey instruments, and

(iv) Demonstrated understanding of the use of the equipment described in subparagraph (B)(iii) of this subdivision by successful completion of a practical examination.

(C) Provide annual refresher safety training for each radiographer and radiographer's assistant at intervals not to exceed thirteen (13) months. Such training shall include:

(i) Results of internal inspections made in the twelve (12) months preceding the training event,

(ii) New procedures adopted and use of new equipment acquired in the twelve (12) months preceding the training event,

(iii) Regulatory changes that occurred in the twelve (12) months preceding the training event, and

(iv) Errors or accidents observed in the twelve (12) months preceding the training event.

(D) Except as provided in subparagraph (D)(iv) of this subdivision, require the Radiation Safety Officer to conduct an inspection program of the job performance of each radiographer and radiographer's assistant to ensure that the department's regulations, license or registration requirements, and operating and emergency procedures are followed. Such inspection program shall:

(i) Include observation of the performance of each radiographer and radiographer's assistant during an actual industrial radiographic operation, at intervals not to exceed six (6) months,

(ii) Provide that, if a radiographer or a radiographer's assistant has not participated in an industrial radiographic operation for more than six (6) months since the last inspection, the radiographer shall demonstrate knowledge of the training requirements of subparagraph (A)(iv) of this subdivision and the radiographer's assistant shall demonstrate knowledge of the training requirements of subparagraph (B)(iii) of this subdivision by a practical examination before these individuals can next participate in a radiographic operation,

(iii) The Commissioner may consider alternatives in those situations where the individual serves as both radiographer and radiation safety officer, and

(iv) In those operations where a single individual serves as both radiographer and radiation safety officer, and performs all radiography operations, an inspection program is not required;

(E) Maintain records of the training performed pursuant to this subdivision including certification documents, written, oral and practical examinations and responses, refresher safety training and inspections of job performance as required by this section;

(F) Include the following subjects in the training required by subdivision (3)(A) of this subsection:

(i) Fundamentals of radiation safety including:

(I) Characteristics of gamma and x-radiation,

(II) Units of radiation dose and quantity of radioactivity,

(III) Hazards of exposure to radiation,

(IV) Levels of radiation from sources of radiation, and

(V) Methods of controlling radiation dose (time, distance and shielding);

(ii) Radiation detection instruments including:

(I) Use, operation, calibration and limitations of radiation survey instruments,

(II) Survey techniques, and

(III) Use of personnel monitoring equipment;

(iii) Equipment to be used including:

(I) Operation and control of radiographic exposure equipment, remote handling equipment, and storage containers, including pictures or models of source assemblies,

(II) Operation and control of radiation machines,

(III) Storage, control, and disposal of sources of radiation, and

(IV) Inspection and maintenance of equipment,

(iv) The requirements of pertinent state and federal regulations, and

(v) Case histories of accidents in radiography.

(G) Comply with the additional training requirements specified in subdivisions (3)(A)(ii) and (3)(B)(i) of this subsection within one (1) year of the effective date of this section.

(4) Operating and emergency procedures. Each licensee or registrant shall implement the following measures regarding operating and emergency procedures:

(A) Operating and emergency procedures shall include, as a minimum, instructions for radiography personnel in the following:

(i) Appropriate handling and use of sources of radiation so that no person is likely to be exposed to radiation doses in excess of the limits established in section 22a-153-2 of the Regulations of Connecticut State Agencies,

(ii) Methods and occasions for conducting radiation surveys,

(iii) Methods for posting and controlling access to radiographic areas,

(iv) Methods and occasions for locking and securing sources of radiation,

(v) Personnel monitoring and the use of personnel monitoring equipment,

(vi) Transporting equipment to field locations, including packing of radiographic exposure devices and storage containers in the vehicles, placarding of vehicles when required, and control of the equipment during transportation as described in 49 CFR 100 through189, 390 through 397 and 10 CFR 71,

(vii) The inspection, maintenance and operability checks of radiographic exposure devices, radiation machines, survey instruments, alarming ratemeters, transport containers and storage containers,

(viii) Steps that shall be taken immediately by radiography personnel in the event a pocket dosimeter is found to be off-scale or an alarming ratemeter alarms unexpectedly,

(ix) Procedures for identifying and reporting defects and noncompliance, as required by this section,

(x) A procedure for notifying proper persons in the event of an accident or incident,

(xi) Minimizing exposure of persons in the event of an accident or incident, including a source disconnect, a transport accident or loss of a source of radiation,

(xii) Source recovery procedure if the licensee or registrant will perform source recoveries, and

(xiii) Maintenance of records; and

(B) The licensee or registrant shall maintain copies of current operating and emergency procedures as required by this section, in a location or locations readily accessible to all radiography personnel at each job site and available for inspection by the Commissioner upon request.

(5) Supervision of radiographer's assistants. The radiographer’s assistant shall be under the personal supervision of a radiographer when using radiographic exposure devices, associated equipment, or a sealed source, or while conducting radiation surveys required by subdivision (7)(B) of this subsection to determine that the sealed source has returned to the shielded position or the radiation machine is off after an exposure. The personal supervision shall include:

(A) The radiographer's physical presence at the site where the sources of radiation are being used;

(B) The availability of the radiographer to give immediate assistance if required; and

(C) The radiographer's direct observation of the assistant's performance of the operations referred to in this section.

(6) Personnel monitoring. Each licensee or registrant shall meet the following requirements for monitoring of personnel:

(A) No individual shall act as a radiographer or a radiographer's assistant unless, at all times during radiographic operations, the individual wears, on the trunk of the body, a direct reading dosimeter, an operating alarming ratemeter and a personnel dosimeter that will be processed and evaluated by an accredited NVLAP processor. At

permanent radiographic installations where other appropriate alarming or warning devices are in routine use, or during radiographic operations using radiation machines, the use of an alarming ratemeter is not required. Personnel monitors shall meet the following requirements:

(i) Pocket dosimeters shall have a range from zero to two millisieverts (200 mrem) and shall be recharged at the start of each shift. Electronic personal dosimeters may only be used in place of ion-chamber pocket dosimeters,

(ii) Each personnel dosimeter shall be assigned to and worn by only one individual,

(iii) Film badges shall be exchanged at periods not to exceed one (1) month and other personnel dosimeters processed and evaluated by an accredited NVLAP processor shall be replaced at periods not to exceed three (3) months, and

(iv) After replacement, each film badge shall be returned to the supplier for processing within fourteen (14) calendar days of the end of the monitoring period, or as soon as practicable. In circumstances that make it impossible to return each film badge in fourteen (14) calendar days, such circumstances shall be documented and available for review by the Commissioner. Other personnel dosimeters shall be processed as soon as possible;

(B) Direct reading dosimeters such as pocket dosimeters or electronic personal dosimeters, shall be read and the exposures recorded at the beginning and end of each shift, and records shall be maintained in accordance with this section;

(C) Pocket dosimeters and electronic personal dosimeters shall be checked at periods not to exceed thirteen (13) months for correct response to radiation, and records shall be maintained in accordance with this section. Acceptable dosimeters shall read within plus or minus 20% of the true radiation exposure;

(D) If an individual's pocket dosimeter is found to be off-scale, or the electronic personal dosimeter reads greater than two millisieverts (200 mrem), the radiation safety officer shall be notified and the individual's film badge or other personnel dosimeter shall be sent for processing within 24 hours. In circumstances that make it impossible to process a film badge or personnel dosimeter in 24 hours, such circumstances shall be documented and available for review by the Commissioner. The individual shall not resume work associated with the use of sources of radiation until a determination of the individual's radiation exposure has been made. This determination shall be made by the radiation safety officer or the radiation safety officer's designee. The results of this determination shall be included in the records maintained in accordance with this section;

(E) If a film badge or other personnel dosimeter is lost or damaged, the worker shall cease work immediately until a replacement film badge or other personnel dosimeter is provided and the exposure is calculated for the time period from issuance to loss or damage of the film badge or other personnel dosimeter. The results of the calculated exposure and the time period for which the film badge or other personnel dosimeter

was lost or damaged shall be included in the records maintained in accordance with this section;

(F) Reports received from the film badge or other personnel dosimeter processor shall be retained in accordance with this section; and

(G) Each alarming ratemeter shall:

(i) Be checked to ensure that the alarm functions properly before using at the start of each shift,

(ii) Be set to give an alarm signal at a preset dose rate of five millisieverts (500 mrem) per hour; with an accuracy of plus or minus 20 percent of the true radiation dose rate,

(iii) Require special means to change the preset alarm function, and

(iv) Be calibrated at periods not to exceed twelve (12) months for correct response to radiation. The licensee or registrant shall maintain records of alarming ratemeter calibrations in accordance with this section.

(7) Radiation surveys. The licensee or registrant shall:

(A) Conduct all surveys with a calibrated and operable radiation survey instrument that meets the requirements of subsection (h) of this section;

(B) Conduct a survey of the radiographic exposure device and the guide tube after each exposure when approaching the device or the guide tube. The survey shall determine that the sealed source has returned to its shielded position before exchanging films, repositioning the exposure head, or dismantling equipment. Radiation machines shall be surveyed after each exposure to determine that the machine is off;

(C) Conduct a survey of the radiographic exposure device whenever the source is exchanged and whenever a radiographic exposure device is placed in a storage area as defined in subsection (a) of this section, to ensure that the sealed source is in its shielded position; and

(D) Maintain records in accordance with this section.

(8) Surveillance. During each radiographic operation, the radiographer shall ensure continuous direct visual surveillance of the operation to protect against unauthorized entry into a radiation area or a high radiation area, as defined in section 22a-153-1 of the Regulations of Connecticut State Agencies, except at permanent radiographic installations where all entryways are locked and the requirements of subsection (*l*) of this section are met.

(9) Posting. All areas in which industrial radiography is being performed shall be conspicuously posted as required by section 22a-153-2(k)(2) of the Regulations of Connecticut State Agencies. The exceptions listed in section 22a-153-2(k)(3) of the Regulations of Connecticut State Agencies do not apply to industrial radiographic operations.

(n) Record keeping.

(1) Records for industrial radiography. Each licensee or registrant shall maintain a copy of its license or registration, documents incorporated by reference and amendments to each of these documents until superseded by new documents approved by the Commissioner, or until the Commissioner terminates the license or registration.

(2) Records of receipt and transfer of sources of radiation.

(A) Each licensee or registrant shall maintain records showing the receipts and transfers of sealed sources, devices using DU for shielding and radiation machines, and retain each record for five (5) years after it is made; and

(B) Records required by this subdivision shall include the date, the name of the individual making the record, radionuclide, number of becquerels (curies) or mass (for DU), and manufacturer, model and serial number of each source of radiation and device, as appropriate.

(3) Records of radiation survey instruments. Each licensee or registrant shall maintain records of the calibrations of its radiation survey instruments that are required under subsection (h) of this section and retain each record for five (5) years after it is made.

(4) Records of leak testing of sealed sources and devices containing DU. Each licensee or registrant shall maintain records of leak test results for sealed sources and for devices containing DU. The results shall be stated in units of becquerels (μCi). The licensee or registrant shall retain each record for five (5) years after it is made or until the source in storage is removed.

(5) Records of quarterly inventory.

(A) Each licensee or registrant shall maintain records of the quarterly inventory of sources of radiation, including devices containing depleted uranium as required by subsection (j) of this section, and retain each record for five (5) years.

(B) The record shall include the date of the inventory, name of the individual conducting the inventory, radionuclide, number of becquerels (curies) or mass (for DU) in each device, location of sources of radiation and devices, and manufacturer, model and serial number of each source of radiation and device, as appropriate.

(6) Utilization logs. Each licensee or registrant shall:

(A) Maintain utilization logs showing for each source of radiation the following information:

(i) A description, including the make, model and serial number of the radiation machine or the radiographic exposure device, transport or storage container in which the sealed source is located,

(ii) The identity and signature of the radiographer to whom assigned,

(iii) The location and dates of use, including the dates removed and returned to storage, and

(iv) For permanent radiographic installations, the dates each radiation machine is energized; and

(B) Retain the logs required by subparagraph (A) of this subdivision for five (5) years.

(7) Each licensee or registrant shall maintain records of inspection and maintenance of radiation machines, radiographic exposure devices, transport and storage containers, associated equipment, source changers and survey instruments, as follows:

(A) All records specified in subsection (k) of this section of equipment problems found in daily checks and quarterly inspections of radiation machines, radiographic exposure devices, transport and storage containers, associated equipment, source changers and survey instruments; and retain each record for five (5) years after it is made; and

(B) Each record shall include the date of check or inspection, name of inspector, equipment involved, any problems found, and what repair and maintenance, if any, was performed.

(8) Records of alarm system and entrance control checks at permanent radiographic installations. Each licensee or registrant shall maintain records of alarm system and entrance control device tests required by subsection (*l*) of this section and retain each record for five (5) years after it is made.

(9) Records of training and certification. Each licensee or registrant shall maintain the following records for five (5) years:

(A) Records of training of each radiographer and each radiographer's assistant which include:

(i) radiographer certification documents and verification of certification status,

(ii) copies of written tests,

(iii) dates of oral and practical examinations,

(iv) the names of individuals conducting and receiving the oral and practical examinations, and

(v) a list of items tested and the results of the oral and practical examinations;

(B) Records of annual refresher safety training and semi-annual inspections of job performance for each radiographer and each radiographer's assistant which include:

(i) topics discussed during the refresher safety training,

(ii) the dates the annual refresher safety training was conducted, and

(iii) names of the instructors and attendees; and

(C) For inspections of job performance, the records shall also include a list showing the items checked and any non-compliance observed by the radiation safety officer or designee.

(10) Copies of operating and emergency procedures. Each licensee or registrant shall maintain a copy of current operating and emergency procedures until the Commissioner terminates the license or registration. Superseded material shall be retained for five (5) years after the change is made.

(11) Records of personnel monitoring. Each licensee or registrant shall maintain the following exposure records specified in subsection (m)(6) of this section:

(A) Direct dosimeter readings and yearly operability checks required by subsections (m)(6)(B) and (m)(6)(C) of this section, for five (5) years after the record is made;

(B) Alarming ratemeter calibrations, for five (5) years after the record is made;

(C) From the film badge or NAVLAP accredited processor, until the Commissioner terminates the license or registration; and

(D) Estimates of exposures as a result of off-scale personal direct reading dosimeters, or lost or damaged film badges or other personnel dosimeter, until the Commissioner terminates the license or registration.

(12) Records of radiation surveys. Each licensee or registrant shall maintain a record of each exposure device survey conducted before the device is placed in storage as specified in subsection (m)(7)(C) of this section. Each record shall be maintained for five (5) years after it is made.

(13) Form of records. Each record required by this section shall be legible throughout the specified retention period. The record may be the original, a reproduced copy, microform or an electronic copy provided that the record is authenticated by authorized personnel and is capable of being reproduced or of reproducing a clear copy throughout the required retention period. Records such as letters, drawings and specifications shall include all pertinent information, such as stamps, initials and signatures. The licensee or registrant shall maintain adequate safeguards against tampering with and loss of records.

(14) Location of documents and records. Each licensee or registrant shall maintain copies of the following records:

(A) Required by this section and other applicable sections of the department's regulations; and

(B) Sufficient to demonstrate compliance at each applicable field station and each temporary job site in a location readily accessible and clearly identified to all personnel working at such stations and job sites and including:

(i) The license or registration authorizing the use of sources of radiation,

(ii) A copy of sections 22a-153-1 through 22a-153-3 and 22a-153-6 of the Regulations of Connecticut State Agencies**,**

(iii) Utilization logs for each source of radiation dispatched from that location as required by subdivision (6) of this subsection,

(iv) Records of equipment problems identified in daily checks of equipment as required by subdivision (7)(A) of this subsection,

(v) Records of alarm system and entrance control checks required by subdivision (8) of this subsection, if applicable,

(vi) Records of dosimeter readings as required by subdivision (11) of this subsection,

(vii) Operating and emergency procedures as required by subdivision (10) of this subsection,

(viii) Evidence of the latest calibration of the radiation survey instruments in use at the site, as required by subdivision (3) of this subsection,

(ix) Evidence of the latest calibrations of alarming ratemeters and operability checks of dosimeters as required by subdivision (11) of this subsection,

(x) Survey records as required by subdivision (12) of this subsection and section 22a-153-2(m)(3) of the Regulations of Connecticut State Agencies, as applicable, for the period of operation at the site, and

(xi) The shipping papers for the transportation of radioactive materials required by 49 CFR 100 through 189, 390 through 397 and 10 CFR 71.

(o) Notifications.

(1) In addition to the reporting requirements specified in 10 CFR 30.50 and in section 22a-153-2 of the Regulations of Connecticut State Agencies, each licensee or registrant shall provide a written report to the Commissioner within thirty (30) days of the occurrence of any of the following incidents involving radiographic equipment:

(A) Unintentional disconnection of the source assembly from the control cable;

(B) Inability to retract the source assembly to its fully shielded position and secure it in this position;

(C) Failure of any component, which is critical to safe operation of the device, to properly perform its intended function; or

(D) An indicator on a radiation machine that fails to show radiation is being produced, an exposure switch that fails to terminate production of radiation when turned to the off position or a safety interlock that fails to terminate x-ray production.

(2) The licensee or registrant shall include the following information in each report submitted under subsection (o)(1) of this section and in each report of overexposure submitted under section

22a-153-2(n)(3) of the Regulations of Connecticut State Agencies that involves failure of safety components of radiography equipment:

(A) Description of the equipment problem;

(B) Cause of each incident, if known;

(C) Name of the manufacturer and model number of equipment involved in the incident;

(D) Place, date and time of the incident;

(E) Actions taken to establish normal operations;

(F) Corrective actions taken or planned to prevent recurrence; and

(G) Names and qualifications of personnel involved in the incident.

(3) Any licensee or registrant conducting radiographic operations or storing sources of radiation at any location not listed on the license or registration for a period in excess of one hundred eighty (180) days in a calendar year, shall notify the Commissioner prior to exceeding the one hundred eighty (180) days.

(p) Radiographer certification.

(1) Application. In order to be certified by the Commissioner to perform radiographic operations, a person shall submit an application to department's Bureau of Air Management, Division of Radiation to take the examination identified in subdivision (2) of this subsection as follows:

(A) On forms furnished by the department;

(B) Accompanied by a non-refundable fee in an amount designated by the Commissioner; and

(C) An individual whose certification ID card has been suspended or revoked shall obtain written approval from the Commissioner to apply to retake the examination.

(2) Examination. For the purpose of determining the qualifications of applicants, the examination shall be administered as follows:

(A) At times and places determined by the Commissioner. The scope of the examination and the methods of procedure, including determination of the passing score, shall be prescribed by the Commissioner. The examination will assess the applicant’s knowledge to use sources of radiation and related equipment safely and the applicant’s knowledge of sections 22a-153-2, 22a-153-3 of the Regulations of Connecticut State Agencies and 49 CFR 100 through 189, 390 through 397 and 10 CFR 71;

(B) By persons authorized by the Commissioner;

(C) A candidate failing an examination may apply for re-examination in accordance with subsection (p)(1) of this section. A candidate shall not retake the same version of the examination;

(D) In English;

(E) A candidate for examination shall present a valid picture identification card, such as a driver's license, at the time of the examination;

(F) Calculators will be permitted during the examination, except calculators or computers with preprogrammed data or formulas;

(G) Any individual observed by a proctor to be compromising the integrity of the examination shall be required to surrender the examination, the answer sheet and any work paper. Such individual will not be allowed to complete the examination, will forfeit the examination fee and will leave the examination site without disturbing other examinees. Such individual shall wait at least ninety (90) days before he or she may submit a new application and fee for examination;

(H) Examination material shall be returned to the proctor at the end of the examination. No photographic or other copying of examination questions or materials shall be permitted. Disclosure by any individual of the contents of any examination prior to its administration is prohibited; and

(I) Names and scores of individuals taking the examination are a matter of public record.

(3) Certification identification (ID) card. The Department will issue a certification ID card to each person who successfully completes the requirements of subsection (m)(3)(A)(i) of this section and receives a passing score on the examination prescribed in subdivision (2) of this subsection, as follows:

(A) Each person's certification ID card shall contain his or her photograph. The Commissioner will take the photograph at the time the examination is administered;

(B) The certification ID card remains the property of the Commissioner who may revoke or suspend such card for good cause;

(C) Any individual who wishes to replace his or her certification ID card shall submit to the Commissioner a written request for a replacement certification ID card, stating the reason a replacement certification ID card is needed. A non-refundable fee shall be submitted with the written request for a replacement certification ID card. The individual shall maintain a copy of the request in his or her possession while performing industrial radiographic operations until a replacement certification ID card is received from the Department;

(D) Each certification ID card shall be valid for a period of five (5) years, unless revoked or suspended in accordance with subparagraph (F) of this subdivision. Each certification ID card expires at the end of the day, in the month and year stated on the certification ID card;

(E) The department shall issue renewals of certification ID cards as follows:

(i) Applications for examination to renew a certification ID card shall be filed in accordance with subdivision (1) of this subsection,

(ii) The examination for renewal of a certification ID card shall be administered in accordance with subdivision (2) of this subsection, and

(iii) A renewal certification ID card shall be issued in accordance with subdivision (1) of this subsection.

(F) The Commissioner may revoke or suspend a certification ID card of any radiographer who violates applicable laws or regulations, as follows:

(i) Such violator may be required to show cause at a formal hearing as to why their certification ID card should not be revoked or suspended in accordance with subparagraph (F)(ii) of this subdivision, and

(ii) When a Department order has been issued for an industrial radiographer to cease and desist from the use of sources of radiation or the Commissioner revokes or suspends such radiographer's certification ID card, the industrial radiographer shall surrender the certification ID card to the Department until the order is changed or the suspension expires.

(4) Reciprocity. The department will grant reciprocal recognition of radiographer certification provided that:

(A) The individual holds a valid certification in the appropriate category issued by a certifying entity;

(B) The requirements and procedures of the certifying entity afford the same or comparable certification standards as those afforded by subsection (m)(3)(A) of this section;

(C) The individual presents the certification to the department prior to performing industrial radiographic operations in the state;

(D) No escalated enforcement action is pending and involves the applicant before the NRC or in any other state; and

(E) Individuals who are granted reciprocal certification by the Commissioner shall maintain the certification upon which the reciprocal recognition was granted, or prior to the expiration of such certification, shall meet the requirements of subsection (m)(3)(A) of this section.

(5) Radiographic personnel performing industrial radiography shall meet the following requirements:

(A) At a job site, the following shall be supplied by the licensee or registrant:

(i) At least one operable, calibrated survey instrument for each exposure device or radiation machine in use,

(ii) A current whole body personnel dosimeter for each person performing radiographic operations,

(iii) An operable, calibrated pocket dosimeter with a range of zero to 200 milliroentgens for each person performing radiographic operations,

(iv) An operable, calibrated, alarming ratemeter for each person performing radiographic operations using a radiographic exposure device, and

(v) The appropriate barrier ropes and signs;

(B) Each radiographer at a job site shall have on his or her person a valid certification ID card issued by a certifying entity;

(C) Industrial radiographic operations shall not be performed if any of the items in subdivisions (5)(A) and (5)(B) of this subsection are not available at the job site or are inoperable; and

(D) During an inspection, the Commissioner may terminate an operation if any of the requirements of this section are not met. Operations shall not be resumed until all required conditions are met.

(q) Certification and examination.

(1) Requirements for an independent certifying organization. An independent certifying organization shall:

(A) Be an organization such as a society or association, whose members participate in, or have an interest in, the field of industrial radiography;

(B) Make its membership available to the general public nationwide. Membership shall not be restricted because of race, color, religion, sex, age, national origin or disability;

(C) Have a certification program open to nonmembers, as well as members;

(D) Be an incorporated, nationally recognized organization that is involved in setting national standards of practice within its fields of expertise;

(E) Have an adequate staff, a viable system for financing its operations, and a policy and decision-making review board;

(F) Have a set of written organizational by-laws and policies that provide adequate assurance of lack of conflict of interest and a system for monitoring and enforcing those by-laws and policies;

(G) Have a committee, whose members can carry out their responsibilities impartially, to review and approve the certification guidelines and procedures, and to advise the organization's staff in implementing the certification program;

(H) Have a committee, whose members can carry out their responsibilities impartially, to review complaints against certified individuals and to determine appropriate sanctions;

(I) Have written procedures describing all aspects of its certification program, maintain records of the current status of each individual's certification and the administration of its certification program;

(J) Have procedures to ensure that certified individuals are provided due process with respect to the administration of its certification program, including the process of becoming certified and any sanctions imposed against certified individuals;

(K) Have procedures for proctoring examinations, including qualifications for proctors. These procedures must ensure that the individuals proctoring each examination are not employed by the same company or corporation, or a wholly-owned subsidiary of such company or corporation, as any of the examinees;

(L) Exchange information about certified individuals with the Nuclear Regulatory Commission and other independent certifying organizations or Agreement States and allow periodic review of its certification program and related records; and

(M) Provide a description to the Nuclear Regulatory Commission of its procedures for choosing examination sites and for providing an appropriate examination environment.

(2) Requirements for certification programs. All certification programs shall:

(A) Require applicants for certification to

(i) receive training in the topics set forth in subsection (m)(3)(F) of this section, or equivalent State or Nuclear Regulatory Commission regulations, and

(ii) satisfactorily complete a written examination covering these topics;

(B) Require applicants for certification to provide documentation that demonstrates that the applicant has:

(i) received training in the topics set forth in subsection (m)(3)(F) of this section or equivalent state or Nuclear Regulatory Commission regulations;

(ii) satisfactorily completed a minimum period of on-the-job training as specified in subsection (m)(3)(A) of this section; and

(ii) received verification by a licensee or registrant that the applicant has demonstrated the capability of independently working as a radiographer.

(C) Include procedures to ensure that all examination questions are protected from disclosure;

(D) Include procedures for denying an application and revoking, suspending and reinstating a certification;

(E) Provide a certification period of not less than three (3) years and no more than five (5) years;

(F) Include procedures for renewing certifications and, if the procedures allow renewals without examination, require evidence of recent full-time employment and annual refresher training; and

(G) Provide a timely response to inquiries, by telephone or letter, from members of the public, about an individual's certification status.

(3) Requirements for a written examination. All examinations must be:

(A) Designed to test an individual's knowledge and understanding of the topics listed in section subsection (m)(3)(F) of this section or equivalent State or Nuclear Regulatory Commission requirements;

(B) Written in a multiple-choice format; and

(C) Have test items drawn from a question bank containing questions based on the material in subsection (m)(3)(F) of this section.

The Regulations of Connecticut State Agencies are amended by adding section 22a-153-4, as follows:

(NEW)

Sec. 22a-153-4. Diagnostic x-rays and imaging systems in the healing arts.

(a) Definitions. For the purposes of this section, the following definitions apply. Terms used in this section that are not defined in this section are as provided in section 22a-153-1 of the Regulations of Connecticut State Agencies.

(1) "Accessible surface" means the external surface of the enclosure or housing of the radiation producing machine as provided by the manufacturer.

(2) "Aluminum equivalent" means the thickness of type 1100 aluminum alloy affording the same attenuation, under specified conditions, as the material in question.

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

(4) "Attenuation block" means a block or stack, having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters, of type 1100 aluminum alloy or other materials having equivalent attenuation.

(5) "Automatic exposure control" or "AEC" means a device, including a phototimer and an ion chamber, that automatically controls one or more technique factors in order to obtain a required quantity of radiation at a preselected location or locations.

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

(7) "Beam-limiting device" means a device that provides a means to restrict the dimensions of the x-ray field.

(8) "Bone densitometry system" means a medical device that uses electronically-produced ionizing radiation or radioactive material to determine the density of bone structures of human patients.

(9) "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.

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

(11) "Certified components" means components of x-ray systems that are subject to regulations promulgated under the federal Radiation Control for Health and Safety Act of 1968, Public Law 90-602.

(12) "Certified system" means any x-ray system that has one or more certified components.

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

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

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

(16) "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.

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

(18) "Diagnostic imaging system" means an assemblage of components for the generation, emission, reception, transformation, storage and visual display of the resultant image.

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

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

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

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

(23) "Entrance exposure rate" means the exposure free in air per unit time at a SID.

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

(25) "Fluoroscopic imaging assembly" means a subsystem in which x-ray photons produce a visible image. It includes the image receptors 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.

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

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

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

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

(30) "Heat unit" means a unit of energy equal to the product of the peak kilovoltage, milliamperes and exposure time in seconds, calculated as kVp x mA x second.

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

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

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

(34) "kWs" means kilowatt second.

(35) "Leakage technique factors" means the technique factors that are used in measuring leakage radiation, are associated with the diagnostic source assembly and are defined as follows:

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

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

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

(36) "Licensed radiographer" means a person holding a license issued pursuant to section 20-74bb of the Connecticut General Statutes.

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

(38) "Line-voltage regulation" means the difference between the no-load and the load line potentials expressed as a percent of the load line potential, calculated using the following equation:

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

V_n = No-load line potential; and
V_l = Load line potential.

(39) "mA" means milliampere.

(40) "mAs" means milliampere second.

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

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

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

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

(45) "Radiograph" means an image receptor on which the image is created directly or indirectly by an x-ray pattern.

(46) "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.

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

(48) "Recording" means producing a permanent form of an image resulting from x-ray photons.

(49) "Scattered radiation" means radiation that, during passage through matter, has been deviated in direction.

(50) "Secondary protective barrier" means the material that attenuates stray radiation.

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

(52) "Source-image receptor distance" or "SID" means the distance from the source to the center of the input surface of the image receptor.

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

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

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

(56) "Stray radiation" means the sum of leakage and scattered radiation.

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

(58) "Tube rating chart" means the set of curves that specify the rated limits of operation of the tube in terms of the technique factors.

(59) "Type 1100 aluminum alloy" means a material composed of 99.00 percent minimum aluminum and 0.12 percent copper.

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

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

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

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

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

(65) "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 including, but not limited to, any stretcher equipped with a radiolucent panel and any table equipped with a cassette tray, cassette tunnel, image intensifier or spot-film device beneath the tabletop.

(b) Applicability. This section applies to:

(1) Every registrant of a diagnostic x-ray system; and

(2) Every person who is required to register a diagnostic x-ray system.

(c) Radiation safety.

(1) Each registrant shall operate any x-ray system under the registrant's administrative control in compliance with the following requirements:

(A) Each registrant shall require an individual operating an x-ray system to be adequately instructed in safe operating procedures and be competent in the safe use of the equipment as specified in subsection (j) of this section;

(B) Each registrant shall create and make available to x-ray operators written safety procedures, including patient holding and any restrictions of the operating technique required for the safe operation of the particular x-ray system;

(C) In the vicinity of the diagnostic x-ray system's control panel, each registrant shall provide a chart specifying, at a minimum, the following information:

(i) Patient's body part versus technique factors to be utilized,

(ii) Except for dental intraoral radiography, the source to image receptor distance to be used, and

(iii) Skin entrance exposure dose for a typical exam;

(D) 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 a radiographic exposure. Other than the patient being examined:

(i) 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 unless the medical needs of the patient dictate otherwise,

(ii) 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, and

(iii) Human patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of not less than 0.25 millimeter lead equivalent material or shall be so positioned that the nearest portion of the body is at least two meters from both the tube head and the nearest edge of the image receptor;

(E) Except if shielding as required by this subdivision would interfere with the diagnostic procedure, shielding of not less than 0.5 mm lead equivalent material shall be used for human patients during radiographic procedures, including:

(i) Gonad shielding for patients who have not passed reproductive age, in which their gonads are in the direct beam, and

(ii) Thyroid shielding for children and for adults in all plain cranial-facial imaging;

(F) Thyroid shielding shall be used on children and should be used on adults in all dentocranialfacial imaging where the use of such shielding does not interfere with the anatomic area being imaged;

(G) Individuals shall not be exposed to the useful beam except for healing arts purposes or if authorized by a licensed radiographer. Deliberate exposure of an individual for the following purposes is prohibited:

(i) For training, demonstration or other non-healing arts purposes, excluding human research subjects, and

(ii) For the purpose of healing arts screening except as authorized by subparagraph (I) of this subdivision;

(H) For circumstances in which a patient or film must be provided with auxiliary support during a radiation exposure:

(i) Mechanical holding devices shall be used when the technique permits,

(ii) Written safety procedures, as required by subparagraph (B) of this subdivision, shall indicate the requirements for selecting a holder and the procedure the holder shall follow,

(iii) The human holder shall be instructed in personal radiation safety and protected as required by subparagraph (D) of this subdivision,

(iv) Licensed operators shall not hold patients except in the case of emergencies,

(v) In those cases in which the patient must hold the film, except during intraoral examinations, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 millimeter lead equivalent material, and

(vi) Each facility shall have leaded aprons and protective gloves available in sufficient numbers to provide protection to all personnel who are involved with x-ray operations and who are otherwise not shielded;

(I) The registrant shall minimize patient and personnel exposure commensurate with the needed diagnostic information using the following procedures and auxiliary equipment:

(i) The speed of the screen and film combinations used shall be the fastest speed consistent with the diagnostic objective of the examinations. Film cassettes without intensifying screens shall not be used for any routine diagnostic radiological imaging with the exception of standard film packets for intraoral use in dental radiography,

(ii) The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality, with the exception of panoramic and cephalometric radiography for which the minimum film speed shall be rare earth or 400 speed,

(iii) Portable or mobile x-ray equipment shall be used only for examinations where it is impractical to transfer the patient to a stationary x-ray installation,

(iv) An x-ray system subject to subsection (g) of this section shall not be utilized in procedures where the source to patient distance is less than 30 centimeters, and

(v) If grids are used between the patient and the image receptor to decrease scatter to the film and improve contrast, the grid shall be positioned with the tube side facing the right direction, and the grid centered to the central ray; and be of the proper focal distance for the SIDs being used, if the grid is of the focused type;

(J) Each registrant shall maintain the following information for each x-ray system for inspection by the Commissioner:

(i) Model and serial numbers of all major components, and user's manuals for those components,

(ii) Records of surveys, calibrations, maintenance and modifications performed on the x-ray system, and

(iii) A copy of all correspondence with the department concerning an x-ray system.

(2) No registrant shall operate an x-ray system for diagnostic purposes if such x-ray system does not meet the provisions of this section.

(d) X-ray film processing facilities and operations. Each registrant of an installation using a radiographic x-ray system and radiographic film shall handle and process radiographic film as follows:

(1) For processing of manually developed film:

(A) In processing tanks constructed of mechanically rigid, corrosion resistant material;

(B) Where the temperature of any solution in a processing tank is maintained within the range of 60^{o} F to 80^{o} F (16^{o} C to 27^{o} C). Except as provided in subsection (h)(3)(F) of this section, film shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer, or, in the absence of such recommendations, with the time-temperature relationships of Table 4-1; and

Table 4-1. Time-temperature chart for manual radiographic film developing.

Thermometer Reading (Degrees)		Minimum Developing Time (Minutes)
^{o}C	^{o}F	
26.7	80	2
26.1	79	2
25.6	78	2.5
25.0	77	2.5
24.4	76	3
23.9	75	3
23.3	74	3.5
22.8	73	3.5
22.2	72	4
21.7	71	4
21.1	70	4.5
20.6	69	4.5
20.0	68	5
19.4	67	5.5
18.9	66	5.5
18.3	65	6
17.8	64	6.5
17.2	63	7
16.7	62	8
16.1	61	8.5
15.6	60	9.5

(C) With devices that will indicate the actual temperature of the developer and signal the passage of a preset time appropriate to the developing time required.

(2) For processing with automatic processors and other closed processing systems:

(A) Except as provided in subsection (h)(3)(F) of this section, films shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer, or, in the absence of such recommendations, with the time-temperature relationships of Table 4-2; and

Table 4-2. Time-temperature relationships for automatic processing of radiographic film.

Developer Temperature		Minimum Immersion Time[a/]

°C	°F	Seconds
35.5	96	19
35	95	20
34.5	94	21
34	93	22
33.5	92	23
33	91	24
32	90	25
31.5	89	26
31	88	27
30.5	87	28
30	86	29
29.5	85	30
[a/] Immersion time only, no crossover time included.		

(B) The specified developer temperature and immersion time shall be posted in the darkroom or on the automatic processor.

(3) Additional equipment and storage requirements.

(A) Pass boxes, if provided, shall be constructed to exclude light from the darkroom when cassettes are placed in or removed from the boxes, and shall incorporate adequate shielding from stray radiation to prevent exposure of undeveloped film;

(B) The darkroom shall be light tight and use proper safelighting such that any film type in use exposed in a cassette to x-radiation sufficient to produce an optical density from one to two when processed shall not suffer an increase in density greater than 0.1 or 0.05 for mammography when exposed in the darkroom for two (2) minutes with all safelights on. If used, daylight film handling boxes shall preclude fogging of the film;

(C) Darkrooms used by more than one individual shall prevent accidental entry while undeveloped films are being handled or processed;

(D) Film shall be stored in a cool, dry place and shall be protected from exposure to stray radiation. Film in open packages shall be stored in a light tight container;

(E) Film cassettes and intensifying screens shall be inspected periodically and shall be cleaned and replaced as necessary to achieve radiographs of good diagnostic quality;

(F) Outdated x-ray film shall not be used for diagnostic radiographs, unless the film has been stored in accordance with the manufacturer's recommendations and a sample of the film passes a sensitometric test for normal ranges of base plus fog and speed; and

(G) Film developing solutions shall be prepared in accordance with the directions given by the manufacturer, and shall be maintained in strength by replenishment or renewal so that full development is accomplished within the time specified by the manufacturer.

(4) Records of any processing deviations from subsections (d)(1) and (d)(2) of this section shall be sufficient to demonstrate compliance with subsections (d)(1) and (d)(2) of this section.

(e) Operation of a diagnostic x-ray system. Any registrant using a diagnostic x-ray system shall operate such system in accordance with the following requirements:

(1) The control panel containing the main power switch shall bear the following warning statement, legible and accessible to view:

"WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

(2) On battery-powered x-ray generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation;

(3) The leakage radiation from the diagnostic source assembly measured at a distance of one meter in any direction from the source shall not exceed 25.8 μC/kg (100 milliroentgens) in one (1) hour when the x-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters;

(4) The radiation emitted by a component other than the diagnostic source assembly shall not exceed 0.5 μC/kg (2 milliroentgens) in one (1) hour at 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 square centimeters with no linear dimension greater than 20 centimeters.

(5) Beam quality.

(A) Half-value layer.

(i) The half-value layer of the useful beam for a given x-ray tube potential shall not be less than the values shown in Table 4.3. If it is necessary to determine such half-value layer at an x-ray tube potential that is not listed in Table 4.3, linear interpolation or extrapolation shall be used,

TABLE 4.3. Half-value layers.

Design Operating	Measured Potential	Half-Value Layer In mm Aluminum

Range	(kVp)	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

(ii) For capacitor energy storage equipment, compliance with the requirements of subsection (e)(5)(A)(i) of this section shall be determined with the system fully charged and a setting of 10 mAs for each exposure, and

(iii) The required minimal half-value layer of the useful beam shall include the filtration contributed by all materials that are permanently between the source and the patient.

(B) Filtration controls. For x-ray systems that have variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with any filters and shall prevent an exposure unless the minimum amount of filtration necessary to produce the HVL required by subsection (e)(5)(A)(i) of this section is in the useful beam for the given kVp that has been selected;

(6) For equipment installed after the effective date of this section, where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes that have been selected shall be indicated clearly prior to initiation of the exposure. Such indication shall be both on the x-ray control panel and at or near the tube housing assembly that has been selected;

(7) The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless tube housing movement is a designed function of the x-ray system;

(8) Technique indicators.

(A) 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 set prior to the exposure shall be indicated; and

(B) The requirement of subparagraph (A) of this subdivision 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 a fluoroscopist;

(9) Diagnostic x-ray systems and their associated components used on humans and certified pursuant to the 21 CFR 1020 shall be maintained in compliance with applicable requirements of that certification; and

(10) All position locking, holding and centering devices on x-ray system components and systems shall function as intended.

(f) Fluoroscopic x-ray systems. Any registrant using a fluoroscopic x-ray system shall operate such system in accordance with this subsection.

(1) Each registrant shall limit the useful beam as follows:

(A) Provide the fluoroscopic imaging assembly with a primary protective barrier that intercepts the entire cross-section of the useful beam at any SID, and ensure that the x-ray tube used for fluoroscopy does not produce x-rays unless the barrier is in position to intercept the entire useful beam.

(B) Fluoroscopic beam limitation.

(i) For certified fluoroscopic systems with or without a spot film device, neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3 percent of the SID. The sum of the excess length and the excess width shall be no greater than 4 percent of the SID,

(ii) For uncertified fluoroscopic systems with a spot film device, the x-ray beam with the shutters fully opened during fluoroscopy or spot filming shall be no larger than the largest spot film size for which the device is designed. Measurements shall be made at the maximum SID available but at no less than 20 centimeters table top to the film plane distance,

(iii) For uncertified fluoroscopic systems without a spot film device, the requirements of subsection (f)(1)(B)(i) of this section apply,

(iv) Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID or a visible area of greater than 300

square centimeters shall be provided with means for stepless adjustment of the x-ray field,

(v) All equipment with a fixed SID and a visible area of 300 square centimeters or less shall be provided with either stepless adjustment of the x-ray field or with means to further limit the x-ray field size at the plane of the image receptor to 125 cm^2 or less,

(vi) If provided, stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum attainable to a field size 5 centimeters by 5 centimeters or less,

(vii) For equipment manufactured after February 25, 1978, when the angle between the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, and

(viii) For non-circular x-ray fields used with circular image receptors, the error in alignment shall be determined along the length and width dimensions of the x-ray field that pass through the center of the visible area of the image receptor.

(C) Spot-film beam limitation. A registrant using a spot-film device shall meet the following requirements:

(i) Provide means 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 that has been selected on the spot film selector. Such adjustment shall be automatic, 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 a spot film device manufactured after June 21, 1979, if the x-ray field size is less than the size of the selected portion of the film, the means for adjustment of the field size shall be only at the operator's option,

(ii) Neither the length nor the width of the x-ray field in the plane of the image receptor shall differ from the corresponding dimensions of the selected portion of the image receptor by more than 3 percent of the SID when adjusted for full coverage of the selected portion of the image receptor. The sum, without regard to sign, of the length and width differences shall not exceed 4 percent of the SID,

(iii) Allow for adjustment of 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, 5centimeters by 5 centimeters,

(iv) Align the center of the x-ray field in the plane of the film with the center of the selected portion of the film to within 2 percent of the SID, and

(v) On spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, provide means to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, and determine compliance with the beam axis indicated to be perpendicular to the plane of the image receptor.

(D) If applicable, an override to any of the automatic x-ray field size adjustments required in subsection (f)(1)(B) and (C) of this section shall:

(i) Be designed for use only in the event of system failure,

(ii) Incorporate a signal visible at the fluoroscopist's position that will indicate whenever the automatic field size adjustment is overridden, and

(iii) Be clearly and durably labeled as follows:

FOR X-RAY FIELD
LIMITATION SYSTEM FAILURE

(2) Activation of the fluoroscopic tube. Each registrant shall control X-ray production in the fluoroscopic mode by a device that requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the x-ray exposure at any time, but means may be provided to permit completion of any single exposure of the series in process.

(3) Each registrant shall limit the entrance exposure rates provided in this subdivision:

(A) Fluoroscopic equipment that is provided with automatic exposure rate control shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 2.6 mC/kg (10 roentgens) per minute at the point where the center of the useful beam enters the patient, except:

(i) During recording of fluoroscopic images, or

(ii) When an optional high level control is provided. When so provided, the equipment shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 1.3 mC/kg (5 roentgens) per minute at the point where the center of the useful beam enters the patient unless the high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

(B) Fluoroscopic equipment that is not provided with automatic exposure rate control shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 1.3 mC/kg (5 roentgens) per minute at the point where the center of the useful beam enters the patient, except:

(i) During recording of fluoroscopic images, or

(ii) When an optional high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

(C) Fluoroscopic equipment that is provided with both automatic exposure and a manual mode shall not be operable at any combination of tube potential and current that results in an exposure rate in excess of 2.6 mC/kg (10 roentgens) per minute in either mode at the point where the center of the useful beam enters the patient, except in the following circumstances:

(i) During recording of fluoroscopic images, or

(ii) When the mode or modes have an optional high level control, in which case that mode or modes shall not be operable at any combination of tube potential and current that results in an exposure rate in excess of 1.3 mC/kg (5 roentgens) per minute at the point where the center of the useful beam enters the patient, unless the high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

(D) Any fluoroscopic equipment manufactured after May 19, 1995 that can exceed 1.3 mC/kg (5 roentgens) per minute shall be equipped with an automatic exposure rate control. All entrance exposure rate limits shall be 2.6 mC/kg (10 roentgens) per minute with an upper limit of 5.2 mC/kg (20 roentgens) per minute when high level control is activated.

(E) Compliance with the requirements of this subdivision shall be determined as follows:

(i) If the source is below the x-ray table, the exposure rate shall be measured one centimeter above the tabletop or cradle;

(ii) If the source is above the x-ray table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting

device or spacer positioned as closely as possible to the point of measurement;

(iii) For a C-arm type of fluoroscope, the exposure rate shall be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly, with the source positioned at any available SID, provided that the end of the beam-limiting device or spacer is no closer than 30 centimeters from the input surface of the fluoroscopic imaging assembly, and

(iv) For a lateral type fluoroscope, the exposure rate shall be measured at a point 15 centimeters from the centerline of the x-ray table and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. A movable tabletop 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.

(4) Periodic measurement of entrance exposure rate shall be performed by a qualified expert for both typical and maximum values by placing materials in the useful beam and taking the following actions:

(A) Such measurements shall be made annually or after any maintenance of the system that might affect the exposure rate;

(B) Results of these measurements shall be posted where any fluoroscopist may have ready access to such results while using the fluoroscope and in the record required in subsection (c)(1)(J) of this section. The measurement results shall be stated in coulombs per kilogram (roentgens) per minute and include the technique factors used in determining such results. The name of the individual performing the measurements and the date the measurements were performed shall be included in the results;

(C) Conditions of periodic measurement of typical entrance exposure rate are as follows:

(i) The measurement shall be made under the conditions that satisfy the requirements of subsection (e)(3)(E) of this section,

(ii) The kVp, mA and other selectable parameters shall be adjusted to those settings typical of clinical use on a 23 centimeters thick abdominal patient, and

(iii) The x-ray system that incorporates automatic exposure rate control shall have sufficient attenuative material placed in the useful beam to produce a milliamperage and/or kilovoltage to satisfy the conditions of subparagraph (C)(ii) of this subdivision; and

(D) Conditions of periodic measurement of maximum entrance exposure rate are as follows:

(i) The measurement shall be made under the conditions that satisfy the requirements of subsection (e)(3)(E) of this section,

(ii) The kVp, mA or other selectable parameters shall be adjusted to those settings which give the maximum entrance exposure rate, and

(iii) The x-ray system that incorporates automatic exposure rate control shall have sufficient attenuative material placed in the useful beam to produce the maximum entrance exposure rate of the system.

(5) Each registrant shall limit the barrier transmitted radiation rate as follows:

(A) The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, shall not exceed 0.5 μC/kg (two milliroentgens) per hour at ten centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each mC/kg (roentgen) per minute of entrance exposure rate; and

(B) Measuring compliance of barrier transmission.

(i) 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,

(ii) 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,

(iii) 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, and

(iv) Movable grids and compression devices shall be removed from the useful beam during the measurement.

(6) During fluoroscopy and cinefluorography, each registrant shall provide for the kV and the mA to be indicated continuously.

(7) Each registrant shall use SSDs not less than:

(A) 30 centimeters on stationary fluoroscopic systems manufactured on or after August 1, 1974;

(B) 35.5 centimeters on stationary fluoroscopic systems manufactured prior to August 1, 1974;

(C) 30 centimeters on all mobile fluoroscopes; or

(D) 20 centimeters for all mobile fluoroscopes when used for specific surgical applications.

(8) Each registrant shall provide means to preset the cumulative on-time of the fluoroscopic x-ray tube as follows:

(A) The maximum cumulative time of the timing device shall not exceed five (5) minutes without resetting; and

(B) 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.

(9) Each registrant shall control scattered radiation as follows:

(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 that 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:

(i) Is at least 120 centimeters from the center of the useful beam, or

(ii) The radiation has passed through not less than 0.25 millimeter lead equivalent material including, but not limited to, drapes, Bucky-slot cover panel, or self-supporting curtains, in addition to any lead equivalency provided by the protective apron referred to in subsection (c)(1)(D) of this section; and

(C) The Commissioner may grant exemptions to subparagraph (B) of this subdivision 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 Commissioner shall not permit such exemption.

(10) For fluoroscopic systems equipped with spot film mode, each *licensee or* registrant shall meet the exposure reproducibility requirements of subsection (g) of this section when operating in the spot film mode.

(11) Radiation therapy simulation systems. Each registrant operating a radiation therapy simulation system shall be exempt from all the requirements of subdivision (3) of this section. A registrant operating such a system shall be exempt from:

(A) The requirements of subdivisions (1) and (5) of this subsection, 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

(B) The requirements of subsection (8) of this subsection 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.

(12) Operator qualification. Each registrant shall allow only a licensed radiographer who is trained in the safe use of fluoroscopic x-ray systems to operate such systems.

(13) Each registrant shall operate fluoroscopic x-ray equipment as follows:

(A) All imaging formed by the use of fluoroscopic x-ray systems shall be viewed, directly or indirectly, and interpreted by a licensed radiographer;

(B) The use of fluoroscopic x-ray systems by radiologic technologists shall be performed under the supervision of a licensed radiographer for the purpose of localization to obtain images for diagnostic purposes;

(C) Radiologic technology students shall not be allowed to operate fluoroscopic x-ray systems unless directly supervised by a licensed radiographer or radiologic technologisttrained in the safe use of fluoroscopic x-ray systems;

(D) Overhead fluoroscopy shall not be used as a positioning tool for general purpose radiographic examinations; and

(E) In a facility that uses a fluoroscopic x-ray system, maintain a record of the cumulative fluoroscopic exposure time used and the number of spot films for each examination. Such record shall indicate patient identification, type of examination, date of examination and operator's name.

(g) Other radiographic systems. Each registrant of a radiographic system that is not a fluoroscopic, dental intraoral, bone densitometry or computed tomography x-ray system shall operate such system in accordance with the requirements of this subsection.

(1) Each registrant shall limit the useful beam to the area of clinical interest. Evidence of compliance with this requirement shall include proper use of a positive beam limiting device that meets the manufacturer's specifications and the requirements of subdivision (8)(B) of this subsection or evidence of collimation on at least three (3) sides or three (3) corners of the film. Each registrant shall meet the following beam limitation requirements for each of the following radiographic systems:

(A) For all general purpose stationary and mobile x-ray systems.

(i) Only x-ray systems provided with means for independent stepless adjustment of at least two dimensions of the x-ray field shall be used,

(ii) 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, and

(iii) The Commissioner may grant an exemption from the requirements of subparagraphs (A)(i) and (A)(ii) of this subdivision for non-certified x-ray systems, provided the registrant makes a written application for such exemption and in that application demonstrates it is impractical to comply with subparagraphs (A)(i) and (A)(ii) of this subdivision and describes another method used to address the requirements of subparagraphs (A)(i) and (A)(ii) of this subdivision.

(B) For stationary general purpose x-ray systems. In addition to the requirements of subparagraph (A) of this subdivision, a registrant of a stationary general purpose x-ray system, either certified or noncertified, shall meet the following requirements:

(i) Provide a method 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,

(ii) Use a beam-limiting device that indicates numerically the field size in the plane of the image receptor to which it is adjusted, and

(iii) Specify the field size dimensions and SIDs in inches or centimeters, and so that aperture adjustments result in x-ray field dimensions in the plane of the image receptor that correspond to those indicated by the beam-limiting device to within two percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor;

(C) For x-ray systems designed for one image receptor size at a fixed SID:

(i) Provide a 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

(ii) Provide a 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) For x-ray systems other than those identified in subparagraphs (A), (B) and (C) of this subdivision:

(i) Provide a 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 2 percent of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor,

(ii) Provide a means to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID, or 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, and

(iii) For a system that meets the requirements for a general purpose x-ray system specified in subparagraph (A) of this subdivision or for which alignment means are provided, a registrant may provide for the following as an alternative to compliance with subparagraphs (D)(i) and (D)(ii) of this subdivision:

(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.

(2) Each registrant of a radiographic system shall control radiation exposure as follows:

(A) Initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. The operator shall not be able to initiate an exposure when the timer is set to a "zero" or "off" position, if either position is provided;

(B) Provide for visual indication of radiation exposure, observable at or from the operator's protected position whenever x-rays are produced. A signal audible to the operator shall indicate that the exposure has terminated;

(C) 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."

(i) 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 exposure:

(I) Of one-half second or less, or

(II) During serial radiography, when means shall be provided to permit completion of any single exposure of the series in process,

(ii) When an automatic exposure control is provided:

(I) Indication shall be made on the control panel when this mode of operation is selected,

(II) The minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to two pulses, if the x-ray tube is equal to or greater than 50 kVp,

(III) The minimum exposure time for all equipment other than that specified in subclause (ii)(II) of this subparagraph shall be equal to or less than one-sixtieth (1/60) second or a time interval required to deliver five mAs, whichever is greater,

(IV) 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

(V) A visible signal shall indicate when an exposure has been terminated at the limits required by subclause (ii)(IV) of this subparagraph, and manual resetting shall be required before further automatically timed exposures can be made.

(D) 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, determined by the following equation:

$$(X_1 - X_2) \leq 0.1 (X_1 + X_2)$$

where X_1 and X_2 are the average C $kg^{-1}s^{-1}$ (mR/s) values;

(E) The x-ray exposure control shall be so placed that the operator can view the patient while making any exposure; and

(F) Each registrant shall meet the following requirements for operator protection:

(i) For a stationary x-ray system, permanently mount the x-ray control in a protected area so that the operator is required to remain in that protected area during the entire exposure, and

(ii) For mobile and portable x-ray systems that are:

(I) Used continuously for greater than one (1) week in the same location, meet the requirements of subclause (i) of this subparagraph, and

(II) Used for less than one (1) week at the same location, provide either a protective barrier at least 2 meters (6.5 feet) high for operator protection during exposures, or means to allow the operator to be at least 6 feet from the tube housing assembly during the exposure.

(3) Each registrant shall provide a means to limit the SSD on all mobile or portable radiographic systems to equal to or greater than thirty centimeters.

(4) When all technique factors are held constant, including control panel selections associated with automatic exposure control systems, a registrant shall not exceed a coefficient of variation of exposure for both manual and automatic exposure control systems of 0.05. The requirement of this subdivision applies to clinically-used techniques.

(5) Each registrant shall limit radiation emitted from the x-ray tube when the system is fully charged and the exposure switch or timer is not activated to 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.

(6) 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 ten percent of the indicated value for kVp and 20 percent for time.

(7) For equipment operated at 40 to 100 percent of the maximum rated power supply specified by the manufacturer for any fixed x-ray tube potential, the registrant shall:

(A) For equipment having independent selection of x-ray tube current (mA), the average ratios (X_i) of exposure to the indicated milliampere-seconds product (C kg^{-1} mAs^{-1} (or mR/mAs)) obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum, calculated according to the following equation:

$$X_1\text{-}X_2 \leq 0.10\ (X_1+X_2)$$

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 two where the tube current selection is continuous;

(B) For 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, calculated according to the following equation:

$$X_1\text{-}X_2 \leq 0.10\ (X_1+X_2)$$

where X_1 and X_2 are the average values obtained at any two consecutive mAs selector settings, or at two settings differing by no more than a factor of two where the mAs selector provides continuous selection; and

(C) Determination of compliance shall be based on ten exposures taken within a time period of one (1) hour, at each of the two settings. These two settings may include any two focal spot sizes except where one is equal to or less than 0.45 millimeters and the other is greater than 0.45 millimeters. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the x-ray tube manufacturer.

(8) Each registrant of a diagnostic x-ray system incorporating any certified component shall be required to comply with the following additional requirements, as applicable to the certified component:

(A) For stationary and mobile general purpose x-ray systems, limit the beam as follows:

(i) Provide a means of stepless adjustment of the size of the x-ray field. The minimum field size at a SID of 100 centimeters shall be equal to or less than 5 centimeters by 5 centimeters,

(ii) When a light localizer is used to define the x-ray field, such localizer shall provide an average illumination of not less than 160 lux or 15 foot-candles at 100 centimeters or at the maximum SID, whichever is less. The average illumination shall be based upon measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems manufactured on and after May 27, 1980, are exempt from this requirement, and

(iii) The edge of the light field at 100 centimeters or at the maximum SID, whichever is less, shall have a contrast ratio, corrected for ambient lighting, of not less than four in the case of beam-limiting devices designed for use on stationary equipment, and a contrast ratio of not less than three in the case of beam-limiting devices designed for use on mobile equipment. The contrast ratio is defined as I_1/I_2 where I_1 is the illumination 3 millimeters from the edge of the light field toward the center of the field; and I_2 is the illumination 3 millimeters from the edge of the light field away from the center of the field. Compliance shall be determined with a measuring instrument aperture of 1 millimeter in diameter;

(B) If PBL is used, the registrant shall meet the following requirements:

(i) PBL shall prevent the production of x-rays when:

(I) Either the length or width of the x-ray field in the plane of the image receptor differs, except as permitted by subclause (iii) of this subparagraph, from the corresponding image receptor dimensions by more than 3 percent of the SID, or

(II) The sum of the length and width differences as stated in subclause (i)(I) of this subparagraph without regard to sign exceeds 4 percent of the SID,

(ii) Compliance with subparagraph (B)(i) of this subdivision shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor. Compliance shall be determined no sooner than five (5) seconds after insertion of the image receptor,

(iii) The PBL system shall be capable of operation, at the discretion of the operator, such that the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. The minimum field size at a SID of 100 centimeters shall be equal to or less than five centimeters by 5 centimeters, and

(iv) The PBL system shall be designed such that if a change in image receptor does not cause an automatic return to PBL function as described in subparagraph (B)(i) of this subdivision, then any change of image receptor size or SID must cause the automatic return; and

(C) For beam limitation for portable x-ray systems, each registrant shall meet the beam limitation requirements of subdivision (1)(A) or (1)(B) of this subsection.

(9) Each registrant shall use a tube stand or other mechanical support for portable x-ray systems, so that the x-ray tube housing assembly need not be hand-held during exposures.

(h) Intraoral dental radiographic systems. Each registrant of x-ray equipment and associated facilities used for intraoral dental radiography shall operate such equipment and associated facilities in accordance with the requirements this subsection and subsections (c) and (e) of this section.

(1) Each registrant shall provide each X-ray system designed for use with an intraoral image receptor with means to limit SID to not less than 20 centimeters.

(2) No later than sixty (60) months from the effective date of this section, each registrant shall provide each radiographic system designed for use with an intraoral image receptor with rectangular collimation to limit the x-ray beam such that the beam at the minimum SID shall be the approximate dimensions of the image receptor. A position indicating device or accessory device shall be used, except where anatomic constraints or the inability of the human subject to cooperate makes rectangular collimation and beam-film alignment impossible.

(3) Each registrant shall provide for the following radiation exposure controls:

(A) For exposure initiation:

(i) Initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch, and

(ii) Exposure shall not be possible when the timer is set to a "zero" or "off" position, if either position is provided;

(B) For exposure indication:

(i) A visual indicator of radiation exposure shall be observable at or from the operator's protected position whenever x-rays are produced, and

(ii) A signal audible to the operator shall indicate that the exposure is occurring;

(C) For exposure termination:

(i) 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,

(ii) 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 one half (1/2) second or less, and

(iii) Termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "zero;"

(D) 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, determined using the following equation:

$$(X_1 - X_2) \leq 0.1 (X_1 + X_2)$$

where X_1 and X_2 are the average values;

(E) For exposure control location and operator protection, stationary x-ray systems shall 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;

(F) Dental radiographic films shall be developed according to the film manufacturer’s instructions for both the chemistry and time-temperature method; and

(G) For exposure control location and operator protection, mobile and portable x-ray systems that are:

(i) Used for more than one (1) week in the same location shall meet the requirements of subparagraph (E) of this subdivision, and

(ii) Used for less than one week in the same location shall be provided with either a protective barrier at least 6.5 feet high for operator protection, or means to allow the operator to be at least 6 feet from the tube housing assembly while making exposures.

(4) When the equipment is operated on an adequate power supply as specified by the manufacturer, each registrant shall limit the estimated coefficient of variation of radiation exposures to no greater than 0.05 for any specific combination of selected technique factors.

(5) For equipment operated on a power supply specified by the manufacturer for any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rated, each registrant shall provide for the following:

(A) For 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, calculated as follows:

$$X_1 - X_2 \leq 0.10 (X_1+X_2)$$

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 two where the tube current selection is continuous;

(B) For 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, calculated as follows:

$$X_1 - X_2 \leq 0.10 (X_1 +X_2)$$

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 two where the mAs selector provides continuous selection; and

(C) Determination of compliance shall be based on ten exposures taken within a time period of one (1) hour, at each of the two settings. These two settings may include any two focal spot sizes except where one is equal to or less than 0.45 millimeters and the other is greater than 0.45 millimeters. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the x-ray tube manufacturer.

(6) For deviation of technique factors from indicated values for kVp and exposure time, if time is independently selectable, each registrant shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications, each registrant shall not exceed a deviation of 10 percent of the indicated value for kVp and 20 percent for time.

(7) Each registrant of a dental x-ray machine with a nominal fixed kVp of less than 50 kVp shall not be used to make diagnostic dental radiographs of humans.

(8) Each registrant shall use the following administrative controls:

(A) Patient holding devices shall be used when clinically indicated;

(B) The tube housing and the PID shall not be hand-held during an exposure;

(C) The x-ray system shall be operated in such a manner that the useful beam at the patient's skin does not exceed the requirements of subdivision (2) of this subsection;

(D) Dental fluoroscopy without image intensification shall not be used; and

(E) The patient's name, type of examination, dates of examination, the reason for acquiring the images and the finding on the images shall be recorded in the patient record.

(i) Computed tomography x-ray systems.

(1) Each registrant of a CT x-ray system shall meet the following equipment requirements:

(A) For termination of exposure:

(i) 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 of its preset value through the use of either a backup timer or devices that monitor equipment function,

(ii) A visible signal shall indicate when the x-ray exposure is in progress and has been terminated through the means required by subparagraph (A)(i) of this subdivision, and

(iii) The operator shall be able to terminate the x-ray exposure at any time during a scan, or series of scans under CT x-ray system control, of greater than one-half (1/2) second duration;

(B) For tomographic plane indication and alignment:

(i) For any single tomogram system, means shall be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane,

(ii) For any multiple tomogram system, means shall be provided to permit visual determination of the location of a reference plane. This reference plane may be offset from the location of the tomographic planes, and

(iii) If a device using a light source is used to satisfy the requirements of subparagraphs (B)(i) or (B)(ii) of this subdivision, 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;

(C) For beam-on and shutter status indicators and control switches:

(i) The CT x-ray control and gantry shall provide visual indication whenever x-rays are produced and, if applicable, whether the shutter is open or closed, and

(ii) Each emergency button or switch shall be clearly labeled as to its function;

(D) Each CT x-ray system shall be designed such that the CT conditions of operation to be used during a scan or a scan sequence shall be indicated prior to the initiation of a scan or a scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible;

(E) When data are not being collected for image production, the radiation adjacent to the tube port shall not exceed the level provided in subsection (d)(3) of this section;

(F) The angular position where the maximum surface CTDI occurs shall be identified to allow for reproducible positioning of a CT dosimetry phantom; and

(G) For CT x-ray systems containing a gantry manufactured after September 3, 1985:

(i) The total error in the indicated location of the tomographic plane or reference plane shall not exceed 5 millimeters,

(ii) If the x-ray production period is less than one-half (1/2) second, the indication of x-ray production shall be actuated for at least one-half (1/2) 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,

(iii) The deviation of indicated scan increment versus actual increment shall not exceed plus or minus one millimeter with any mass from 0 to 100 kilograms resting on the support device. The patient support device shall be incremented from a typical starting position to the maximum

incremented distance or 30 centimeters, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment may be taken anywhere along this travel, and

(iv) 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.

(2) Each registrant of a CT x-ray systems shall provide for the following in facility design:

(A) Two-way aural communication between the patient and the operator at the control panel; and

(B) Continuous observation of the patient during irradiation through windows, mirrors, closed-circuit television or an equivalent:

(i) Located so that the operator can observe the patient from the control panel, and

(ii) When the primary viewing system is electronic, an alternate viewing system, which may be electronic, shall be available for use in the event of failure of the primary viewing system.

(3) Each registrant shall have a survey made under the direction of a qualified expert as follows:

(A) For each of the following systems:

(i) Each CT x-ray system installed after the effective date of this section,

(ii) Each CT x-ray system not previously surveyed, and

(iii) Every CT x-ray system after any change in the facility or equipment that might cause a significant increase in radiation hazard; and

(B) The registrant shall obtain a written report of the survey from the qualified expert, and a copy of the report shall be made available to the Commissioner upon request.

(4) Each registrant shall provide for calibration of the radiation output of each CT x-ray system as follows:

(A) Performed by, or under the direction of, a qualified expert who is physically present at the facility during such calibration;

(B) Performed at intervals specified by a qualified expert and after any change or replacement of components that, in the opinion of the qualified expert, may cause a change in the radiation output;

(C) Performed with a calibrated dosimetry system. The calibration of such system shall be traceable to a national standard. The dosimetry system shall have been calibrated within the preceding two (2) years;

(D) 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 phantoms shall be right circular cylinders of polymethyl methacrylate of density 1.19 plus or minus 0.01 grams per cubic centimeter. The phantoms shall be at least 14 centimeters in length and shall have diameters of 32.0 centimeters for testing CT x-ray systems designed to image any section of the body and 16.0 centimeters for systems designed to image the head or for whole body scanners operated in the head scanning mode,

(ii) CT dosimetry phantoms shall provide means for the placement of a dosimeter along the axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom. Means for the placement of a dosimeter or alignment device at other locations may be provided,

(iii) Any effects on the doses measured due to the removal of phantom material to accommodate dosimeters shall be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom, and

(iv) All dose measurements shall be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuation materials present;

(E) Required for each type of head, body or whole-body scan performed at the facility;

(F) Performed as follows:

(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 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 subsection (i)(4)(D)(ii) of this section shall be measured. The manufacturer's statement as to the nominal tomographic section thickness for the system may be used to determine CTDI. 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, and

(iii) The spot checks specified in subsection (i)(5) of this section shall be made; and

(G) Calibration procedures shall be in writing. Records of calibrations performed shall be maintained for inspection by the Commissioner upon request.

(5) Each registrant shall use the following spot-check procedures on each CT x-ray system:

(A) All procedures shall be in writing and shall have been developed by a qualified expert;

(B) Procedures shall incorporate the use of a CT dosimetry phantom that has a capability of providing an indication of contrast scale, noise, nominal tomographic section thickness, the resolution capability of the system for low and high contrast objects, and measuring the mean CTN for water or other reference material;

(C) All spot checks shall be included in the calibration required by subsection (i)(4) of this section and at time intervals and under system conditions specified by a qualified expert;

(D) Spot checks shall include acquisition of images obtained with the CT dosimetry phantoms using the same processing mode and CT conditions of operation as are used to perform calibrations required by subsection (i)(4) of this section. Records of the images made shall be retained, until a new calibration is performed, as follows:

(i) Hard copies of the images obtained from the image display device, and

(ii) Stored in digital form on a storage medium compatible with the CT x-ray system; and

(E) Written records of the spot checks performed shall be maintained for inspection by the Commissioner for a period of five (5) years.

(6) Each registrant shall operate each CT x-ray system as follows:

(A) Allow operation only by a licensed radiographer;

(B) Maintain readily available information regarding the operation and calibration of the system including:

(i) Dates of the latest calibration and spot checks and the location within the facility where the results of those tests may be obtained,

(ii) Instructions on the use of the CT dosimetry phantoms including a schedule of spot checks appropriate for the system, allowable variations for the indicated parameters and the results of at least the most recent spot checks conducted on the system,

(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 for adults and pediatrics available at the control panel that specifies for each routine examination the CT conditions of operation and the number of scans per examination; and

(C) If the calibration or spot check of the CT x-ray system identifies that a system operating parameter has exceeded a tolerance established by the qualified expert, use of the CT x-ray system on patients shall be limited to those uses permitted by established written instructions of the qualified expert.

(7) Mammography certification requirements are as follows:

(A) Only x-ray systems, pursuant to the Mammography Quality Standards Reauthorization Act of 1998, Public Law 105-248 and 21 CFR 900, shall be used to screen and diagnose with mammography;

(B) The owner or operator of 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 CFR 900; and

(C) The owner or operator of 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 CFR 900.

(j) Determination of competence.

Competent operation of x-ray equipment requires that an individual have expertise in the following areas:

(1) The use of equipment, including the function of each control and the ability to use a technique chart;

(2) Radiation protection practices, including:

(A) Collimation;

(B) Filtration;

(C) Gonad shielding and other patient protection devices, as necessary;

(D) Restriction of x-ray tube radiation to the image receptor;

(E) Personnel protection; and

(F) Grids;

(3) Film processing, including:

(A) Film speed as related to patient exposure;

(B) Film processing parameters; and

(C) Quality assurance program requirements;

(4) Emergency procedures, including termination of exposure in event of an automatic timing device failure;

(5) Proper use of personnel dosimetry, as necessary; and

(6) Units of radiation.

The Regulations of Connecticut State Agencies are amended by adding section 22a-153-4a, as follows:

(NEW)

Sec. 22a-153-4a. Diagnostic x-rays and imaging systems in veterinary medicine.

(a) Definitions.

For the purposes of this section, all definitions are as provided in sections 22a-153-1 and 22a-153-4 of the Regulations of Connecticut State Agencies.

(b) Applicability.

The requirements of this section apply to a person registered to operate an x-ray system used in veterinary medicine.

(c) Operating requirements.

(1) Except as otherwise provided in subsection (d) of this section, each registrant of a system subject to this section shall comply with the requirements of section 22a-153-4 of the Regulations of Connecticut State Agencies.

(2) For a system installed prior to the effective date of this section or any portable veterinary x-ray system, each registrant shall meet the beam limitation requirements of section 22a-153-4(f)(1)(D) of the Regulations of Connecticut State Agencies.

(3) For any stationary, mobile or portable x-ray system, each registrant shall provide the system operator with either:

(A) A two meter (6.5 feet) high protective barrier for operator protection during exposures, or

(B) A means to allow the operator to be at least 2.7 meters (9 feet) from the tube housing assembly during exposures; and

(d) Exemptions. Each registrant of a system subject to this section is exempt from the following requirements of section 22a-153-4 of the Regulations of Connecticut State Agencies:

(1) Subsection (b)(9)(A);

(2) The restriction of subsection (b)(9)(D);

(3) Subsection (f)(1)(A);

(4) Subsection (f)(2)(F); and

(5) Subsection (f)(3).

The Regulations of Connecticut State Agencies are amended by adding section 22a-153-5, as follows:

(NEW)

Sec. 22a-153-5. Radiation safety requirements for particle accelerators operated for human use.

(a) Applicability. This section applies to any person who receives, possesses, uses, transfers, owns or acquires a particle accelerator intended for human use in Connecticut.

(b) Registration.

(1) No person shall receive, possess, use, transfer own or acquire a particle accelerator for human use except as authorized in a registration issued by the Commissioner.

(2) A person shall submit a written application to the Commissioner and obtain an issued registration prior to operating a particle accelerator for human use in the state. Such application shall be submitted on a form provided by the department and shall include, but is not limited to, the following information:

(A) A statement of the applicant's training and experience to use such accelerator for the purpose requested in a manner to minimize danger to public health and safety or property;

(B) A demonstration that the applicant's proposed or existing equipment, facilities and operating and emergency procedures will adequately protect health and minimize danger to public health and safety or property;

(C) Training and experience of staff qualified to operate such a particle accelerator;

(D) Identification of one of the following entities:

(i) The Radiation Safety Officer, or

(ii) Members of the applicant's radiation safety committee that will approve in advance a proposal for the use of a particle accelerator;

(E) A description of the applicant's training program for particle accelerator system operators; and

(F) Any other information requested by the Commissioner.

(3) The Commissioner will issue a registration for the use of a particle accelerator to an applicant of a complete application if the Commissioner determines:

(A) The applicant's proposed program for use of a particle accelerator is adequate to protect public health and safety;

(B) The applicant has appointed a medical committee of at least three members to evaluate all proposals for research, diagnostic and therapeutic use of a particle accelerator whenever deemed necessary by the Commissioner. Membership of the committee should include physicians expert in internal medicine, hematology, therapeutic radiology and a person experienced in depth dose calculations and protection against radiation;

(C) The individuals designated on the application as the users have substantial training and experience in deep therapy techniques or in the use of particle accelerators to treat humans; and

(D) The individual designated on the application as the user is a physician.

(c) Restrictions on operation.

(1) No registrant shall permit any individual to act as an operator of a particle accelerator until such individual has:

(A) Received instruction in radiation safety and has demonstrated an understanding thereof;

(B) Received instruction concerning and has access to copies of applicable state regulations, registration conditions and the registrant's operating and emergency procedures, and has demonstrated understanding thereof; and

(C) Demonstrated competence to use a particle accelerator and related equipment.

(2) The radiation safety committee or the radiation safety officer shall have the authority to terminate the operations at a particle accelerator facility if such action is deemed necessary to minimize danger to public health and safety or property.

(d) Shielding and safety design requirements.

(1) Each registrant shall consult a qualified expert, approved as such by the Commissioner, in the design of a particle accelerator installation.

(2) When an accelerator is first capable of producing radiation, each registrant shall have a qualified expert, approved as such by the Commissioner, perform a radiation survey.

(3) Each registrant of a particle accelerator installation shall include such primary and secondary barriers necessary to comply with section 22a-153-2(i) of the Regulations of Connecticut State Agencies.

(e) Particle accelerator controls and interlock systems. Each registrant of a particle accelerator shall provide for:

(1) Clearly identified and easily discernible instrumentation, readouts and controls on the particle accelerator control console;

(2) On each entrance into a target room or other high radiation area, a safety interlock that shuts down the particle accelerator under conditions of barrier penetration;

(3) A circuit on each safety interlock that allows for operation independent of all other safety interlocks;

(4) A safety interlock system that prevents operation of the accelerator in the event of any defect or component failure in the safety interlock system;

(5) A safety interlock system designed to prevent resumption of operation of the accelerator after the interlock has been tripped unless controls are manually reset at the position where the safety interlock has been tripped and at the main control console; and

(6) In all high radiation areas, an easily identifiable scram button or other emergency power cutoff switch. Such a cutoff switch shall include a manual reset so that the accelerator cannot be restarted from the accelerator control console without resetting the cutoff switch.

(f) Particle accelerator warning devices. Each registrant of a particle accelerator shall provide for:

(1) Easily observable warning lights on each location designated as high radiation area and each entrance to such location. Such warning lights shall operate only when radiation is being produced;

(2) An audible warning device on each high radiation area except in a facility designed for human exposure. Such warning device shall be clearly discernible in all high radiation areas and shall be activated for fifteen (15) seconds prior to the possible creation of such high radiation; and

(3) Barriers, temporary or otherwise, and pathways leading to high radiation areas that are posted in accordance with section 22a-153-2(k) of the Regulations of Connecticut State Agencies.

(g) Particle accelerator operation procedures. Each registrant of a particle accelerator shall provide for:

(1) Measures to secure the particle accelerator when not in operation to prevent unauthorized use;

(2) Measures to ensure that the safety interlock system is not used to turn off the accelerator beam except in an emergency;

(3) Checks for proper operation of all safety and warning devices, including interlocks, at intervals not to exceed three (3) months. Results of such tests shall be maintained at the accelerator facility for inspection by the Commissioner upon request;

(4) Current electrical circuit diagrams of the accelerator and the associated safety interlock systems maintained for inspection by the Commissioner upon request and available to the operator at each accelerator facility;

(5) Any necessary action taken intentionally to bypass a safety interlock or interlocks shall be:

(A) Authorized by the radiation safety committee or radiation safety officer,

(B) Recorded as to time, date and reason in a permanent log and in a notice posted at the accelerator control console, and

(C) Terminated as soon as possible; and

(6) A copy of the current operating and the emergency procedures to be maintained at the accelerator control panel.

(h) Particle accelerator radiation monitoring. Each registrant of a particle accelerator shall provide for:

(1) Appropriate portable monitoring equipment that is operable and has been appropriately calibrated for the radiations being produced at the facility shall be available at each particle accelerator facility. Such equipment shall be tested for proper operation daily and calibrated at intervals not to exceed one year and after each servicing and repair;

(2) In the event that shielding, operation, equipment or occupancy of adjacent areas is changed, a radiation protection survey performed and documented by a qualified expert, designated as such by the Commissioner;

(3) Continuous monitoring of radiation levels in all high radiation areas. Continuous monitoring devices shall be electrically independent of the accelerator control and safety interlock systems and capable of providing a readout at the control panel;

(4) Calibration of all area monitors at intervals not to exceed one (1) year and after each servicing and repair;

(5) As applicable, periodic surveys to determine the amount of airborne particulate radioactivity present;

(6) As applicable, periodic smear surveys to determine the degree of contamination;

(7) Surveys to be conducted in accordance with the written procedures established by a qualified expert, designated as such by the Commissioner, or by the radiation safety officer; and

(8) Records of all radiation protection surveys, calibrations and instrumentation tests to be maintained for five (5) years at the accelerator facility for inspection by the Commissioner.

(i) Particle accelerator ventilation systems. Each registrant of a particle accelerator shall:

(1) Provide for ventilation systems to ensure that personnel entering any area where airborne radioactivity may be produced will not be exposed to airborne radioactive material in excess of those limits specified in section 22a-153-2(q)(1) of the Regulations of Connecticut State Agencies; and

(2) Not vent, release or otherwise discharge airborne radioactive material to an unrestricted area that exceeds the limits specified in 22a-153-2(q)(2) of the Regulations of Connecticut State Agencies**,** except as authorized pursuant to section 22a-153-2(f)(2) of the Regulations of Connecticut State Agencies. Compliance with this subsection shall be determined using concentrations averaged over a period not greater than one (1) year. Every effort should be made to maintain releases of radioactive material to unrestricted areas as far below applicable limits as is reasonably achievable.

The Regulations of Connecticut State Agencies are amended by adding section 22a-153-6, as follows:

(NEW)
Sec. 22a-153-6. Notices, instructions and reports to workers; consultations with workers during and requests by workers for inspection.

(a) Posting of notices to workers.

(1) Each licensee or registrant shall post current copies of the following documents in a location accessible to all employees during a normal business day:

(A) Sections 22a-153-1 and 22a-153-2 of the Regulations of Connecticut State Agencies;

(B) The current license or certificate of registration and any conditions or documents incorporated by reference into such license or registration;

(C) The operating procedures applicable to activities under the license or registration; and

(D) Any notice of violation involving radiological working conditions, proposed imposition of civil penalty, or order issued, by the Commissioner and any response from the licensee or registrant.

(2) As an alternative to posting of a document specified subsection (a)(1) of this section, the licensee or registrant may post a notice that describes the document and states where at the facility it may be examined.

(3) **[Agency Form X] "**Notice to Employees" shall be posted by each licensee or registrant as required by this section.

(4) Documents received from the department posted pursuant to subsection (a)(1)(D) of this section shall be posted within five (5) working days after receipt of the documents. The licensee's or registrant's response, if any, shall be posted within five (5) working days after dispatch from the licensee or registrant. Such documents shall remain posted for a minimum of five (5) working days or until action correcting the violation has been completed, whichever is later.

(5) Documents, notices or forms posted pursuant to this subsection shall appear in a sufficient number of places to permit individuals engaged in work under the license or registration to have access to them on the way to or from any particular work location to which the document applies, shall be conspicuous and shall be replaced if defaced or altered.

(b) Instructions for individuals engaged in activities related to a registration or license for a source of ionizing radiation.

(1) Each licensee or registrant shall provide instructions as follows:

(A) Each individual likely to receive an occupational dose shall be:

(i) Informed of the storage, transfer or use of sources of radiation in the workplace,

(ii) Instructed in the health protection problems associated with exposure to radiation or radioactive material to the individual and potential offspring, in precautions or procedures to minimize exposure and in the purposes and functions of protective devices employed,

(iii) Instructed in, and instructed to observe, to the extent within the worker's control, the applicable provisions of the Commissioner's regulations and licenses for the protection of personnel from exposures to radiation or radioactive material,

(iv) Instructed of his responsibility to report promptly to the licensee or registrant any condition that may constitute, lead to or cause a violation of the Commissioner's regulations or license condition, or any unnecessary exposure to radiation or radioactive material,

(v) Instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material, and

(vi) Shall be advised as to the radiation exposure reports which workers shall be furnished pursuant to subsection (c) of this section, and

(vii) Only trained personnel are permitted to use radiation-generating devices or radioactive material.

(B) The extent of instruction shall be commensurate with potential exposure presented in the workplace.

(c) Notifications and reports to individuals engaged in activities related to a registration or license for a source of ionizing radiation.

(1) Each licensee or registrant shall provide the following:

(A) Radiation exposure data for the individual and the results of any measurements, analyses and calculations of radioactive material deposited or retained in the body of that individual shall be reported to the individual as specified in this subsection.

The information reported shall include data and results obtained pursuant to the Commissioner's regulations, orders or license conditions, as shown in records maintained by the licensee or registrant pursuant to section 22a-153-2(n)(7) of the Regulations of Connecticut State Agencies. Each notification and report shall:

(i) Be in writing,

(ii) Include appropriate identifying data including the name of the licensee or registrant, the name of the individual and the individual's identification number, preferably social security number,

(iii) Include the individual's exposure information, and

(iv) Contain the following statement:

"This report is furnished to you under the provisions section 22a-153-6 of the Regulations of Connecticut State Agencies. You should preserve this report for further reference.";

(B) Each licensee or registrant shall furnish to each worker annually a written report of the worker's dose as shown in records maintained by the licensee or registrant pursuant to section 22a-153-2(n)(7) of the Regulations of Connecticut State Agencies;

(C) Each licensee or registrant shall furnish a written report of the worker's exposure to sources of radiation at the request of a worker formerly engaged in activities controlled by the licensee or registrant. The report shall include the dose record for each year the worker was required to be monitored pursuant to section 22a-153-2(i) of the Regulations of Connecticut State Agencies. Such report shall be furnished within thirty (30) days from the date of the request, or within thirty (30) days after the dose of the individual has been determined by the licensee or registrant, whichever is later. The report shall cover the period of time that the worker's activities involved exposure to sources of radiation and shall include the dates and locations of work under the license or registration in which the worker participated during this period;

(D) When a licensee or registrant is required pursuant to section 22a-153-2(o)(2), (o)(3) or (o)(4) of the Regulations of Connecticut State Agencies to report to the Commissioner any exposure of an individual to sources of radiation, the licensee or the registrant shall also provide the individual a written report on the exposure data included therein. Such reports shall be transmitted at a time not later than the transmittal to the Commissioner; and

(D) At the request of a worker who is terminating employment with the licensee or registrant in work involving exposure to radiation or radioactive material, during the current year, each licensee or registrant shall provide at termination to each

such worker, or to the worker's designee, a written report regarding the radiation dose received by that worker from operations of the licensee or registrant during the current year or fraction thereof. If the most recent individual monitoring results are not available at that time, a written estimate of the dose shall be provided together with a clear indication that this is an estimate. A written report documenting the actual radiation dose shall be provided to the worker as soon as the information becomes available.

(d) Representatives of licensees or registrants and workers during inspection.

(1) Each licensee or registrant shall afford to the Commissioner at all reasonable times opportunity to inspect materials, machines, activities, facilities, premises and records pursuant to regulations adopted pursuant to chapter 446a of the Connecticut General Statutes.

(2) During an inspection, the Commissioner's representatives may consult privately with workers as specified in subsection (e) of this section. The licensee or registrant may accompany the Commissioner's representatives during other phases of an inspection.

(3) If, at the time of inspection, an individual has been authorized by the workers to represent them during the Commissioner's inspection, the licensee or registrant shall notify the Commissioner’s representatives of such authorization and shall give the workers representative an opportunity to accompany the Commissioner’s representatives during the inspection of physical working conditions.

(4) Each workers representative shall be routinely engaged in work under control of the licensee or registrant and shall have received instructions as specified in subsection (b) of this section.

(5) Different representatives of the licensee or registrant and workers may accompany the Commissioner’s representatives during different phases of an inspection if there is no resulting interference with the conduct of the inspection. However, only one workers representative at a time may accompany the inspectors.

(6) With the approval of the licensee or registrant and the workers representative, an individual who is not routinely engaged in work under control of the licensee or registrant, for example, a consultant to the licensee or registrant or to the workers representative shall be afforded the opportunity to accompany the Commissioner's representatives during the inspection of physical working conditions.

(7) Notwithstanding the other provisions of this subsection, the Commissioner's representatives are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection. With regard to areas containing information classified by a federal agency as in the interest of national security, an individual who accompanies a Commissioner’s representative may have access to such information only if authorized. With regard to any area containing proprietary information, the workers

representative for that area shall be an individual previously authorized by the licensee or registrant to enter that area.

(e) Consultation with workers during inspections.

(1) The Commissioner's representatives may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of these regulations and licenses to the extent the Commissioner's representatives deem necessary for the conduct of an effective and thorough inspection.

(2) During the course of an inspection, any worker may bring privately to the attention of the inspectors, either orally or in writing, any past or present condition that the worker has reason to believe may have contributed to or caused any violation of the Commissioner's regulations, a license condition or any unnecessary exposure of an individual to sources of radiation under the licensee's or registrant's control. Any such notice in writing shall comply with the requirements of subsection (f)(1) of this section.

(3) The provisions of subsection (e)(2) of this section shall not be interpreted as authorization to disregard instructions pursuant to subsection (b) of this section.

(f) Requests by workers for inspections.

(1) Any worker or representative of workers believing that a violation of the Commissioner's regulations or license conditions exists or has occurred in work under a license or registration with regard to radiological working conditions in which the worker is engaged may request an inspection by giving notice of the alleged violation to the Department of Environmental Protection, Division of Radiation. Any such notice shall be in writing, shall set forth the specific grounds for the notice and shall be signed by the worker or a representative of the workers. A copy shall be provided to the licensee or registrant by the Department of Environmental Protection, Division of Radiation no later than at the time of inspection except that, upon the request of the worker giving such notice, such worker's name and the name of individuals referred to therein shall not appear in such copy or on any record published, released or made available by the Commissioner, except for good cause shown.

(2) If, upon receipt of such notice, the Department of Environmental Protection, Division of Radiation determines that the complaint meets the requirements set forth in subsection (f)(1) of this section, and that there are reasonable grounds to believe that the alleged violation exists or has occurred, an inspection shall be made as soon as practicable to determine if such alleged violation exists or has occurred. Inspections pursuant to this subsection need not be limited to matters referred to in the complaint.

(3) No licensee, registrant or contractor or subcontractor of a licensee or registrant shall discharge or in any manner discriminate against any worker because such worker has filed any complaint or instituted or caused to be instituted any proceeding under these regulations or has testified or is about to testify in any such proceeding or because of the exercise by such worker on behalf of such worker or others of any option afforded by this section.

The Regulations of Connecticut State Agencies are amended by adding section 22a-153-7, as follows:

(NEW)

Sec. 22a-153-7. Therapeutic radiation machines.

(a) Definitions. For the purposes of this section, the definitions of this subsection apply. Terms used in this section that are not defined in this section are as provided in sections 22a-153-1, [22a-153-2 and 22a-153-4] of the Regulations of Connecticut State Agencies.

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

(2) "ADCL" means Accredited Dosimetry Calibration Laboratory.

(3) “Air kerma” or "K" means the kinetic energy released in air by ionizing radiation measured in joules per kilogram or grays. Kerma is determined as the quotient of dE by dM, where dE is the sum of the initial kinetic energies of all the charged ionizing particles liberated by uncharged ionizing particles in air of mass dM.

(4) "ARRT" means the American Registry of Radiologic Technologists.

(5) "Authorized user" means a person with the training required for operation of an identified piece of equipment regulated by this section.

(6) "Beam limiting device" means a field defining collimator, integral to the therapeutic radiation machine, which provides a means to restrict the dimensions of the useful beam.

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

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

(9) "Contact therapy system" means a therapeutic radiation machine with a short target to skin distance, usually less than five (5) centimeters.

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

(11) “Dosimetry system” means an instrument for measuring and quantifying the dose of x-rays or other radiation absorbed by matter or the intensity of a source of radiation.

(12) “Electron therapy system” mean any electromechanical device that produces electrons for therapeutic use.

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

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

(15) “Medical dosimetrist” means a person other than a licensed practitioner who participates in, performs, and/or assists under the supervision of a licensed practitioner and authorized medical physicist in the procedures required in the design, preparation, and evaluation processes for the use of ionizing radiation for therapeutic purposes, and who has met and continues to meet the standard in subsection (c)(5) of this section.

(16) "Moving beam radiation therapy" means radiation therapy with any planned displacement of radiation field or patient relative to each other, or with any planned change of absorbed dose distribution, including, but not limited to, arc, skip, conformal, intensity modulation and rotational therapy.

(17) "MV", "Megavolt," or "MeV" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one million volts in a vacuum, where "MV" applies for photons and "MeV" for electrons.

(18) "Nominal treatment distance" means:

(A) For electron irradiation, the distance from the scattering foil, virtual source or exit window of the electron beam to the entrance surface of the irradiated object along the central axis of the useful beam; and

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

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

(20) “Photon therapy systems” means any electromechanical device that produces photons for therapeutic use.

(21) "Primary dose monitoring system" means a system that will monitor the useful beam during irradiation and that will terminate irradiation when a pre-selected number of dose monitor units have been delivered.

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

(23) "Redundant beam monitoring system" means a combination of two dose monitoring systems in which each system is designed to terminate irradiation in accordance with a pre-selected number of dose monitor units.

(24) "Secondary dose monitoring system" means a system that will terminate irradiation in the event of failure of the primary dose monitoring system.

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

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

(27) "Therapeutic radiation machine" means X-ray or electron-producing equipment designed and used for external beam radiation therapy. Equipment used as a “therapeutic radiation machine” may also be used as a simulator.

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

(39) “Wedge filter” means a filter that effects continuous change in transmission over all or a part of the useful beam.

(b) Applicability. This section applies to any registrant of a therapeutic radiation machine or a radiation therapy simulator system.

(c) General requirements.

(1) Registration. No person shall operate a therapeutic radiation machine unless such person holds a valid registration issued by the Commissioner.

(A) An application for a registration shall be made on a form prescribed by the Commissioner. Each applicant for a registration shall submit all the information required by the form and the accompanying instructions.

(2) Each registrant shall comply with the requirements of this section. Any registrant of a therapeutic radiation machine that cannot be operated in compliance with this section shall not be used to irradiate human patients or human research subjects.

(3) Every individual associated with the operation of a therapeutic radiation machine shall be instructed in and shall comply with the provisions of the registrant's registration and all applicable requirements of the Regulations of Connecticut State Agencies.

(4) In any facility in which a therapeutic radiation machine is operated, written safety procedures shall be available to any operator in the control area. The safety procedures shall be developed by an authorized medical physicist. Every operator shall be familiar with the procedures.

(5) Every therapeutic radiation machine shall be operated so that no person is exposed to the useful beam except for medical therapy purposes, unless such exposure has been ordered in writing by a licensed practitioner of the healing arts. No person shall be deliberately exposed to the useful beam for training, demonstration or other non-healing arts purposes.

(6) Each registrant shall develop and implement a site-specific written quality management program at each facility under its control. The quality management program shall assist the registrant to ensure that the physical parameters established during the commissioning of a

therapeutic radiation machine or radiation therapy simulator system remain within acceptable limits. Each quality management program shall include, at a minimum, the following elements:

(A) Procedures to ensure the accuracy and precision of all measurement equipment for calibration of therapeutic radiation machines and instruments used for patient dosimetry;

(B) Protocols, consistent with current procedures of the AAPM, for the calibration of therapeutic radiation machines, including an annual independent check of the machine output;

(C) Periodic tests of treatment planning computer systems to:

(i) Ensure accuracy of dose calculation algorithms,

(ii) Ensure that any software modifications were correctly implemented and that beam data were not corrupted,

(iii) Ensure that new hardware was properly installed, and

(iv) Verify that user have received proper training and are proficient in the use of the system;

(D) All required quality assurance requirements specified in this section; and

(E) A requirement to review the plan on an annual basis to evaluate the program's effectiveness and revise the plan, as necessary. The annual review shall be summarized in a written report.

(7) Each registrant shall implement procedures for auditing the effectiveness of a radiation therapy quality management program, as follows:

(A) At intervals not to exceed four (4) years, audits must be conducted by an organized review program supervised by the American College of Radiology, American College of Radiation Oncology or a program found to be equivalent by the Commissioner based on the scope of the audit and the experience of the sponsoring organization in performing such audits;

(B) The registrant shall promptly review the audit findings, address the need for modifications or improvements and document the actions taken;

(C) Any deficiencies noted during the audit shall be corrected in accordance with appropriate auditing program standards; and

(D) Written information submitted to the registrant during the audit and reports of corrective actions shall be available for review by the Commissioner upon request.

(8) For each therapeutic radiation machine, the registrant shall maintain the following records and reports:

(A) A report of each acceptance test;

(B) A record of each survey, calibration and quality assurance check, as well as the name of every person who performed such survey, calibration or check;

(C) A record of every act of maintenance or modification performed after the effective date of this section, as well as the name of each person who performed such maintenance or modification; and

(D) After any service, repair, replacement or other modification capable of significantly affecting the characteristics of the radiation beam, a record of the signature of the authorized medical physicist authorizing the return of therapeutic radiation machine to clinical use.

(9) All records required by this section shall be retained for a period of five (5) years unless another retention period is specified in this section. All required records shall be retained at a location in Connecticut and shall be made available to the Commissioner to inspect and copy upon request.

(10) The requirements of this subsection shall not apply to registrants who use therapeutic radiation machines exclusively for non-human subjects.

(d) Certification and qualification of personnel.

(1) External beam radiation therapy authorized user. The registrant for any therapeutic radiation machine subject to subsections (i) or (j) of this section shall require an authorized user conducting external beam radiation therapy to be a physician who satisfies the requirements of subparagraph (A), (B) or (C) of this subdivision, as provided in subparagraphs (D) and (E) of this subdivision:

(A) Is certified in:

(i) Radiology, therapeutic radiology or radiation oncology by the American Board of Radiology,

(ii) Radiation oncology by the American Osteopathic Board of Radiology,

(iii) Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology," or

(iv) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons;

(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;

(i) 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 ionization radiation, and

(IV) Radiation biology,

(ii) To satisfy the requirement for supervised work experience, training shall be under the supervision of an authorized user and shall include:

(I) Review of the full calibration measurements and periodic quality assurance checks,

(II) Evaluation of prepared treatment plans and calculation of treatment times and patient treatment settings,

(III) Use of administrative controls to prevent medical events,

(IV) Implementation of emergency procedures in the event of the abnormal operation of an external beam radiation therapy unit or console, and

(V) Checking and using radiation survey meters, and

(iii) To satisfy the requirement for a period of supervised clinical experience, training shall include one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two (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 or contraindications,

(II) Selecting proper dose and how it is to be administered,

(III) Calculating the external beam radiation therapy doses and collaborating with the authorized user in the review of patients' progress and consideration of the need to modify originally prescribed doses or treatment plans as warranted by patients' reaction to radiation, and

(IV) Post-administration follow-up and review of case histories; or

(C) For operation of any therapeutic radiation machine of less than 500 kV, alternative equivalent qualifications upon approval by the Commissioner on a case-by-case basis; and

(D) A prospective authorized user physician seeking certification pursuant to subparagraph (B) or (C) of this subdivision shall request the Commissioner's approval by submitting a written request and a summary of pertinent qualifications to the Commissioner for approval; and

(E) A registrant utilizing the services of an authorized user who satisfies the training requirements of this subdivision pursuant to subparagraph (B) or (C) shall not allow such a prospective authorized user to act until such time as said physician's training has been reviewed and approved by the Commissioner.

(2) Authorized medical physicist. The registrant for any therapeutic radiation machine subject to subsection (i) or (j) of this section shall obtain or utilize the services of an authorized medical physicist and shall require the authorized medical physicist to:

(A) Register with the Commissioner as a provider of radiation services in the area of calibration and compliance surveys of external beam radiation therapy units;

(B) Hold one of the following certifications:

(i) By the American Board of Radiology in:

(I) Therapeutic radiological physics,

(II) Roentgen-ray and gamma-ray physics,

(III) X-ray and radium physics, or

(IV) Radiological physics;

(ii) By the American Board of Medical Physics in Radiation Oncology Physics; or

(iii) By the Canadian College of Medical Physics; and

(C) Pursue continuing professional development in accordance with the guidelines from the applicable certifying board.

(3) Authorized medical dosimetrist. The registrant for any therapeutic radiation machine subject to subsection (i) or (j) of this section shall obtain or utilize the services of an authorized medical dosimetrist and shall require the authorized medical dosimetrist to:

(A) Register with the Commissioner as a provider of radiation services in the

area of radiotherapy treatment plan design, preparation and evaluation under the supervision of a radiation therapy authorized user and authorized medical physicist;

(B) Hold a certification issued by the Medical Dosimetrist Certification Board;

(C) Pursue continuing professional development in accordance with the guidelines from the Medical Dosimetrist Certification Board; and

(D) Dosimetrists not meeting the criteria of an authorized medical dosimetrist may perform duties only under the direct supervision of an authorized medical dosimetrist.

(4) Operator. A registrant of a therapeutic radiation machine shall ensure that any person who operates a therapeutic radiation machine for medical use is either an ARRT Registered Radiation Therapy Technologist or has completed a radiation therapy technologist training program that complies with the requirements of the Joint Review Committee on Education in Radiologic Technology. A registrant shall maintain at the facility records of the name and certification history of every operator. Records of 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.

(5) Visiting authorized user. A registrant may permit any physician to act as a visiting authorized user 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;

(B) The visiting authorized user meets the requirements established for an authorized user in subdivision (1)(A) or (1)(B) of this subsection; and

(C) The registrant maintains copies of all records related a visiting authorized user for five (5) years from the date of last use.

(e) Radiation shielding and safety design plan.

(1) The registrant of any therapeutic radiation machine shall install radiation shielding that meets the following requirements:

(A) Each wall, floor or ceiling struck by the useful beam shall have primary barriers;

(B) Each wall, floor or ceiling without a primary barrier shall have a secondary barrier; and

(C) Installed primary and secondary barriers shall allow the registrant to comply with sections 22a-153-2(e) and (f) of the Regulations of Connecticut State Agencies.

(2) For any new therapeutic radiation machine installation or modification, the registrant shall submit a radiation shielding plan to the Commissioner no later than ninety (90) days prior to the actual installation or modification. Each plan shall include:

(A) The name and contact information of the individual responsible for preparation of the radiation shielding plan;

(B) The name and contact information of the facility supervisor;

(C) The street address of the therapeutic radiation machine facility, including room number; and

(D) A description of the new facility or modification.

(3) For the installation of any new therapeutic radiation machine or modification of a therapeutic radiation machine that produces only photons with a maximum energy less than or equal to 150 kV, in addition to the information specified in subdivision (2) of this subsection, the registrant shall include the following information in the radiation shielding plan:

(A) Equipment specifications, including the manufacturer and model number of the therapeutic radiation machine, as well as the maximum technique factors;

(B) Maximum design workload for the facility including:

(i) Total weekly radiation output, expressed in gray (rad) or air kerma at 1 meter,

(ii) Total beam-on time per day or week,

(iii) The average treatment time per patient, and

(iv) The anticipated number of patients to be treated per day or week;

(C) A facility blueprint or drawing indicating:

(i) Scale,

(ii) Direction of North,

(iii) Normal location of the therapeutic radiation machine's radiation port or ports and the travel and traverse limits for each port,

(iv) General direction or directions of the useful beam,

(v) The location of each window and door, and

(vi) The location of the therapeutic radiation machine control panel. If the control panel is located inside the therapeutic radiation machine treatment room, the location of the operator's booth shall be noted on the plan;

(D) The structural composition and thickness or lead or concrete equivalent of each wall, door, partition, floor and ceiling of the room or rooms housing a therapeutic radiation machine;

(E) The type of occupancy of all adjacent areas inclusive of space above and below the room or rooms housing a therapeutic radiation machine. If there is an exterior wall, show distance to the closest area or areas where individuals may be present; and

(F) At least one example calculation that shows the methodology used to determine the amount of shielding required for each primary or secondary or leakage barrier, restricted area, unrestricted area and entry door in the facility and the type of shielding. If commercial software is used to generate shielding requirements:

(i) Identify the software used including version and revision date, and

(ii) If the software used to generate shielding requirements is not in the public domain, submit quality control sample calculations to verify the result obtained with the software.

(4) For the installation of any new therapeutic radiation machine or modification of a therapeutic radiation machine that produces electrons or photons with a maximum energy in excess of 150 kV, in addition to the information specified in subdivision (2) of this subsection, the registrant shall include the following information in the radiation shielding plan:

(A) Equipment specifications including:

(i) The manufacturer and model number of the therapeutic radiation machine,

(ii) Gray (rad) at the isocenter and the target to isocenter distance, and

(iii) The energy and type of radiation produced;

(B) Maximum design workload for the facility including:

(i) Total weekly radiation output, expressed in gray (rad) or air kerma at 1 meter,

(ii) Total beam-on time per day or week,

(iii) The average treatment time per patient, and

(iv) The anticipated number of patients to be treated per day or week;

(C) A facility blueprint or drawing indicating:

(i) Scale,

(ii) Direction of North,

(iii) Relative orientation of the therapeutic radiation machine,

(iv) Thickness and density of shielding materials, and

(v) The location and size of each penetration though a shielding barrier with details of each door and maze;

(D) The structural composition and thickness or lead/concrete equivalent of each wall, door, partition, floor and ceiling of the room or rooms concerned;

(E) The type of occupancy of all adjacent areas inclusive of space above and below the room or rooms housing a therapeutic radiation machine. If there is an exterior wall, show distance to the closest area or areas where individuals may be present;

(F) A description of all assumptions that were in shielding calculations including, but not limited to:

(i) Design energy,

(ii) Work load,

(iii) Presence of integral beam-stop in unit,

(iv) Occupancy and uses of adjacent areas,

(v) Fraction of time that useful beam will intercept each permanent barrier, and

(vi) Acceptable radiation exposure in both restricted and unrestricted areas; and

(G) At least one example calculation that shows the methodology used to determine the amount of shielding required for each primary or secondary/leakage barrier, restricted area, unrestricted area and entry door in the facility and the type of shielding. If commercial software is used to generate shielding requirements:

(i) Identify the software used including version and revision date, and

(ii) If the software used to generate shielding requirements is not in the public domain, submit quality control sample calculations to verify the result obtained with the software.

(5) For the installation of any new therapeutic radiation machine or modification of a therapeutic radiation machine that is capable of operating above 10 MV, in addition to the information specified in subdivision (4) of this subsection, the registrant shall include the following information in the radiation shielding plan:

(A) The structural composition, thickness, minimum density and location of all neutron shielding material;

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

(C) At least one example calculation that shows the methodology used to determine the amount of neutron shielding required for each restricted area, unrestricted area, entry door and maze in the facility and the type of neutron shielding material utilized in the facility. If commercial software is used to generate shielding requirements:

(i) Identify the software used including version and revision date, and

(ii) If the software used to generate shielding requirements is not in the public domain, submit quality control sample calculations to verify the result obtained with the software; and

(D) The method and instrumentation that will be used to verify the adequacy of all neutron shielding installed in the facility.

(f) Radiation protection surveys.

(1) Each registrant shall ensure that a radiation protection survey of the facility is performed with an operable radiation measurement survey instrument calibrated in accordance with this subsection. The radiation protection survey shall be performed by, or under the direction of, an authorized medical physicist or qualified expert. The survey shall verify that, with the therapeutic radiation machine in a "BEAM ON" condition, with the largest clinically available treatment field and with a scattering phantom in the useful beam of radiation:

(A) Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in section 22a-153-2(c)(1) of the Regulations of Connecticut State Agencies; and

(B) Radiation levels in unrestricted areas do not exceed the limits specified in sections 22a-153-2(d)(1) and (2) of the Regulations of Connecticut State Agencies.

(2) A radiation protection survey shall be performed on all existing facilities within ninety (90) days of the effective date of this section. The registrant of any facility constructed after the effective date of this section shall perform a radiation protection survey prior to operation of the facility for medical use. A registrant shall perform additional radiation protection surveys under the following circumstances, prior to any subsequent medical use:

(A) After any change in the treatment room shielding;

(B) After any change in the location of the therapeutic radiation machine within the treatment room;

(C) After relocating the therapeutic radiation machine; or

(D) Before using the therapeutic radiation machine in a manner that could result in increased radiation levels in areas outside the external beam radiation therapy treatment room.

(3) Any radiation protection survey record shall include the following information:

(A) Each instance in which the facility, in the opinion of an authorized medical physicist or other qualified expert, is in violation of an applicable regulation;

(B) The date of the measurements;

(C) The reason the survey was conducted;

(D) The manufacturer's name, model number and serial number of the therapeutic radiation machine;

(E) The instrument or instruments used to measure radiation levels;

(F) A description or illustration of the areas surrounding the surveyed treatment room;

(G) The measured dose rate at several points in each area expressed in microsieverts per hour or millirems per hour adjusted for expected workload, use and occupancy factors;

(H) The calculated maximum level of radiation over a period of one (1) week for each restricted and unrestricted area; and

(I) The signature of the individual responsible for conducting the survey.

(4) If any survey indicates radiation levels in excess of the respective limits specified in subdivision (1) of this subsection, the registrant shall lock the control in the "OFF" position and not use the unit until the registrant is authorized by the Commissioner to use the unit. After the unit is locked and before the Commissioner’s approval to resume use, the registrant may use the unit as may be necessary to repair, replace or test the therapeutic radiation machine, the therapeutic radiation machine shielding or the treatment room shielding.

(5) If a survey required by subsection (f)(2) of this section indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted, before using the therapeutic radiation machine for medical use, the registrant shall:

(A) Equip the unit with beam direction interlocks or add additional radiation shielding to ensure compliance with sections 22a-153-2(f)(1) and (f)(2)(A) of the Regulations of Connecticut State Agencies;

(B) Perform the survey required by subsection (f)(2) of this section again. If the

results of the survey reduce exposure in unrestricted areas to permissible levels, the registrant shall maintain records of the results of the initial survey, a description of the modification made to comply with this subsection and the results of the second survey, or

(C) If the results of the survey conducted pursuant to subparagraph (B) of this subdivision indicate the radiation levels in unrestricted areas exceed permissible levels despite the installation of measures as specified in subparagraph (A) of this subdivision, request and receive a registration amendment under section 22a-153-2(f)(2)(B) of the Regulations of Connecticut State Agencies that authorizes radiation levels in unrestricted areas greater than those allowed in sections 22a-153-2(f)(1) and (f)(2)(A) of the Regulations of Connecticut State Agencies.

(6) Each registrant shall submit a copy of the survey record for any survey performed pursuant to subdivision (2) or (5)(B) of this subsection to the Commissioner within thirty (30) days of the day the survey is conducted.

(7) Calibration of survey instruments.

(A) Each registrant shall ensure that the survey instruments used to show compliance with this subsection have been calibrated before first use, at intervals not to exceed twelve (12) calendar months and following repair;

(B) Each registrant, or calibration service contracted by the registrant with the authorized medical physicist's approval, shall:

(i) Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 10 percent, and

(ii) Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 20 percent if a correction factor or graph is conspicuously attached to the instrument;

(C) Each registrant shall retain a record of each calibration required by this subdivision for five (5) years; and

(D) Each registrant may obtain the services of an ADCL or NVLAP accredited facility.

(g) Radiation therapy planning computer systems.

(1) The registrant shall ensure that an authorized medical physicist performs acceptance testing of radiation therapy planning computer systems prior to first clinical use to verify the manufacturer's specifications.

(2) The registrant shall ensure that an authorized medical physicist commissions the radiation therapy planning computer system prior to first clinical use. Commissioning shall include:

(A) Input of all facility-specific data into the radiation therapy planning computer system;

(B) Validation of the input parameters; and

(C) Validation of the accuracy of computed doses, rendered treatment geometries and isocenter (or radioactive source) localization, for a sampling of such output parameters deemed by the authorized medical physicist to be representative of the full range of clinical use at the registrant's facility.

(3) The registrant shall maintain a complete report of all commissioning activities and shall make such reports available to the Commissioner to inspect and copy upon request.

(4) A subset of the commissioning tests, as deemed appropriate by the authorized medical physicist, shall be performed at an interval no less than once per calendar year, or after any changes or upgrades to the treatment planning system's configuration.

(h) Dosimetry equipment.

(1) Each registrant shall have a calibrated dosimetry system available for use. The dosimetry system shall be calibrated at an energy or energy range appropriate for the radiation being measured. The system shall have been calibrated by NIST or by an AAPM ADCL. The calibration shall have been performed within the previous twenty four (24) months and after any servicing that may have affected system calibration.

(2) Each registrant shall have available for use a dosimetry system for quality assurance check measurements. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with subdivision (1) of this subsection. This comparison shall have been performed within the previous twelve (12) calendar months and after each servicing that may have affected system calibration. The quality assurance check system may be the same system used to meet the requirement in subdivision (1) of this subsection.

(3) Each registrant shall maintain a record of each dosimetry system calibration, intercomparison and comparison for the duration of the license or registration. For each calibration, intercomparison or comparison, the record shall include:

(A) The date;

(B) The model numbers and serial numbers of the instruments that were calibrated, inter-compared or compared;

(C) The correction factors determined;

(D) The names of the individuals who performed the calibration, intercomparison or comparison; and

(E) Evidence that the calibration, intercomparison or comparison was performed by, or under the direct supervision of, an authorized medical physicist.

(i) Therapeutic radiation machines < 500 kV. Each registrant shall operate any therapeutic radiation machine less than 500 kV according to the requirements of this subsection.

(1) For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in subdivision (2) of this subsection for the specified operating conditions. Records of leakage radiation measurements shall be maintained at the facility for inspection by the Commissioner upon request.

(2) 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 following values:

(A) For 5-50 kV systems, the leakage air kerma rate measured at any position five centimeters from the tube housing assembly shall not exceed one mGy (100 mrad) in any one hour; and

(B) For >50 and <500 kV systems, the leakage air kerma rate:

(i) Measured at a distance of one meter from the target in any direction shall not exceed 1 cGy (1 rad) in any one hour. This air kerma rate measurement may be averaged over areas no larger than 100 square centimeters when the source is operated at maximum design parameters, and

(ii) Measured at a distance of five (5) centimeters from the surface of the tube housing assembly shall not exceed 30 cGy (30 rad) per hour.

(3) Beam limiting devices shall meet the following requirements:

(A) Permanent diaphragms or cones used for limiting the useful beam shall provide at least the same degree of attenuation as required for the tube housing assembly;

(B) All adjustable or removable beam limiting devices, diaphragms, cones or blocks shall not transmit more than 5 percent of the useful beam for the most penetrating beam used; and

(C) When adjustable beam limiting devices are used, the position and shape of the radiation field shall be indicated by a light beam.

(4) The filter system shall be so designed that:

(A) Filters cannot be accidentally displaced at any possible tube orientation;

(B) For equipment installed after the effective date of this section, an interlock system shall prevent 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 meter under any operating conditions; and

(C) Each filter shall be marked as to its material of construction and its thickness.

(5) The x-ray tube shall be so mounted that it can not accidentally turn or slide with respect to the housing aperture. The tube housing assembly shall be capable of being immobilized for stationary portal treatments.

(6) The tube housing assembly shall be so marked that it is possible to determine the location of the source to within 5 millimeters, and such marking shall be readily accessible for use during calibration procedures.

(7) Contact therapy tube housing assemblies shall have a removable shield of material, equivalent in attenuation to 0.5 millimeters of lead at 100 kV, which can be positioned over the entire useful beam exit port during periods when the beam is not in use.

(8) An irradiation control device shall be provided to terminate the irradiation after a pre-set time interval, as follows:

(A) A timer with a display shall be provided at the treatment control panel. The timer shall have a pre-set time selector and an elapsed time or time remaining indicator;

(B) The timer shall be a cumulative timer that activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. For equipment other than ortho-voltage, after irradiation is terminated and before irradiation can be reinitiated, the elapsed time indicator shall be reset;

(C) If any dose monitoring system present has not previously terminated irradiation, the timer shall terminate irradiation when a pre-selected time has elapsed;

(D) The timer shall permit accurate pre-setting and determination of exposure times as short as one second;

(E) The timer shall not permit an exposure if set at zero;

(F) When irradiation is controlled by a shutter mechanism, the timer shall not activate until the shutter is opened unless calibration includes a timer error correction to compensate for mechanical lag; and

(G) The timer shall be accurate to within 1 percent of the selected value or one second, whichever is greater.

(9) The control panel, in addition to the displays required by other provisions in this subsection, shall have:

(A) An indication of whether electrical power is available at the control panel and if activation of the X-ray tube is possible;

(B) An indication of whether X-rays are being produced;

(C) An indication of the X-ray tube potential and current;

(D) The means for terminating an exposure at any time;

(E) A locking device that will prevent unauthorized use of the therapeutic radiation machine; and

(F) For therapeutic radiation machines manufactured after the effective date of this section, a positive display of each specific filter in the beam.

(10) If a control panel allows the operator to energize more than one x-ray tube:

(A) The operator shall be able to activate only one x-ray tube at any time;

(B) The control panel shall indicate which x-ray tube is activated; and

(C) The tube housing assembly shall indicate when that tube is energized.

(11) There shall be a means of determining the central axis TSD to within 1 centimeter and reproducing this measurement to within 2 millimeters.

(12) Unless it is possible to bring the x-ray output to the prescribed exposure parameters within five seconds after the x-ray "ON" switch is energized, the beam shall be attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly. In addition, after the unit is at operating parameters, the shutter shall be controlled by the operator from the control panel. An indication of shutter position shall appear at the control panel.

(13) Each therapeutic radiation machine equipped with a beryllium or other low-filtration window shall be clearly labeled upon the tube housing assembly. The control panel shall have a permanent warning device that is activated when no additional filtration is present to indicate that the dose rate is very high.

(14) In addition to shielding adequate to meet requirements of subsection (e) of this section, any treatment room containing a therapeutic radiation machine capable of operating in the range 50kV-500kV shall meet the following design requirements:

(A) The treatment room shall provide continuous two-way aural communication between the patient and the operator at the control panel; and

(B) The treatment room shall allow for continuous observation of the patient during irradiation, and the viewing system shall be so located that the operator can observe the patient from the control panel. The therapeutic radiation machine shall not be used for patient irradiation unless at least one viewing system is operational.

(15) Any treatment room that contains a therapeutic radiation machine capable of operating above 150 kV shall meet the following requirements:

(A) All protective barriers shall be fixed except for entrance doors or beam interceptors;

(B) The control panel shall be located outside the treatment room or in a totally enclosed booth inside the room; and

(C) Interlocks shall be provided such that all entrance doors, including doors to any interior booths, shall be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, the exposure beam shall be terminated, and it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel.

(16) Full calibration of a therapeutic radiation machine subject to this subsection shall be performed by, or under the direct supervision of, an authorized medical physicist. Full calibration shall include all measurements in the most recent recommendations for annual calibration of the NCRP or the AAPM. Full calibration shall be conducted as follows:

(A) Before the first medical use following installation or reinstallation of the therapeutic radiation machine,

(B) At intervals not exceeding twelve (12) calendar months,

(C) Before medical use under either of the following conditions:

(i) 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, or

(ii) Following any component replacement, major repair or modification of components that could significantly affect the characteristics of the radiation beam,

(D) Notwithstanding the requirements of subparagraph (C) of this subdivision:

(i) Full calibration of therapeutic radiation machines with multi-energy capabilities is required only for those modes 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 subparagraph (C)(i) of this subdivision; and

(E) The registrant shall maintain a record of each calibration for the duration of the registration. The record shall include: the date of the calibration; the manufacturer's name, model number and serial number for both the therapeutic radiation machine and the x-ray tube; the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine; and the signature of the authorized medical physicist responsible for performing the calibration.

(17) Each registrant shall perform periodic quality assurance checks on each therapeutic radiation machine capable of operation at greater than or equal to 50 kV, as follows:

(A) In accordance with written procedures established by the authorized medical physicist that specify the frequency at which tests or measurements are to be performed;

(B) The quality assurance check procedures shall specify that the quality assurance check shall be performed during the calibration required in subdivision (16)(A) of this subsection. The acceptable tolerance for each parameter measured in the quality assurance check, when compared to the value for that parameter determined in the calibration specified in subdivision (16)(A) of this subsection shall be stated;

(C) The cause for a parameter exceeding a tolerance set by the authorized medical physicist shall be investigated and corrected before the system is used for patient irradiation;

(D) Whenever a quality assurance check indicates a significant change in the operating characteristics of a system, as specified in the authorized medical physicist 's quality assurance check procedures, the system shall be recalibrated as required in subdivision (16)(A) of this subsection;

(E) The registrant shall use the dosimetry system described in subsection (h)(2) of this section to make the quality assurance check required in subparagraph (B) of this subdivision;

(F) The registrant shall have the authorized medical physicist review and sign the results of each radiation output quality assurance check within one (1) calendar month of the date that the check was performed;

(G) The registrant shall ensure that safety quality assurance checks of therapeutic radiation machines subject to this subsection are performed at intervals not to exceed one (1) month;

(H) Notwithstanding the requirements of subparagraphs (F) and (G) of this subdivision, the registrant shall ensure that no therapeutic radiation machine is used to administer radiation to humans unless the quality assurance checks required by subparagraphs (F) and (G) of this subdivision have been performed within the thirty (30) day period immediately prior to said administration;

(I) To satisfy the requirement of subparagraph (H) of this subdivision, safety quality assurance checks shall ensure proper operation of:

(i) Electrical interlocks at each external beam radiation therapy room entrance,

(ii) The "BEAM-ON" and termination switches,

(iii) Beam condition indicator lights on the access door(s), control console and in the radiation therapy room,

(iv) Viewing systems, and

(v) If applicable, electrically operated treatment room doors from inside and outside the treatment room; and

(J) The registrant shall maintain a record of each quality assurance check required by this subdivision for five (5) years. The record shall include: the date of the quality assurance check; the manufacturer's name, model number and serial number of the therapeutic radiation machine; the manufacturer's name; model number and serial number for each instrument used to measure the radiation output of the therapeutic radiation machine; and the signature of the individual who performed the periodic quality assurance check.

(18) Each registrant shall operate any therapeutic radiation machine according to the following procedures:

(A) The therapeutic radiation machine shall not be used for irradiation of patients unless the requirements of subdivisions (16) and (17) of this subsection have been met;

(B) Therapeutic radiation machines shall not be left unattended during patient treatment unless secured pursuant to subdivision (8) of this subsection;

(C) When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used;

(D) The tube housing assembly shall not be held by an individual during operation unless the assembly is designed to require such holding and the peak tube potential of the system does not exceed 50 kV. In such cases, the holder shall wear protective gloves and an apron of not less than 0.5 millimeters lead equivalency at 100 kV;

(E) A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console; and

(F) No individual other than the patient shall be in the treatment room during exposures from therapeutic radiation machines operating above 150 kV unless conditions of *subdivision* (15)(B) of this subsection. At energies less than or equal to 150 kV, any individual, other than the patient, in the treatment room shall be protected by a barrier sufficient to meet the requirements of section 22a-153-2 of the Regulations of Connecticut State Agencies.

(19) Each facility location authorized to use a therapeutic radiation machine in accordance with this subsection shall possess appropriately calibrated portable monitoring equipment. At a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 μSv (1 mrem) per hour to 10 mSv (1000

mrem) per hour. Each survey instrument shall be operable and calibrated in accordance with subsection (h) of this section.

(j) Photon therapy systems ≥500 kV and electron therapy systems ≥ 500 keV. Each registrant shall operate photon therapy systems 500kV and above and electron therapy systems 500keV and above according to the requirements of this subsection.

(1) A registrant shall have available at each facility under his control appropriately calibrated portable monitoring equipment. At a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates in the range 10 μSv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. Each survey instrument shall be operable and calibrated in accordance with subsection (f)(7) of this section.

(2) Leakage radiation outside the maximum useful beam in photon and electron modes shall comply with the following requirements:

(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 that is perpendicular to and centered on the central axis of the useful beam at the nominal treatment distance, 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 square centimeters at a minimum of 16 points uniformly distributed in the plane;

(B) Except for the area defined in subparagraph (A) of this subdivision, the absorbed dose due to leakage radiation excluding neutrons at one meter from the electron path between the electron source and the target or electron window shall not exceed 0.5 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 square centimeters;

(C) For equipment manufactured after the effective date of this section, the neutron absorbed dose outside the useful beam shall be in compliance with International Electrotechnical Commission (IEC) Document 601-2-1, as amended from time to time; and

(D) For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in subparagraphs (A) through (C) of this subdivision for the specified operating conditions. Records on leakage radiation measurements shall be maintained at the facility for inspection by the Commissioner.

(3) The registrant shall control leakage radiation through beam limiting devices as follows:

(A) All adjustable or interchangeable beam limiting devices shall attenuate the radiation 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:

(i) A maximum of 5 percent and average of 2 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 7 centimeters outside the periphery of the useful beam, and

(ii) A maximum of 10 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 2 centimeters outside the periphery of the useful beam but less than 7 centimeters outside the periphery of the useful beam; and

(B) Measurement of leakage radiation shall be made as follows:

(i) For photon radiation, measurements of leakage radiation through the beam limiting devices shall be made with the beam limiting devices closed and any residual aperture blocked by at least two-tenth value layers of suitable absorbing material. If overlapping beam limiting devices are present, the leakage radiation through each set shall be measured independently at the depth of maximum dose. Measurements shall be made using a radiation detector of area not exceeding 10 square centimeters, and

(ii) For 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 square centimeter suitably protected against radiation that has been scattered from material beyond the radiation detector. Measurements shall be made using 1 centimeter of water equivalent build up material.

(4) Use of filters and wedges shall comply with the following requirements:

(A) Each wedge filter that is removable from the system shall be clearly marked with an identification number. For removable wedge filters, the nominal wedge angle shall appear on the wedge or wedge tray, if permanently mounted to the tray. If the wedge or wedge tray is significantly damaged, the wedge transmission factor shall be re-determined;

(B) If the absorbed dose rate information required by subdivision (9) of this subsection relates exclusively to operation with a field flattening filter or beam scattering foil in place, such foil or filter shall be removable only by the use of tools; and

(C) For equipment manufactured after the effective date of this section that utilizes wedge filters, interchangeable field flattening filters or interchangeable beam scattering foils:

(i) Irradiation shall not be possible until a selection of a filter or a positive selection to use "no filter" has been made at the treatment control panel, either manually or automatically. An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position,

(ii) A display shall be provided at the treatment control panel showing any wedge filters, interchangeable field flattening filters and interchangeable beam scattering foils in use, and

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

(5) The registrant shall install redundant beam monitoring systems. The sensors for these systems shall be fixed in the useful beam during treatment to indicate the dose monitor unit rate, as follows:

(A) Equipment manufactured after the effective date of this section shall be provided with at least two independently powered integrating dose meters. Alternatively, common elements may be used if the production of radiation is terminated upon failure of any common element;

(B) Equipment manufactured on or before the effective date of this section shall be provided with at least one radiation detector. This detector shall be incorporated into a useful beam monitoring system; and

(C) The detector and the system into which that detector is incorporated shall meet the following requirements:

(i) Each detector shall be removable only with tools and, if movable, shall be interlocked to prevent incorrect positioning,

(ii) Each detector shall form part of a beam monitoring system from whose readings in dose monitor units the absorbed dose at a reference point can be calculated,

(iii) Each beam monitoring system shall be capable of independently monitoring, interrupting and terminating irradiation,

(iv) For equipment manufactured after the effective date of this section, the design of the beam monitoring systems shall ensure that:

(I) Malfunction of one system shall not affect the correct functioning of any other system, and

(II) Failure of either system shall terminate irradiation or prevent the initiation of radiation, and

(v) Each beam monitoring system shall have a legible display at the treatment control panel. For equipment manufactured after the effective date of this section, 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 subparagraph (C)(v)(c) of this subdivision displayed at the control panel at the time of failure shall be retrievable in at least one system for a twenty (20) minute period.

(6) Beam symmetry shall meet the following requirements:

(A) Bent-beam linear accelerators subject to this section shall be provided with auxiliary devices to monitor beam symmetry;

(B) The devices referenced in subparagraph (A) of this subdivision shall be able to detect field asymmetry greater than 10 percent; and

(C) The devices referenced in subparagraph (A) of this subdivision shall be configured to terminate irradiation if the specifications in subparagraph (B) of this subdivision cannot be maintained.

(7) Selection and display of dose monitor units shall meet the following requirements:

(A) Irradiation shall not be possible until a new selection of a number of dose monitor units has been made at the treatment control panel;

(B) The pre-selected number of dose monitor units shall be displayed at the treatment control panel until reset for the next irradiation;

(C) After termination of irradiation, it shall be necessary to reset the dosimeter display before subsequent treatment can be initiated; and

(D) For equipment manufactured after the effective date of this section, after termination of irradiation, it shall be necessary for the operator to reset the pre-selected dose monitor units before irradiation can be initiated.

(8) Air kerma rate or absorbed dose rate. For equipment manufactured after the effective date of this section, a system shall be provided from whose readings the air kerma rate or absorbed dose rate at a reference point can be calculated. The radiation detectors specified in subdivision (5) of this section may form part of this system. In addition:

(A) The dose monitor unit rate shall be displayed at the treatment control panel;

(B) If the equipment can deliver under any conditions an air kerma rate or absorbed dose rate at the nominal treatment distance more than twice the maximum value specified by the manufacturer, a device shall be provided that terminates

irradiation when the air kerma rate or absorbed dose rate exceeds a value twice the specified maximum. The dose rate at which the irradiation is terminated shall be a record maintained by the registrant;

(C) If the equipment can deliver under any fault conditions an air kerma rate or absorbed dose rate at the nominal treatment distance more than ten (10) times the maximum value specified by the manufacturer, a device shall be provided to prevent the air kerma rate or absorbed dose rate anywhere in the radiation field from exceeding twice the specified maximum value and to terminate irradiation if the excess absorbed dose at the nominal treatment distance exceeds 4 Gy (400 rad); and

(D) For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the maximum leakage values. Records of these maximum values shall be maintained at the installation for inspection by the Commissioner.

(9) Termination of irradiation by the beam monitoring system or systems during stationary beam radiation therapy shall be performed as follows:

(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 percent or 40 dose monitor units above the pre-selected number of dose monitor units set at the control panel has been detected by the secondary dose monitoring system; and

(C) For equipment manufactured after the effective date of this section, an indicator on the control panel shall show which monitoring system has terminated irradiation.

(10) The operator shall be able to terminate irradiation and equipment movement or go from an interruption condition to termination condition at any time from the operator's position at the treatment control panel.

(11) If a therapeutic radiation machine has an interrupt mode, the operator shall be able to interrupt irradiation and equipment movements at any time from the treatment control panel. Following an interruption, the operator shall be able to restart irradiation by operator action without any reselection of operating conditions. If any change is made of a pre-selected value during an interruption, irradiation and equipment movements shall be automatically terminated.

(12) A suitable irradiation control device shall be provided to terminate the irradiation after a pre-set time interval, as follows:

(A) A timer shall be provided that has a display at the treatment control panel. The timer shall have a pre-set time selector and an elapsed time indicator;

(B) The timer shall be a cumulative timer that activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator; and

(C) The timer shall terminate irradiation when a pre-selected time has elapsed, if the dose monitoring systems have not previously terminated irradiation.

(13) Equipment capable of both x-ray therapy and electron therapy shall meet the following additional requirements:

(A) Irradiation shall not be possible until a selection of radiation type, x-rays or electrons, has been made at the treatment control panel;

(B) The radiation type selected shall be displayed at the treatment control panel before and during irradiation;

(C) An interlock system shall be provided to ensure that the equipment can principally emit only the radiation type that has been selected;

(D) An interlock system shall be provided to prevent irradiation with x-rays, except to obtain an image, when electron applicators are fitted;

(E) An interlock system shall be provided to prevent irradiation with electrons when accessories specific for x-ray therapy are fitted; and

(F) An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

(14) Equipment capable of generating radiation beams of different energies shall meet the following requirements:

(A) Irradiation shall not be possible until a selection of energy has been made at the treatment control panel;

(B) The nominal energy value selected shall be displayed at the treatment control panel until reset manually for the next irradiation. After termination of irradiation, it shall be necessary to reset the nominal energy value selected before subsequent treatment can be initiated;

(C) Irradiation shall not be possible until the appropriate flattening filter or scattering foil for the selected energy is in its proper location; and

(D) For equipment manufactured after the effective date of this section, the selection of energy shall be in compliance with International Electrotechnical Commission (IEC) Document 601-2-1, as amended from time to time.

(15) Any therapeutic radiation machine capable of both stationary beam radiation therapy and moving beam radiation therapy shall meet the following requirements:

(A) Irradiation shall not be possible until a selection of stationary beam radiation therapy or moving beam radiation therapy has been made at the treatment control panel;

(B) The mode of operation shall be displayed at the treatment control panel;

(C) An interlock system shall be provided to ensure that the equipment may operate only in the mode that has been selected;

(D) An interlock system shall be provided to prevent irradiation if any selected parameter in the treatment room does not agree with the selected parameter at the treatment control panel;

(E) Moving beam radiation therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental movement. For equipment manufactured after the effective date of this section:

(i) An interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any 10 degrees of rotation or 1 centimeter of linear motion differs by more than 20 percent from the selected value,

(ii) Where angle terminates the irradiation in moving beam radiation therapy, the dose monitor units delivered shall differ by less than 5 percent from the dose monitor unit value selected,

(iii) An interlock shall be provided to prevent motion of more than 5 degrees or one centimeter beyond the selected limits during moving beam radiation therapy,

(iv) An interlock shall be provided to require that a selection of direction be made at the treatment control panel in all units that are capable of both clockwise and counter-clockwise moving beam radiation therapy, and

(v) Moving beam radiation therapy shall be controlled with both primary position sensors and secondary position sensors to obtain the selected relationships between incremental dose monitor units and incremental movement;

(F) Where the beam monitor system terminates the irradiation in moving beam radiation therapy, the termination of irradiation shall be as required by subdivision (10) of this subsection; and

(G) For equipment manufactured after the effective date of this section, an interlock system shall be provided to terminate irradiation if movement:

(i) Occurs during stationary beam radiation therapy, or

(ii) Does not start or stops during moving beam radiation therapy unless such stoppage is a pre-planned function.

(16) In addition to shielding adequate to meet requirements of subsection (e) of this section, each facility shall meet the following design requirements:

(A) All protective barriers shall be fixed, except for access doors to the treatment room or movable beam interceptors;

(B) The control panel shall:

(i) Be located outside the treatment room,

(ii) Provide an indication of whether electrical power is available at the control panel and if activation of the radiation is possible,

(iii) Provide an indication of whether radiation is being produced, and

(iv) Include an access control device that will prevent unauthorized use of the therapeutic radiation machine;

(C) Windows, mirrors, closed-circuit television or an equivalent viewing system shall be provided to permit continuous observation of the patient from the control panel following positioning and during irradiation. The therapeutic radiation machine shall not be used for patient irradiation unless at least one viewing system is operational;

(D) The control panel shall allow for continuous two-way aural communication between the patient and the operator. The therapeutic radiation machine shall not be used for irradiation of patients unless continuous two-way aural communication is possible;

(E) Treatment room entrances shall be provided with warning lights to indicate when the useful beam is "ON" and when it is "OFF." Such lights shall be in a readily observable position near the outside of all access doors;

(F) Interlocks shall be provided such that all access controls are activated before treatment can be initiated or continued. If the radiation beam is interrupted by any access control, it shall not be possible to restore the machine to operation without resetting the access control and reinitiating irradiation by manual action at the control panel;

(G) If the shielding material in any protective barrier requires the presence of a beam interceptor to ensure compliance with sections 22a-153-2(f)(1) and (2) of the Regulations of Connecticut State Agencies, interlocks shall be provided to prevent the production of radiation, unless the beam interceptor is in place, whenever the useful beam is directed at the designated barrier or barriers;

(H) At least one emergency power cutoff switch shall be located in the radiation therapy room. Such a switch shall terminate all equipment electrical power including radiation and mechanical motion. This switch is in addition to the termination switch required by subdivision (12) of this subsection. All emergency power cutoff switches shall include a manual reset so that the therapeutic radiation machine cannot be restarted from the unit's control console without resetting the emergency cutoff switch;

(I) All safety interlocks shall be designed so that any defect or component failure in the safety interlock system prevents or terminates operation of the therapeutic radiation machine; and

(J) Surveys for residual activity shall be conducted on all therapeutic radiation machines capable of generating photon and electron energies above ten (10) MV prior to machining, removing or working on therapeutic radiation machine components which may have become activated due to photo-neutron production.

(17) Each facility with a therapeutic radiation machine greater than or equal to 500 kV shall have authorized medical physicist support as follows:

(A) The authorized medical physicist shall be responsible for:

(i) Full calibration and protection surveys as required by this section,

(ii) Supervision and review of dosimetry,

(iii) Beam data acquisition and transfer for computerized dosimetry and supervision of its use,

(iv) Quality assurance, including quality assurance check review,

(v) Consultation with the authorized user in treatment planning, as needed, and

(vi) Calculations and assessments regarding medical events; and

(B) If the authorized medical physicist is not a full-time employee of the registrant, the operating procedures required by subdivision (18) of this subsection shall also specifically address how the authorized medical physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the authorized medical physicist can be contacted.

(18) Operating procedures.

(A) No individual, other than the patient, shall be in the treatment room during treatment or during any irradiation for testing or calibration purposes;

(B) Therapeutic radiation machines shall not be made available for medical use unless the requirements of subdivisions (20) and (21) of this subsection have been met;

(C) Therapeutic radiation machines, when not in operation, shall be secured to prevent unauthorized use;

(D) If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used; and

(E) A copy or the location of the current operating procedures shall be maintained at the therapeutic radiation machine control console. Emergency procedures shall be available at the therapeutic radiation machine control console.

(19) Acceptance testing, commissioning and full calibration measurements shall be performed as follows:

(A) Acceptance testing, commissioning and full calibration of a therapeutic radiation machine subject to this subsection shall be performed by, or under the direct supervision of, an authorized medical physicist;

(B) Acceptance testing and commissioning shall be performed in accordance with the requirements specified and documented by an authorized medical physicist and shall be conducted before the first medical use following installation or reinstallation of the therapeutic radiation machine;

(C) Full calibration shall include measurement of all parameters relevant to the clinical services provided at the facility. The authorized medical physicist shall document this selection of relevant parameters. All parameters that are evaluated during the full calibration shall have action levels, which if exceeded, must have a specific course of action as delineated by the authorized medical physicist. Calibration of each parameter at each energy shall be completed at intervals not exceeding twelve (12) calendar months.

(D) The authorized medical physicist shall perform all elements of a full calibration necessary to determine that all parameters are within acceptable limits following any component replacement, major repair or modification of components that could significantly affect the characteristics of the radiation beam. If the repair, replacement or modification does not affect all modes or energies, measurements shall be performed on the effected mode or energy that is in most frequent clinical use at the facility. The remaining energies or modes may be validated with quality assurance check procedures against the criteria in subparagraph (C)(i) of this subdivision; and

(E) Each registrant shall maintain a record of each calibration for the duration of the registration. The record shall include: the date of the calibration; the manufacturer's name, model number and serial number for 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 authorized medical physicist responsible for performing the calibration.

(20) Each registrant shall perform the following periodic quality assurance checks:

(A) Daily quality assurance checks shall be performed on all therapeutic radiation machines. The daily quality assurance checks may be performed under the direction of the authorized medical physicist. The authorized medical physicist shall document the selection of parameters requiring daily evaluation. All parameters that are evaluated during the daily quality assurance testing shall have action levels, which if exceeded, must have a specific course of action as delineated by the authorized medical physicist;

(B) Monthly quality assurance checks shall be performed on all therapeutic radiation machines in accordance with the requirements specified and documented by the authorized medical physicist. Monthly checks are designed as a subset of the full calibration checks. Monthly testing shall be performed by, or under the direct supervision of, an authorized medical physicist;

(C) The registrant shall use an appropriate dosimetry system described in subsection (h) of this section to make the periodic quality assurance checks required in subparagraph (B) of this subdivision;

(D) The registrant shall review the results of each periodic radiation output check according to the following procedures:

(i) The authorized medical physicist shall be immediately notified if any parameter during daily quality assurance testing is not within its acceptable tolerance. The therapeutic radiation machine shall not be used for medical purposes until the authorized medical physicist has determined that all parameters are within their acceptable tolerances,

(ii) If all quality assurance check parameters appear to be within their acceptable range, the quality assurance check shall be reviewed and signed by the authorized medical physicist within ten (10) business days, and

(iii) The authorized medical physicist shall review and sign the results of each radiation output quality assurance check at intervals occurring once each calendar month;

(E) Therapeutic radiation machines subject to this subsection shall have additional safety quality assurance checks as deemed appropriate by the authorized medical physicist performed at intervals specified by the authorized medical physicist;

(F) To satisfy the requirement of subparagraph (B) of this subdivision, quality assurance checks shall ensure proper operation of:

(i) Electrical interlocks at each external beam radiation therapy room entrance,

(ii) Proper operation of the "BEAM-ON", interrupt and termination switches,

(iii) Beam condition indicator lights on the access doors, control console,

(iv) Viewing systems, and

(v) Treatment room doors that are electrically operated from inside and outside the treatment room; and

(G) Each registrant shall promptly repair any system identified in subparagraph (F) of this subdivision that is not operating properly; and

(H) The registrant shall maintain a record of each quality assurance check required by this subdivision for five (5) years. The record shall include: the date of the quality assurance check; the manufacturer's name, model number and serial number of the therapeutic radiation machine; the manufacturer's name, model number and serial number for each instrument used to measure the radiation output of the therapeutic radiation machine; and the signature of the individual who performed the periodic quality assurance check.

(k) Radiation therapy simulator system.

(1) The owner or operator of any radiation therapy simulator system shall comply with the following requirements:

(A) Maintain and implement written operating and safety procedures in accordance with manufacturer’s recommended specifications;

(B) Display a technique chart in the vicinity of the control panel; and

(C) Operate the simulator only when no individual other than the patient is in the simulation room when the simulator produces ionizing radiation.

(2) The registrant of any radiation therapy simulator operated in the general radiographic mode shall evaluate the following parameters at first clinical use and at intervals determined and documented by an authorized medical physicist:

(A) Visual identification of the center of the x-ray field to within a 2 millimeter diameter,

(B) Determine the source to image distance to within 2 millimeters;

(C) The delineator wires match the indicated setting within 2 millimeters;

(D) The gantry movements are within 1 degree of the indicated position;

(E) The collimator movements are within 1 degree of the indicated position;

(F) When all technique factors are held constant, including control panel selections associated with automatic exposure control systems, the coefficient of variation shall not exceed 0.05; and

(G) The linearity of the system over the clinically appropriate range of use.

(3) The registrant of any computed tomographic radiation therapy simulator system shall meet the requirements of this subdivision, performing all testing prior to first clinical use and at intervals determined and documented by the authorized medical physicist, unless otherwise specified:

(A) For each day of clinical use, the gantry laser plane shall be within 2 millimeters of the imaging plane, and the external lasers (if installed) shall define a plane within 2 millimeters of the offset distance determined during the initial commissioning;

(B) The computed tomographic number of water shall be 0 +/-5 HU, measured in the center of the scan field of view;

(C) The field uniformity shall be evaluated to ensure the values are consistent with the values determined during the initial commissioning;

(D) Table motion shall be tested in the vertical and longitudinal direction to ensure accurate motion over the range used clinically;

(E) Warning lights shall indicate the presence of radiation being produced;

(F) The electron density to computed tomographic number conversion shall be evaluated over a complete range of clinically applicable values;

(G) The spatial resolution of the system shall be evaluated;

(H) The contrast resolution of the system shall be evaluated; and

(I) The authorized medical physicist shall validate the accuracy of the transfer of patient data to each radiotherapy planning system in clinical use that is interfaced with the computed tomographic simulator.

(*l*) Treatment chart review.

(1) An authorized medical physicist shall develop a chart review protocol for reviewing the accuracy of treatment delivery, which shall require review of the following parameters, as applicable:

(A) New or modified treatment fields;

(B) Treatment prescriptions;

(C) Imulation instructions;

(D) Isodose distributions;

(E) Special dose calculations and measurements;

(F) Monitor unit calculations;

(G) *In vivo* dose measurements;

(H) Treatment delivery records;

(I) Cumulative doses; and

(J) If a computerized treatment verification system is used, the physics chart check protocol shall also include review of the following information in the computerized treatment verification system:

(i) Treatment setup instructions,

(ii) Treatment field dose parameters, and

(iii) Cumulative doses delivered.

(2) A chart review, following the protocol established in accordance with subsection (*l*)(1), shall be performed of every patient's chart following each treatment event to ensure accuracy of calculations, appropriateness of charting data and fulfillment of the physician's documented prescription. Any deviation in the delivered dose from the physician's documented prescription that exceeds the registrant's established reporting threshold or current applicable regulatory reporting thresholds should be reported to the responsible radiation oncologist for evaluation and potential corrective action. A chart review for each patient shall be conducted by or under the direct supervision of the authorized medical physicist at least once every seven (7) consecutive days of clinical operation.

(3) Within one (1) calendar month of the completion of each patient's treatment, an authorized medical physicist shall review the entire patient treatment chart to affirm the fulfillment of the authorized user's prescription dose.

The Regulations of Connecticut State Agencies are amended by adding section 22a-153-8, as follows:

(NEW)

Sec. 22a-153-8. Use of radionuclides in the healing arts.

(a) Definitions. Terms used in the section that are not defined in this section are as provided in section 22a-153-1 and section 22a-153-2 of the Regulations of Connecticut State Agencies. For the purposes of this section:

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

(2) "Authorized nuclear pharmacist" means a pharmacist who:

(A) Meets the requirements in subsection (n) or (o) of this section;

(B) Is identified as an authorized nuclear pharmacist on 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 Commissioner, Nuclear Regulatory Commission or an Agreement State or Licensing State; or

(C) Is identified as an authorized nuclear pharmacist on a permit issued by a Commissioner, Nuclear Regulatory Commission or an Agreement State or Licensing State specific license of broad scope that is authorized to permit the use of radioactive material.

(3) "Authorized user" means a physician, dentist or podiatrist who:

(A) Meets the requirements in subsections (p), (cc)(1)(B), (dd)(4)(A), (ee)(4) through (6), (ff)(9) and (10), (gg)(2) and (hh)(17) of this section;

(B) Is identified as an authorized user on a license or equivalent permit or registration issued by the Commissioner, Nuclear Regulatory Commission or an Agreement State or Licensing State; or

(C) Is identified as an authorized user on a permit issued by the Commissioner, Nuclear Regulatory Commission or an Agreement State or Licensing State specific license of broad scope that is authorized to permit the medical use of radioactive material.

(4) "Client's address" means the address of use or a temporary job site for the purpose of providing mobile medical service as provided in 10 CFR 35.80.

(5) "Dedicated check source" means a radioactive source that is used to assure the consistent response of a radiation detection or measurement device over several months or years.

(6) "Dentist" means an individual licensed to practice dentistry or dental medicine pursuant to section 20-106 of the Connecticut General Statutes.

(7) "Diagnostic clinical procedures manual" means a collection of written procedures that describes each method and other instructions and precautions by which the registrant or licensee performs diagnostic clinical procedures.

(8) "High dose-rate remote afterloader" or "HDR" means a device that remotely delivers a dose rate in excess of 12 gray (1200 rads) per hour at the treatment site.

(9) "Low dose-rate remote afterloader" or "LDR" means a device that remotely delivers a dose rate of less than or equal to 2 gray (200 rads) per hour at the treatment site.

(10) "Manual brachytherapy" means a type of therapy in which brachytherapy sources are manually applied or inserted.

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

(12) "Medium dose-rate remote afterloader" or "MDR" means a device that remotely delivers a dose rate of greater than 2 gray (200 rads), but less than, or equal to, 12 gray (1200 rads) per hour at the treatment site.

(13) "Mobile medical service" means the transportation of radioactive material or its medical use at the client's address.

(14) "Output" means the exposure rate, dose rate or a quantity related in a known manner to these rates from a brachytherapy source, or a teletherapy, remote afterloader or gamma stereotactic radiosurgery unit for a specified set of exposure conditions.

(15) "Patient intervention" means actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration.

(16) "Podiatrist" means a doctor of "podiatric medicine" as defined in section 20-50 of the Connecticut General Statutes.

(17) "Preceptor" means an individual who provides or directs the training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, or a Radiation Safety Officer.

(18) "Prescribed dosage" means the specified activity or range of activity of a radiopharmaceutical drug as documented:

(A) In a written directive as specified in subsection (e)(5) of this section; or

(B) In accordance with the directions of the authorized user for procedures performed pursuant to subsections (cc), (dd) and (ee) of this section.

(19) "Prescribed dose" means:

(A) For gamma stereotactic radiosurgery, the total dose as documented in the written directive;

(B) For teletherapy, the total dose and dose per fraction as documented in the written directive;

(C) For manual brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or

(D) For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

(20) "Pulsed dose-rate remote afterloader" or "PDR" means a special type of remote afterloading device that uses a single source capable of delivering dose rates in the "high dose-rate" range, but:

(A) Is approximately one-tenth of the activity of typical high dose-rate remote afterloader sources; and

(B) Is used to simulate the radiobiology of a low dose rate treatment by inserting the source for a given fraction of each hour.

(21) "Radioactive drug" means any chemical compound containing radioactive material that may be used on or administered to patients or human research subjects as an aid in the diagnosis, treatment or prevention of disease or other abnormal condition.

(22) “radiopharmaceutical dose” means a radioactive substance used in the body for diagnosis or therapeutic purposes.

(23) "Sealed Source and Device Registry" means the national registry that contains the Nuclear Regulatory Commission registration certificates, which summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for such products.

(24) "Stereotactic radiosurgery" means the use of external radiation in conjunction with a stereotactic guidance device to deliver a dose to a treatment site with precision.

(25) "Structured educational program" means an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.

(26) "Teletherapy" means a method of radiation therapy in which collimated gamma rays are delivered at a distance from the patient or human research subject.

(27) "Therapeutic dosage" means a dosage of unsealed radioactive material that is intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.

(28) "Therapeutic dose" means a radiation dose delivered from a sealed source containing radioactive material to a patient or human research subject for palliative or curative treatment.

(29) "Treatment site" means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

(30) “Trunnions” means devices used to mount a stereotactic head frame and securely lock it into a coordinate frame for three-dimensional positioning accuracy.

(31) "Unit dosage" means a dosage that is administered as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared.

(32) "Written directive" means an authorized user's written order for the administration of radioactive material or radiation from radioactive material to a specific patient or human research subject, as specified in subsection (i) of this section.

(b) Research involving human subjects. The requirements of this section apply only to the use of radionuclides in or on human subjects. A registrant or licensee may conduct research involving human subjects using radioactive materials in accordance with the requirements of this section provided the registrant or licensee meets the following requirements:

(1) The registrant or licensee shall, at a minimum, obtain prior informed consent from the human subjects and obtain 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, and the research is authorized according to one of the following requirements:

(A) The research is conducted, funded, supported or regulated by a Federal agency that has implemented the Federal Policy for the Protection of Human Subjects; or

(B) A registrant or licensee shall apply for and receive approval of a specific amendment to a license or registration issued by the department before conducting such research.

(2) Any research involving human subjects authorized in subsection (b)(1) of this section shall be conducted using radioactive material authorized for medical use in the license or registration; and

(3) Nothing in this subsection relieves a registrant or licensee from the duty to comply with all applicable state and federal requirements governing radioactive drugs or devices.

(c) Licensing.

(1) No person shall manufacture, produce, prepare, acquire, receive, possess, use or transfer radioactive material for medical use without having been issued a registration or a specific license issued by the Department, the Nuclear Regulatory Commission, an Agreement State or as allowed in subsection (c)(2) or (c)(3) of this section.

(2) An individual may receive, possess, use or transfer radioactive material in accordance with the regulations in this section under the supervision of an authorized user as provided in subsection (i) of this section**,** unless prohibited by registration or license condition.

(3) An individual may prepare unsealed radioactive material for medical use in accordance with the requirements in this section under the supervision of an authorized nuclear pharmacist or authorized user as provided in subsection (h) of this section, unless prohibited by registration or license condition.

(4) An application for a registration or license as required by subdivision (1) of this subsection shall be made by filing a form prepared by the Commissioner.

(d) Exemptions.

The Commissioner may, upon application in writing of any interested person or upon the Commissioner’s own initiative, grant such exemptions from this section as determined to be authorized by law, not endangering life or property or the common defense and security and otherwise in the public interest.

(e) Registrant or licensee radiation protection program responsibilities.

(1) In addition to the radiation protection program requirements of section 22a-153-2(d) of the Regulations of Connecticut State Agencies, a registrant or licensee's management must approve in writing:

(A) Requests for a registration or license application, renewal or amendment before submittal to the Commissioner;

(B) Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist or authorized medical physicist; and

(C) Radiation protection program changes that do not require an amendment and are

permitted under subsection (f) of this section.

(2) A registrant or licensee's management shall appoint a Radiation Safety Officer (RSO) who agrees in writing to be responsible for implementing the radiation protection program. The registrant or licensee, through the RSO, shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulations.

(3) For up to sixty (60) days each year, a registrant or licensee may permit an authorized user or another qualified individual to function as a temporary RSO and to perform the functions of a RSO, as provided in subdivision (5) of this subsection, provided the licensee takes the actions required in subdivisions (2), (4), (5) and (8) of this subsection. A registrant or licensee may simultaneously appoint more than one temporary RSO, if needed, to ensure that the licensee has a temporary RSO that satisfies the requirements to be an RSO for each of the different uses of radioactive material permitted by the registration or license.

(4) A registrant or licensee shall establish in writing the authority, duties and responsibilities of the Radiation Safety Officer.

(5) A registrant or licensee shall provide the Radiation Safety Officer sufficient authority and resources, to:

(A) Identify radiation safety problems;

(B) Initiate, recommend or provide corrective actions;

(C) Stop unsafe operations; and

(D) Verify implementation of corrective actions.

(6) Any registrant or licensee who is authorized for two or more different types of radioactive material use under subsections (ee), (ff), (hh) and (ii) of this section or two or more types of units under subsection (hh) of this section shall establish a Radiation Safety Committee to oversee all uses of radioactive material permitted by the registration or license. Such a committee must include an authorized user of each type of use permitted by the registration or license, the Radiation Safety Officer, a representative of the nursing service and a representative of management who is neither an authorized user nor a Radiation Safety Officer, and may include other members as the registrant or licensee deems appropriate.

(7) A registrant or licensee's Radiation Safety Committee shall meet at intervals not to exceed six (6) months. The registrant or licensee shall maintain and record minutes of each meeting.

(8) A registrant or licensee shall retain a record of actions taken pursuant to subdivisions (1), (2) and (4) of this subsection as required by subsection (jj) of this section.

(f) Revision of radiation protection program.

(1) A registrant or licensee may revise its radiation protection program without approval of the Commissioner if:

(A) The revision is in compliance with regulations promulgated under section 22a-153 of the Connecticut General Statutes and the registration or license;

(B) The revision has been reviewed and approved by the Radiation Safety Officer, management and Radiation Safety Committee; and

(C) The affected individuals are instructed on the revised program before the changes are implemented.

(2) A registrant or licensee shall retain a record of each change in accordance with subsection (jj)(3) of this section.

(g) Duties of an authorized user and authorized medical physicist.

(1) A registrant or licensee shall assure that only authorized users for the type of radioactive material used:

(A) Prescribe the radiopharmaceutical dosage or dose to be administered through the issuance of a written directive or reference to the diagnostic clinical procedures manual;

(B) Direct, as specified in subsections (h) or (i) of this section, or in license conditions, the administration of radioactive material for medical use to patients or human research subjects; and

(C) Prepare and administer, or supervise the preparation and administration of, radioactive material for medical use in accordance with subsections (c)(2), (c)(3) and (h) of this section.

(2) A registrant or licensee shall allow that only an authorized medical physicist, or in the case of subparagraph (C) of this subdivision, the RSO, as applicable, perform:

(A) Full calibration measurements as described in subsections (hh)(7), (hh)(8) and (hh)(9) of this section;

(B) Periodic spot checks as described in subsections (hh)(10), (hh)(11) and (hh)(12) of this section; and

(C) Radiation surveys as described in subsection (hh)(14) of this section.

(h) Supervision.

(1) A registrant or licensee that permits the receipt, possession, use or transfer of radioactive material by an individual under the supervision of an authorized user or as allowed by subsection (c) of this section shall:

(A) In addition to the requirements in 19 CFR 12, instruct the supervised individual in the registrant or licensee's written radiation protection procedures, written directive procedures, requirements of this section and registration or license conditions with respect to the use of radioactive material; and

(B) Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of radioactive material, written radiation protection procedures, written directive procedures, requirements of this section and registration or license conditions with respect to the medical use of radioactive material.

(2) A registrant or licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by subsection (c)(3) of this section, shall:

(A) Instruct the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual's involvement with radioactive material; and

(B) Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of radioactive material for medical use, the written radiation protection procedures, this section and registration or license conditions.

(3) A registrant or licensee that permits supervised activities under subdivisions (1) and (2) of this subsection is responsible for the acts and omissions of the supervised individual.

(i) Written directives.

(1) A written directive must be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 1.11 Megabecquerels (MBq) (30 microcuries (µCi)), any therapeutic dosage of unsealed byproduct material or any therapeutic dose of radiation from byproduct material.

(2) If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive must be documented as soon as possible, and in no event in more than forty-eight (48) hours after following the oral directive, in writing, signed and dated in the patient's record.

(3) The written directive must contain the patient or human research subject's name and the following information:

(A) For any administration of quantities greater than 1.11 MBq (30 μCi) of sodium iodide I-131, the dosage;

(B) For an administration of a therapeutic dosage of unsealed byproduct material other than sodium iodide I-131, the radioactive drug, dosage and route of administration;

(C) For gamma stereotactic radiosurgery, the total dose, treatment site and values for the target coordinate settings per treatment for each anatomically distinct treatment site;

(D) For teletherapy, the total dose, dose per fraction, number of fractions and treatment site;

(E) For high dose-rate remote afterloading brachytherapy, the radionuclide, treatment site, dose per fraction, number of fractions and total dose; or

(F) For all other brachytherapy, including low, medium and pulsed dose rate remote afterloaders:

(i) Before implantation, the treatment site, the radionuclide and dose, and

(ii) After implantation but before completion of the procedure, the radionuclide, treatment site, number of sources and total source strength and exposure time or the total dose.

(4) A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed byproduct material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose or the next fractional dose.

(5) If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision must be documented and signed by the authorized user as soon as possible, but in no event in more than forty eight (48) hours of the oral revision, in the patient's record.

(6) The registrant or licensee shall retain a copy of the written directive in accordance with the recordkeeping requirements of this section.

(j) Procedures for administrations requiring a written directive.

(1) For any administration of a dose that requires a written directive, the registrant or licensee shall develop, implement and maintain written procedures to provide high confidence that:

(A) The patient's or human research subject's identity is verified before each administration; and

(B) Each administration is in accordance with the written directive.

(2) At a minimum, the procedures required by subdivision (1) of this subsection must address the following items as applicable to the registrant or licensee's use of byproduct material:

(A) Verifying the identity of the patient or human research subject;

(B) Verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive;

(C) Checking both manual and computer-generated dose calculations; and

(D) Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units.

(3) A registrant or licensee shall retain a copy of the procedures required under subdivision (1) of this subsection in accordance with the recordkeeping requirements of this section.

(k) Suppliers for sealed sources or devices for medical use. For medical use, a registrant or a licensee may only use:

(1) Sealed sources or devices initially manufactured, labeled, packaged and distributed in accordance with a license issued under 10 CFR 30 and 10 CFR 32.74 or equivalent requirements of an Agreement State or a Licensing State;

(2) Sealed sources or devices noncommercially transferred from a licensee holding a license issued under 10 CFR 35; or

(3) Teletherapy sources manufactured and distributed in accordance with a license issued under 10 CFR 30 or the equivalent requirements of an Agreement State or a Licensing State;

(l) **Training for Radiation Safety Officer.** Except as provided in subsection (o) of this section, a registrant or licensee shall require an individual fulfilling the responsibilities of the RSO as provided in subsection (e) of this section to be an individual who:

(1) Is certified by a specialty board whose certification process includes all of the requirements in subdivision (2) of this subsection and whose certification has been recognized by the Nuclear Regulatory Commission or an Agreement State, or;

(2) Has completed a structured educational program meeting the following requirements of this subdivision and subdivision (3) of this subsection:

(A) Two hundred (200) hours of didactic training in the following areas:

(i) Radiation physics and instrumentation,

(ii) Radiation protection,

(iii) Mathematics pertaining to the use and measurement of radioactivity,

(iv) Radiation biology, and

(v) Radiation dosimetry; and

(B) One (1) year of full-time radiation safety experience under the supervision of the individual identified as the RSO on a Nuclear Regulatory Commission or Agreement State license that authorizes similar type or types of use or uses of radioactive material including the following activities:

(i) Shipping, receiving and performing related radiation surveys,

(ii) Using and performing checks for proper operation of dose calibrators, survey meters and instruments used to measure radionuclides,

(iii) Securing and controlling radioactive material,

(iv) Using administrative controls to avoid mistakes in the administration of radioactive material,

(v) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures,

(vi) Using emergency procedures to control radioactive material, and

(vii) Disposing of radioactive material; and

(3) Has obtained written certification, signed by a preceptor RSO, that the individual has satisfactorily completed the requirements in subdivision (2) of this subsection and has achieved a level of radiation safety knowledge sufficient to function independently as an RSO for medical uses of radioactive material; or

(4) As an alternative to meeting the requirements of subdivision (1) or subdivisions (2) and (3) of this subsection, an authorized user, authorized medical physicist or authorized nuclear pharmacist identified on an applicable registration or license and who has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual has RSO responsibilities.

(m) Training for an authorized medical physicist. The registrant or licensee shall require the authorized medical physicist to be an individual who:

(1) Is certified by a specialty board whose certification process includes all of the training and experience requirements in subdivision (2) of this subsection and whose certification has been recognized by the Nuclear Regulatory Commission or an Agreement State; or

(2) Meets the following requirements:

(A) Holds a master's or doctorate degree in physics, biophysics, radiological physics, medical physics or health physics, or an equivalent training program approved by the Commissioner, another Agreement State or the Nuclear Regulatory Commission and has completed one year of full-time training in therapeutic radiological physics and an additional year of full-time practical experience under the supervision of a medical physicist at a medical institution that includes the tasks listed in subsections (u), (ff)(6)(E), (hh)(7) and (8) of this section, as applicable; and subsections (hh)(9) through (12) and (hh)(14) of this section.

(B) Has obtained a written certification, signed by a preceptor authorized medical physicist, that the individual has satisfactorily completed the requirements in subdivision (2)(A) of this subsection 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.

(n) Training for an authorized nuclear pharmacist. The registrant or licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

(1) Is certified as a nuclear pharmacist by a specialty board whose certification process includes all of the requirements in subdivision (2) of this subsection and whose certification has been recognized by the Nuclear Regulatory Commission or an Agreement State; or

(2) The individual has:

(A) Completed seven hundred (700) hours in a structured educational program consisting of both:

(i) Didactic training in radiation physics and instrumentation; radiation protection; mathematics pertaining to the use and measurement of radioactivity; chemistry of radioactive material for medical use; and radiation biology, and

(ii) Supervised practical experience in a nuclear pharmacy involving:

(I) Shipping, receiving and performing related radiation surveys,

(II) Using and performing checks for proper operation of dose calibrators, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides,

(III) Calculating, assaying and safely preparing dosages for patients or human research subjects,

(IV) Using administrative controls to avoid medical events in the administration of radioactive material, and

(V) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

(B) Has obtained written certification, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in subdivision (2)(A) of this subsection and has achieved a level of competency sufficient to operate a nuclear pharmacy independently.

(o) Exceptions from training requirements.

(1) An individual identified as a Radiation Safety Officer, a medical physicist or a nuclear pharmacist on a Nuclear Regulatory Commission, an Agreement State license or on a permit issued by a Nuclear Regulatory Commission or Agreement State broad scope licensee that authorizes medical use or the practice of nuclear pharmacy, prior to the effective date of this section is exempt from the training requirements of subsections (*l*), (m) and (n) of this section, respectively.

(2) Physicians, dentists or podiatrists identified as authorized users for the medical, dental or podiatric use of radioactive material on a Nuclear Regulatory Commission or Agreement State license or on a permit issued by a Nuclear Regulatory Commission or Agreement State broad scope licensee that authorizes medical use or the practice of nuclear pharmacy, issued prior to the effective date of this section who perform only those medical uses for which they were authorized are exempt from the training requirements of subsections (cc)(3), (dd)(4), (ee)(1), (ee)(5), (ee)(6), (ff)(9), (ff)(10), (gg)(2) and (hh)(17).

(p) Recentness of training. The training and experience specified in this section must have been obtained within the seven (7) years preceding the date of application, or the individual must have had related continuing education and experience since the required training and experience was completed.

(q) Possession, use and testing of instruments to measure the activity of unsealed radioactive materials. Each licensee or registrant shall:

(1) For direct measurements performed in accordance with subsection (s) of this section, possess and use instrumentation to measure the activity of unsealed radioactive materials prior to administration to each patient or human research subject;

(2) Test the instrumentation required in subdivision (1) of this subsection in accordance with nationally recognized standards or the manufacturer's instructions;

(3) In the tests required in subdivision (2) of this subsection, include tests for constancy, linearity, accuracy and geometry dependence, as appropriate to demonstrate proper operation of the instrument; and

(4) Retain a record of each instrument test required by this subsection in accordance with subsection (jj)(6) of this section.

(r) Calibration of survey instruments. Each registrant or licensee shall calibrate survey instruments as follows:

(1) Survey instruments used to show compliance with this section and section 22a-153-2 of the Regulations of Connecticut State Agencies shall have been calibrated before first use, annually and following any repair that may affect the calibration;

(2) To satisfy the requirements of subdivision (1) of this subsection:

(A) Calibrate all required scale readings up to 10 millisieverts (1000 mrem) per hour with a radiation source;

(B) Have each radiation survey instrument calibrated:

(i) At energies appropriate for use and at intervals not to exceed twelve (12) months or after instrument servicing, except for battery changes,

(ii) For linear scale instruments, at two points located approximately one-third and two-thirds of full-scale on each scale; for logarithmic scale instruments, at mid-range of each decade, and at two points of at least one decade; and for digital instruments, at 3 points between 0.02 and 10 millisieverts (2 and 1000 mrem) per hour, and

(iii) For dose rate instruments, so that an accuracy within plus or minus 20 percent of the true radiation dose rate can be demonstrated at each point checked; and

(C) Conspicuously note on the instrument the date of calibration;

(3) Survey instruments shall not be used if the difference between the indicated exposure rate and the calculated exposure rate is greater than 20 percent; and

(4) Retain a record of each survey instrument calibration in accordance with subsection (jj)(7) of this section.

(s) Determination of dosages of radioactive material for medical use. Each registrant or licensee shall determine radioactive material dosages for medical use as follows:

(1) Determine and record the activity of each dosage prior to medical use;

(2) For a unit dosage, a determination required by subdivision (1) of this subsection shall be made either by direct measurement or by a decay correction, based on the measurement made by a manufacturer or preparer licensed pursuant to 10 CFR 32.72 or equivalent provisions of the, Nuclear Regulatory Commission, Agreement State or Licensing State;

(3) For other than unit dosages, a determination required by subdivision (1) of this subsection shall be made by direct measurement of radioactivity or by a combination of measurements of radioactivity and mathematical calculations or combination of volumetric measurements and mathematical calculations, based on the measurement made by a manufacturer or preparer licensed pursuant to 10 CFR 32.72 or equivalent provisions of the, Nuclear Regulatory Commission, Agreement State or Licensing State;

(4) Unless otherwise directed by the authorized user, no dosage that differs from the prescribed dosage by more than 20 percent shall be used; and

(5) Retain a record of the dosage determination required by this section in accordance with subsection (jj)(8) of this section.

(t) Authorization for calibration, transmission and reference sources. Any person authorized by subsection (c) of this section for medical use of radioactive material may receive, possess and use the following radioactive material for check, calibration and reference use:

(1) Sealed sources manufactured and distributed by persons specifically licensed pursuant to 10 CFR 35.74 or equivalent provisions of the Nuclear Regulatory Commission, Agreement State or Licensing State and that do not exceed 1.11 gigabecquerels (30 mCi) each;

(2) Any radioactive material with a half-life of one hundred twenty (120) days or less in individual amounts not to exceed 555 megabecquerels (15 mCi);

(3) Any radioactive material with a half-life greater than one hundred twenty (120) days in individual amounts not to exceed the smaller of:

(A) 7.4 megabecquerels (200 μCi); or

(B) 1000 times the quantities in Appendix B of 10 CFR 30; and

(4) Technetium-99m in amounts as needed.

(u) Requirements for possession of sealed sources and brachytherapy sources. A registrant or licensee in possession of a sealed source or brachytherapy source shall:

(1) Follow the radiation safety and handling instructions supplied by the manufacturer or equivalent instructions approved by the Commissioner;

(2) For possession of a sealed source:

(A) Test the source for leakage in accordance with section 22a-153-2 of the Regulations of Connecticut State Agencies; and

(B) Test the source for leakage at intervals not to exceed six (6) months or at other intervals approved by the Commissioner, an Agreement State, a Licensing State or the Nuclear Regulatory Commission in the Sealed Source and Device Registry;

(3) If the leak test reveals the presence of 185 becquerels (4.99×10^{-9} Ci) or more of removable contamination:

(A) Immediately withdraw the sealed source from use and store, dispose or cause it to be repaired in accordance with the requirements of 10 CFR 10 and 10 CFR 20; and

(B) File a report with the Commissioner within five (5) days of receiving the leak tests results in accordance with subsection (kk)(3) of this section; and

(4) Except for gamma stereotactic radiosurgery sources, conduct a semi-annual physical inventory of all sources and retain each inventory record in accordance with subsection (jj)(9) of this section.

(v) Labels. A registrant or licensee shall label each syringe and vial that contains a radioactive drug to identify the radioactive drug. Each syringe shield and vial shield shall also be labeled unless the label on the syringe or vial is visible when shielded.

(w) Vial shields. A registrant or licensee shall require each individual preparing or handling a vial that contains a radioactive drug to keep the vial in a vial radiation shield, as practical.

(x) Surveys for ambient radiation dose rate and contamination. Each registrant or licensee shall conduct surveys for ambient radiation dose rate and contamination as follows:

(1) With a radiation detection survey instrument at the end of each day of use in all areas where radioactive drugs containing radioactive material requiring a written directive were prepared for use or administered;

(2) Conduct the surveys required by subdivision (1) of this subsection so as to be able to measure dose rates as low as one microsievert (0.1 mrem) per hour;

(3) Establish dose rate action levels for the surveys required by subdivision (1) of this subsection and require that the individual performing the survey immediately notify the RSO if a dose rate exceeds an action level;

(4) Survey for removable contamination each week of use in all areas where generators and bulk radioactive drugs are prepared for use or administered and each week where radioactive materials are stored;

(5) Establish removable contamination action levels for the surveys required by subdivision (4) of this subsection and require that the individual performing the survey immediately notify the RSO contamination exceeds action levels;

(6) If patients or human research subjects are confined when they cannot be released pursuant to subsection (y) of this section, the surveys required by subdivision (1) of this subsection are not required; and

(7) Retain a record of each survey in accordance with subsection (jj)(10) of this section.

(y) Release of individuals containing radioactive drugs or implants. A registrant or licensee may authorize the release from its control of an individual who has been administered unsealed byproduct material or impacts containing byproduct material if such release meets the requirements of 10 CFR 35.75.

(z) Mobile medical service technical requirements. A registrant or licensee providing mobile medical service shall meet the requirements of 10 CFR 35.80.

(aa) Storage and control of volatiles and gases. Each licensee or registrant shall store and control volatiles and gases as required by this subsection.

(1) A registrant or licensee shall store and use a multi-dose container in a properly functioning fume hood.

(2) A registrant or licensee who administers radioactive gases shall do so in a room with a negative pressure vented to the atmosphere.

(3) Any system with which a registrant or licensee administers radioactive gases shall either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the gas in a shielded container.

(4) A registrant or licensee shall check the operation of any collection system operated pursuant to this section periodically according to the manufacturer's instructions. Records of these checks shall be maintained for a minimum of five (5) years.

(bb) Decay in storage. A registrant or licensee may hold by-product materials with a physical half-life of less than one hundred twenty (120) days for decay-in-storage disposal if the requirements of 10 CFR 35.92 are met.

(cc) Use of radioactive material for uptake, dilution or excretion studies.

(1) A registrant or licensee may use any unsealed radioactive material, in quantities that do not require a written directive, for a diagnostic use involving measurements of uptake, dilution or excretion that is:

(A) Obtained from a person licensed pursuant to 10 CFR 32.72 or equivalent regulations of an Agreement State, a Licensing State or the Nuclear Regulatory Commission;

(B) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in subsections (cc)(3) and (dd)(4) of this section, or an individual under the supervision of either as specified in subsection (h) of this section;

(C) Obtained from and prepared by the department, Nuclear Regulatory Commission, Agreement State or Licensing State registrant or licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug protocol accepted by FDA; or

(D) Prepared by the registrant or 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.

(2) Survey instrument. A registrant or licensee authorized to use radioactive material for uptake, dilution and excretion studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of one microsievert (0.1 mrem) per hour to 500 microsieverts (50 mrems) per hour. The instrument shall be operable and calibrated in accordance with subsection (r) of this section.

(3) Training. Except as provided in subsection (o) of this section, a registrant or licensee shall require an authorized user of an unsealed radioactive material for the uses authorized under subsection (cc)(1) of this section to be a physician who:

(A) Is certified by a medical specialty board whose certification process includes all of the requirements in subparagraph (C) of this subdivision and whose certification has been recognized by the Nuclear Regulatory Commission or an Agreement State; or

(B) Is an authorized user under subsections (dd)(4) or (ee)(4) of this section, or equivalent Agreement State or Nuclear Regulatory Commission requirements; or

(C) Meets the following requirements:

(i) Has completed sixty (60) hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution and excretion studies that includes:

(I) Classroom and laboratory training in radiation physics and instrumentation; radiation protection; mathematics pertaining to the use and measurement of radioactivity; chemistry of radioactive material for medical use; and radiation biology, and

(II) Work experience, under the supervision of an authorized user who meets the requirements in this subdivision, subsection (dd)(4) or subsection (ee)(4) of this section or equivalent Agreement State or Nuclear Regulatory Commission requirements involving ordering, receiving and unpacking radioactive materials safely and performing the related radiation surveys; calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters; calculating, measuring and safely preparing patient or human research subject dosages; using administrative controls to prevent a medical event involving the use of unsealed radioactive material; using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and administering dosages to patients or human research subjects, and

(ii) Has obtained written certification, signed by a preceptor authorized user, who meets the requirements in this subdivision, subsection (dd)(4) or subsection (ee)(4) of this section or equivalent Agreement State, or Nuclear Regulatory Commission requirements, that the individual has satisfactorily completed the requirements in subdivision (3)(C)(i) of this section and has achieved a level of competency sufficient to independently function as an authorized user for the medical uses authorized under subdivision (1) of this subsection.

(dd) Use of unsealed radioactive material for which a written direction is not required.

(1) Use of unsealed radioactive material for imaging and localization studies. A registrant or licensee may use, for imaging and localization studies, any radioactive material prepared for medical use, in quantities that do not require a written directive as described in subsection (i) of this section that is:

(A) Obtained from a person licensed pursuant to 10 CFR 35.200 or equivalent regulations of another Agreement State, a Licensing State or the Nuclear Regulatory Commission;

(B) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in subsection (dd)(4) of this section, or an individual under the supervision of either as specified in subsection (h) of this section;

(C) Obtained from and prepared by a Commissioner-approved, Nuclear Regulatory Commission, Agreement State or Licensing State registrant or licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug protocol accepted by FDA;

(D) Prepared by the registrant or licensee in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug protocol accepted by FDA; or

(E) If the material is a radioactive aerosol or gas, only if the conditions of subsection (aa) of this section are met and if such use is addressed in the registration or license.

(2) Radionuclide contaminants. A registrant or licensee that complies with the following requirements for radioactive drugs is not required to obtain a written directive under subsection (i) of this section:

(A) The registrant or licensee shall not administer to humans a radioactive drug containing:

(i) More than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 µCi of Mo-99 per mCi of Tc-99m),

(ii) More than 0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 chloride injection (0.02 µCi of Sr-82 per mCi of Rb-82 chloride),

(iii) More than 0.2 kilobecquerel of strontium-85 per megabecquerel of rubidium-82 chloride injection (0.2 µCi of Sr-85 per mCi of Rb-82);

(B) To demonstrate compliance with subparagraph (A) of this subdivision, the registrant or licensee preparing radioactive drugs from radionuclide generators shall:

(i) Measure the concentration of radionuclide contaminant in the first eluate after receipt of a molybdenum-99/technetium-99m generator, and

(ii) Measure the concentration of radionuclide contaminant in each eluate or extract, as appropriate for other generator systems;

(C) Retain a record of each measurement in accordance with subsection (jj)(13) of this section; and

(D) Report immediately to the Commissioner each occurrence of radionuclide contaminant concentration exceeding the limits specified in subparagraph (A) of this subdivision.

(3) Possession of survey instruments. A registrant or licensee authorized to use radioactive material for imaging and localization studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 microsievert (0.1 mrem) per hour to 500 microsieverts (50 mrems) per hour and a portable radiation measurement survey instrument capable of measuring dose rates over the range of 10 microsieverts (1 mrem) per hour to 10 millisieverts (1000 mrems) per hour. The instruments shall be operable and calibrated in accordance with subsection (r) of this section.

(4) Training for imaging and localization studies. Except as provided in subsection (o) of this section, the registrant or licensee shall require an authorized user of unsealed radioactive material for the uses authorized under subsection (dd)(1) of this section to be a physician who:

(A) Is certified by a medical specialty board whose certification process includes all of the requirements in subparagraph (C) of this subdivision and whose certification has been recognized by an Agreement State or the Nuclear Regulatory Commission;

(B) Is an authorized user under subsection (ee)(4) of this section, or equivalent Agreement State or Nuclear Regulatory Commission requirements; or

(C) Meets the following requirements:

(i) Has completed seven hundred (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 that includes, at a minimum:

(I) Classroom and laboratory training in radiation physics and instrumentation; radiation protection; mathematics pertaining to the use and measurement of radioactivity; chemistry of radioactive material for medical use; radiation biology, and

(II) Work experience, under the supervision of an authorized user who meets the requirements in this subdivision or subsection (ee)(4) of this section, or equivalent Agreement State or Nuclear Regulatory Commission requirements, involving ordering, receiving and unpacking radioactive materials safely and performing the related radiation surveys; calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters; calculating, measuring, and safely preparing patient or human research subject dosages; using administrative controls to prevent a medical event involving the use of unsealed radioactive material; using procedures to contain spilled radioactive material safely and using proper decontamination procedures; administering radiopharmaceutical dosages to patients

or human research subjects; and eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radiochemical purity and processing the eluate with reagent kits to prepare labeled radioactive drugs, and

(ii) Has obtained written certification, signed by a preceptor authorized user, who meets the requirements in this subdivision or subsection (ee)(4) of this section, or equivalent Agreement State or Nuclear Regulatory Commission requirements, that the individual has satisfactorily completed the requirements in subdivision (4)(C)(i) of this subsection and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under subsection (dd)(1) of this section.

(ee) Use of unsealed radioactive material for which a written directive is required.

(1) A registrant or licensee may use any unsealed radioactive material for diagnostic or therapeutic medical use for which a written directive is required that is:

(A) Obtained from a person licensed in accordance with 10 CFR 35.300;

(B) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in subsection (dd)(4) or (ee)(4) of this section or an individual under the supervision of either as specified in subsection (o) of this section;

(C) Obtained from and prepared by a Commissioner-approved, Nuclear Regulatory Commission, Agreement State or Licensing State licensee in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug protocol accepted by the FDA for use in research; or

(D) Prepared by the registrant or licensee in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug protocol accepted by FDA for use in research.

(2) Safety Instruction. In addition to the requirements of section 22a-153-6(b) of the Regulations of Connecticut State Agencies, each registrant or licensee shall:

(A) Provide radiation safety instruction to personnel caring for patients or human research subjects that have received therapy with a radioactive drug, and cannot be released in accordance with subsection (y) of this section. The training must be provided initially and at least annually. The instruction shall be appropriate to the assigned duties of persons receiving instruction and include the following:

(i) Patient or human research subject control, and

(ii) Visitor control that includes routine visitation to hospitalized individuals in accordance with section 22a-153-2 of the Regulations of Connecticut State Agencies; contamination control; waste control; and notification of the RSO, or his or her designee and the authorized user if the patient or the human research subject dies or has a medical emergency; and

(B) Retain a record of individuals receiving instruction in accordance with subsection (jj)(14) of this section.

(3) Safety precautions. Each licensee or registrant shall:

(A) For each patient or human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with subsection (y) of this section:

(i) Quarter the patient or the human research subject either in:

(I) A private room with a private sanitary facility, or

(II) A room, with a private sanitary facility, with another individual who also has received similar radiopharmaceutical therapy and who cannot be released in accordance with subsection (y) of this section,

(ii) Visibly post the patient's or the human research subject's room with a "Radioactive Materials" sign and note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or the human research subject's room, and

(iii) Either monitor material and items removed from the patient's or the human research subject's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle such material and items as radioactive waste; and

(B) The Radiation Safety Officer, or his or her designee, and the authorized user shall be notified immediately if the hospitalized patient dies or has a medical emergency. The licensee shall also notify the Commissioner in accordance with subsection (kk)(5) of this section it is possible that any individual could receive exposures in excess of section 22a-153-2(f) of the Regulations of Connecticut State Agencies as a result of the deceased's body.

(3) Possession of survey instruments. A registrant or licensee authorized to use radioactive material for which a written directive is required shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of one microsievert (0.1 mrem)

per hour to 500 microsieverts (50 mrems) per hour and a portable radiation measurement survey instrument capable of measuring dose rates over the range of 10 microsieverts (1 mrem) per hour to 10 millisieverts (1000 mrems) per hour. The instruments shall be operable and calibrated in accordance with subsection (r) of this section.

(4) Training. Except as provided in subsection (o) of this section, each registrant or licensee shall require an authorized user of radioactive material for the uses authorized under subdivision (1) of this section to be a physician who meets the requirements in 10 CFR 35.390.

(5) Training for the oral administration of sodium iodide I-131 in quantities less than or equal to 1.22 gigabecquerels (33 millicuries). Except as provided in subsection (o) of this section, each registrant or licensee shall require an authorized user for the oral administration of sodium iodide I-131 in quantities less than or equal to 1.22 gigabecquerels (33 millicuries), for which a written directive is required, to be a physician who meets the requirements of 10 CFR 35.392.

(6) Training for the oral administration of sodium iodide I-131 in quantities greater than 1.22 gigabecquerels (33 millicuries). Except as provided in subsection (o) of this section, each registrant or licensee shall require an authorized user for the oral administration of sodium iodide I-131 in quantities greater than 1.22 gigabecquerels (33 millicuries), to be a physician who meets the requirements of 10 CFR 35.394.

(ff) Manual brachytherapy.

(1) Use of sealed sources. A registrant or licensee shall use only brachytherapy sources for therapeutic medical uses that are either:

(A) Approved in the Sealed Source and Device Registry; or

(B) In research in accordance with an effective Investigational Device Exemption application accepted by the FDA, provided the requirements of subsection (k)(1) of this section are met.

(2) Surveys after source implant and removal. A registrant or licensee shall:

(A) Immediately after implanting sources in a patient or a human research subject, perform a survey to locate and account for all sources that have not been implanted;

(B) Immediately after removing the last temporary implant source from a patient or a human research subject, make a survey of the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed; and

(C) Retain a record of the surveys in accordance with subsection (jj)(15) of this section.

(3) Brachytherapy sources inventory. Each registrant or licensee shall:

(A) Maintain accountability at all times for all brachytherapy sources in storage or use;

(B) Promptly after removing sources from a patient or a human research subject, return brachytherapy sources to a secure storage area; and

(C) Maintain a record of the brachytherapy source accountability in accordance with subsection (jj)(16) of this section.

(4) Safety instruction. In addition to the requirements of section 22a-153-6(b) of the Regulations of Connecticut State Agencies, a registrant or licensee shall:

(A) Provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects that are undergoing implant therapy and cannot be released in accordance with subsection (y) of this section. Instruction must be commensurate with the duties of the personnel and shall include the following:

(i) Size and appearance of the brachytherapy sources,

(ii) Safe handling and shielding instructions,

(iii) Patient or human research subject control,

(iv) Visitor control, including routine visitation of hospitalized individuals in accordance with section 22a-153-2(f)(1)(A) of the Regulations of Connecticut State Agencies and visitation authorized in accordance with section 22a-153-2(f)(2)(B) of the Regulations of Connecticut State Agencies, and

(v) Notification of the RSO, or his or her designee, and an authorized user if the patient or the human research subject dies or has a medical emergency. The registrant or licensee shall also notify the Commissioner in accordance with subsection (kk)(5) of this section if it is possible that any individual could receive exposures in excess of 5 millisievert (500 mrem) as a result of the deceased's body; and

(B) Retain a record of individuals receiving instruction in accordance with subsection (jj)(14) of this section.

(5) Safety precautions for patients or human research subjects. Each registrant or licensee shall:

(A) For each patient or human research subject that is receiving brachytherapy and cannot be released in accordance with subsection (y) of this section:

(i) Not place the patient or human research subject in the same room as an individual who is not receiving brachytherapy, and

(ii) Visibly post the patient's or human research subject's room with a "Radioactive Materials" sign and note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room;

(B) Have emergency response equipment available near each treatment room to respond to a source that inadvertently becomes:

(i) Dislodged from the patient, or

(ii) Lodged within the patient following removal of the source applicators; and

(C) The Radiation Safety Officer, or his or her designee, and the authorized user shall be notified immediately if the hospitalized patient or human research subject dies or has a medical emergency.

(6) Calibration measurements of brachytherapy sealed sources. Each registrant or licensee:

(A) Prior to the first medical use of a brachytherapy sealed source on or after the effective date of this section, shall perform the following:

(i) Determine the source output or activity using a dosimetry system that meets the requirements of subsection (hh)(6)(A) of this section,

(ii) Determine source positioning accuracy within applicators, and

(iii) Use published protocols accepted by nationally recognized bodies to meet the requirements of subparagraphs (A)(i) and (A)(ii) of this subdivision;

(B) May use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine that are made in accordance with subparagraph (A) of this subdivision;

(C) Shall mathematically correct the outputs or activities determined in subparagraph (A) of this subdivision for physical decay at intervals consistent with 1.0 percent physical decay;

(D) Shall have an authorized medical physicist perform or review the calculation measurements made pursuant to subparagraphs (A) through (C) of this subdivision;

(E) Shall have only an authorized medical physicist calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay shall be based on the activity determined in accordance with subparagraphs (A) through (C) of this subdivision;

(F) Shall retain a record of each calibration in accordance with subsection (jj)(17) of this section; and

(G) Shall retain a record of decay calculations required by subparagraph (E) of this subdivision in accordance with subsection (jj)(18) of this section.

(7) Therapy-related computer systems. A registrant or licensee shall perform acceptance testing on the treatment planning system in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing shall include, as applicable, verification of:

(A) The source-specific input parameters required by the dose calculation algorithm;

(B) The accuracy of dose, dwell time and treatment time calculations at representative points;

(C) The accuracy of isodose plots and graphic displays; and

(D) The accuracy of the software used to determine radioactive source positions from radiographic images.

(8) Possession of survey instruments. A registrant or licensee authorized to use manual brachytherapy sources shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 microsievert (0.1 mrem) per hour to 500 microsieverts (50 mrems) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range of 10 microsieverts (1 mrem) per hour to 10 millisieverts (1000 mrems) per hour. The instruments shall be operable and calibrated in accordance with subsection (r) of this section.

(9) Training. Except as provided in subsection (o) of this section, a registrant or licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under subdivision (1) of this subsection to be a physician who meets the requirements of 10 CFR 35.490.

(10) Training for ophthalmic use of strontium-90. Except as provided in subsection (o) of this section, a registrant or licensee shall require an authorized user of a strontium-90 source for ophthalmic uses authorized under subdivision (1) of this subsection to be a physician who meets the requirements of 10 CFR 35.491.

(gg) Sealed sources for diagnosis.

(1) A registrant or licensee shall use only sealed sources for diagnostic medical uses that are:

(A) Approved in the Sealed Source and Device Registry; and

(B) Handled in accordance with the manufacturer's radiation safety instructions.

(2) Training. Except as provided in subsection (o) of this section, a registrant or licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized under subdivision (1) of this subsection to be a physician, dentist or podiatrist who:

(A) Is certified by a specialty board whose certification process includes all of the requirements in subparagraph (B) of this subdivision and whose certification has been recognized by an Agreement State or the Nuclear Regulatory Commission; or

(B) Has had eight (8) hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device that includes:

(i) Radiation physics and instrumentation,

(ii) Radiation protection,

(iii) Mathematics pertaining to the use and measurement of radioactivity,

(iv) Radiation biology, and

(v) Training in the use of the device for the uses requested.

(hh) Photon emitting remote afterloader units, teletherapy units and gamma stereotactic radiosurgery units.

(1) Use of sealed sources in a remote afterloader unit, teletherapy unit or gamma stereotactic radiosurgery unit. A registrant or licensee shall use sealed sources in photon emitting remote afterloader units, teletherapy units or gamma stereotactic radiosurgery units for therapeutic medical uses:

(A) As approved in the Sealed Source and Device Registry; or

(B) In research in accordance with an effective Investigational Device Exemption application accepted by the FDA provided the requirements of subsection (l)(1) of this section are met.

(2) Surveys of patients and human research subjects treated with a remote afterloader unit. Each registrant or licensee shall:

(A) Immediately following treatment of a patient or a human research subject and prior to release from registrant or licensee control, make a survey of the patient or the human research subject and the remote afterloader unit with a portable radiation detection survey instrument to confirm that the source(s) has been removed from the patient or human research subject and returned to the safe, shielded position; and

(B) Retain a record of the surveys in accordance with subsection (jj)(15) of this section.

(3) Installation, maintenance, adjustment and repair. Each licensee or registrant shall:

(A) Allow only a person specifically licensed by the Commissioner, the Nuclear Regulatory Commission or an Agreement State to install, maintain, adjust or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the source or sources shielding, the source or sources driving unit, or other electronic or mechanical component that could expose the source or sources, reduce the shielding around the source or sources or compromise the radiation safety of the unit or the source or sources;

(B) Except for low dose-rate remote afterloader units, allow only a person specifically licensed by the Commissioner, an Agreement State, Licensing State or the Nuclear Regulatory Commission shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units or gamma stereotactic radiosurgery units;

(C) For a low dose-rate remote afterloader unit, allow only a person specifically licensed by the Commissioner, an Agreement State, Licensing State or the Nuclear Regulatory Commission, or an authorized medical physicist shall install, replace, relocate or remove a sealed source or sources contained in the unit; and

(D) Retain a record of the installation, maintenance, adjustment and repair done on remote afterloader units, teletherapy units and gamma stereotactic radiosurgery units in accordance with subsection (jj)(19) of this section.

(4) Safety procedures and instructions for remote afterloader units, teletherapy units and gamma stereotactic radiosurgery units.

(A) A registrant or licensee shall:

(i) Secure the unit, the console, the console keys and the treatment room when not in use or unattended,

(ii) Permit only individuals approved by the authorized user, RSO or authorized medical physicist to be present in the treatment room during treatment with the source or sources,

(iii) Prevent dual operation of more than one radiation producing device in a treatment room, if applicable, and

(iv) Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source or sources in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. This procedure must include:

(I) Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions,

(II) The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure, and

(III) The names and telephone numbers of the authorized users, the authorized medical physicist and the RSO to be contacted if the unit or console operates abnormally;

(B) A registrant or licensee shall maintain a copy of the procedures required by subdivision (4)(A)(iv) of this subsection at the unit console or a notation where such procedures may be immediately obtained;

(C) A registrant or licensee shall post instructions at the unit console to inform the operator of:

(i) The location of the procedures required by subdivision (4)(A)(iv) of this subsection, and

(ii) The names and telephone numbers of the authorized users, the authorized medical physicist and the RSO to be contacted if the unit or console operates abnormally;

(D) A registrant or licensee shall provide instruction, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties, in:

(i) The procedures identified in subdivision (4)(A)(iv) of this subsection, and

(ii) The operating procedures for the unit.

(E) A registrant or licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

(F) A registrant or licensee shall retain a record of individuals receiving instruction required by subparagraph (D) of this subdivision, in accordance with subsection (jj)(14) of this section.

(5) Safety precautions for remote afterloader units, teletherapy units and gamma stereotactic radiosurgery units. Each registrant or licensee shall:

(A) Control access to the treatment room by a door at each entrance;

(B) Equip each entrance to the treatment room with an electrical interlock system that will:

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

(ii) Cause the source or sources to be shielded promptly when an entrance door is opened, and

(iii) Prevent the source from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source or sources on-off control is reset at the console;

(C) Require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels;

(D) Except for low-dose remote afterloader units, construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation;

(E) For licensed activities where sources are placed within the patient's or human research subject's body, only conduct treatments which allow for expeditious removal of a decoupled or jammed source;

(F) In addition to the requirements specified in subparagraphs (A) through (E) of this subdivision;

(i) For medium dose-rate and pulsed dose-rate remote afterloader units, require:

(a) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit to be physically present during the initiation of all patient treatments involving the unit, and

(b) An authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who has been trained to remove the source applicator or applicators in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit,

(ii) For high dose-rate remote afterloader units, require:

(a) An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit, and

(b) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, to be physically present during continuation of all patient treatments involving the unit,

(iii) For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit, and

(iv) Notify the RSO, or his or her designee, and an authorized user as soon as possible, if the patient or human research subject has a medical emergency and, immediately, if the patient dies; and

(G) Have emergency response equipment available near each treatment room, to respond to a source that inadvertently:

(i) Remains in the unshielded position; or

(ii) Lodges within the patient following completion of the treatment.

(6) Dosimetry equipment. Each registrant or licensee shall:

(A) Except for low dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer, have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions must be met;

(i) The system shall have been calibrated using a system or source traceable to the National Institute of Standards and Technology and published protocols accepted by nationally recognized bodies; or by a calibration laboratory accredited by the American Association of Physicists in

Medicine. The calibration must have been performed within the previous two years and after any servicing that may have affected system calibration, or

(ii) The system shall have been calibrated within the previous four (4) years; eighteen (18) to thirty (30) months after that calibration, the system shall have been intercompared with another dosimetry system that was calibrated within the past twenty four (24) months by NIST or by a calibration laboratory accredited by the AAPM. The results of the intercomparison shall have indicated that the calibration factor of the licensee's system had not changed by more than two percent. The licensee may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee shall use a comparable unit with beam attenuators or collimators, as applicable, and sources of the same radionuclide as the source used at the licensee's facility;

(B) Have available for use a dosimetry system for spot-check output measurements, if applicable. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with subparagraph (A) of this subdivision. This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in subparagraph (A) of this subdivision; and

(C) Retain a record of each calibration, intercomparison, and comparison in accordance with subsection (jj)(20) of this section.

(7) Full calibration measurements on teletherapy units. Each registrant or licensee shall:

(A**)** If authorized to use a teletherapy unit for medical use, perform full calibration measurements on each teletherapy unit:

(i) Before the first medical use of the unit, and

(ii) Before medical use under the following conditions:

(I) Whenever spot-check measurements indicate that the output differs by more than +\-5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay,

(II) Following replacement of the source or following reinstallation of the teletherapy unit in a new location, and

(III) Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly, and

(iii) At intervals not exceeding one (1) year;

(B) To satisfy the requirement of subparagraph (A) of this subdivision, full calibration measurements shall include determination of:

(i) The output within +/- 3 percent for the range of field sizes and for the distance or range of distances used for medical use,

(ii) The coincidence of the radiation field and the field indicated by the light beam localizing device,

(iii) The uniformity of the radiation field and its dependence on the orientation of the useful beam,

(iv) Timer accuracy and linearity over the range of use,

(v) On-off error, and

(vi) The accuracy of all distance measuring and localization devices in medical use;

(C) Use the dosimetry system described in subdivision (6)(A) of this subsection to measure the output for one set of exposure conditions. The remaining radiation measurements required in subparagraph (B)(i) of this subdivision may be made using a dosimetry system that indicates relative dose rates;

(D) Make full calibration measurements required by subparagraph (A) of this subdivision in accordance with published protocols accepted by nationally recognized bodies;

(E) Mathematically correct the outputs determined in subparagraph (B)(i) of this subdivision for physical decay for intervals not exceeding one (1) month for cobalt-60, six (6) months for cesium-137, or at intervals consistent with one percent decay for all other nuclides;

(F) Full calibration measurements required by subparagraph (A) of this subdivision and physical decay corrections required by subparagraph (E) of this subdivision shall be performed by the authorized medical physicist; and

(G) Retain a record of each calibration in accordance with subsection (jj)(21) of this section.

(8) Full calibration measurements on remote afterloader units. Each registrant or licensee shall:

(A) If authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit:

(i) Before the first medical use of the unit,

(ii) Before medical use under the following conditions:

(I) Following replacement of the source or following reinstallation of the unit in a new location outside the facility, and

(II) Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly,

(iii) At intervals not exceeding one quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds seventy five (75) days, and

(iv) At intervals not exceeding one (1) year for low dose-rate remote afterloader units;

(B) To satisfy the requirement of subparagraph (A) of this subdivision, full calibration measurements shall include, as applicable, determination of:

(i) The output within +/- 5 percent,

(ii) Source positioning accuracy to within +/- 1 millimeter,

(iii) Source retraction with backup battery upon power failure,

(iv) Length of the source transfer tubes,

(v) Timer accuracy and linearity over the typical range of use,

(vi) Length of the applicators, and

(vii) Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces;

(C) In addition to the requirements for full calibrations for low dose-rate remote afterloader units in subparagraph (B) of this subdivision, perform an autoradiograph of the source or sources to verify inventory and source(s) arrangement at intervals not exceeding one quarter;

(D) Use the dosimetry system described in subdivision (6)(A) of this section to measure the output;

(E) Make full calibration measurements required by subparagraph (A) of this subdivision in accordance with published protocols accepted by nationally recognized bodies;

(F) For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with subparagraphs (A) though (E) of this subdivision;

(G) Mathematically correct the outputs determined in subparagraph (B)(i) of this subdivision for physical decay at intervals consistent with +/- 1 percent physical decay;

(H) Full calibration measurements required by subparagraph (A) of this subdivision and physical decay corrections required by subparagraph (G) of this subdivision shall be performed by the authorized medical physicist; and

(I) Retain a record of each calibration in accordance with subdivision (kk)(21) of this section.

(9) Full calibration measurements on gamma stereotactic radiosurgery units. Each registrant or licensee shall:

(A) If authorized to use a gamma stereotactic radiosurgery unit for medical use, perform full calibration measurements on each unit:

(i) Before the first medical use of the unit,

(ii) Before medical use under the following conditions:

(I) Whenever spot-check measurements indicate that the output differs by more than five percent from the output obtained at the last full calibration corrected mathematically for radioactive decay,

(II) Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location, and

(III) Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly, and

(iii) At intervals not exceeding one (1) year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet;

(B) To satisfy the requirement of subparagraph (A) of this subdivision, full calibration measurements must include determination of:

(i) The output within +/-3 percent,

(ii) Relative helmet factors,

(iii) Isocenter coincidence,

(iv) Timer accuracy and linearity over the range of use,

(v) On-off error,

(vi) Trunnion centricity,

(vii) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off,

(viii) Helmet microswitchs,

(ix) Emergency timing circuits, and

(x) Stereotactic frames and localizing devices (trunnions);

(C) Use the dosimetry system described in subdivision (6)(A) of this subsection to measure the output for one set of exposure conditions. The remaining radiation measurements required in subparagraph (B)(i) of this subdivision may be made using a dosimetry system that indicates relative dose rates;

(D) Make full calibration measurements required by subparagraph (A) of this subdivision in accordance with published protocols accepted by nationally recognized bodies;

(E) Mathematically correct the outputs determined in subparagraph (B)(i) of this subdivision at intervals not exceeding one month for cobalt-60 and at intervals consistent with one percent physical decay for all other radionuclides; and

(F) Full calibration measurements required by subparagraph (A) of this subdivision and physical decay corrections required by subparagraph (E) of this subdivision shall be performed by the authorized medical physicist; and

(G) Retain a record of each calibration in accordance with subsection (jj)(21) of this section.

(10) Periodic spot-checks for teletherapy units. Each licensee or registrant shall:

(A) If authorized to use teletherapy units for medical use, perform output spot-checks on each teletherapy unit once in each calendar month that include determination of:

(i) Timer accuracy and timer linearity over the range of use,

(ii) On-off error,

(iii) The coincidence of the radiation field and the field indicated by the light beam localizing device,

(iv) The accuracy of all distance measuring and localization devices used for medical use,

(v) The output for one typical set of operating conditions measured with the dosimetry system described in subdivision (6)(B) of this subsection, and

(vi) The value obtained at last full calibration corrected mathematically for physical decay by calculating the difference between the measurement made in subparagraph (A)(v) of this subdivision and the anticipated output, expressed as a percentage of the anticipated output;

(B) Perform measurements required by subparagraph (A) of this subdivision in accordance with procedures established by the authorized medical physicist. The authorized medical physicist need not actually perform the spot check measurements;

(C) Have the authorized medical physicist review the results of each spot-check within fifteen (15) days. The authorized medical physicist shall promptly notify the registrant or licensee in writing of the results of each spot-check;

(D) If authorized to use a teletherapy unit for medical use, perform safety spot-checks of each teletherapy facility once in each calendar month and after each source installation to assure proper operation of:

(i) Electrical interlocks at each teletherapy room entrance,

(ii) Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism),

(iii) Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility,

(iv) Viewing and intercom systems,

(v) Treatment room doors from inside and outside the treatment room, and

(vi) Electrically assisted treatment room doors with the teletherapy unit electrical power turned off;

(E) If the results of the checks required in subparagraph (D) of this subdivision indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace or check the malfunctioning system; and

(F) Retain a record of each spot-check required by subparagraph (A) of this subdivision and subparagraph (D) of this subdivision, in accordance with subsection (jj)(22) of this section.

(11) Periodic spot-checks for remote afterloader units. Each registrant or licensee shall:

(A) If authorized to use remote afterloader units for medical use, perform spot-checks of each remote afterloader facility and on each unit:

(i) At the beginning of each day of use of a high dose-rate, medium dose-rate or pulsed dose-rate remote afterloader unit,

(ii) Prior to each patient treatment with a low dose-rate remote afterloader unit, and

(iii) After each source installation;

(B) Have the authorized medical physicist establish written procedures for performing the spot-checks required in subparagraph (A) of this subdivision. The authorized medical physicist need not actually perform the spot-check measurements;

(C) Have the authorized medical physicist review the results of each spot-check within fifteen (15) days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot check;

(D) To satisfy the requirements of subparagraph (A) of this subdivision, spot-checks must, at a minimum, assure proper operation of:

(i) Electrical interlocks at each remote afterloader unit room entrance,

(ii) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility,

(iii) Viewing and intercom systems in each high dose-rate, medium dose-rate and pulsed dose-rate remote afterloader facility,

(iv) Emergency response equipment,

(v) Radiation monitors used to indicate the source position,

(vi) Timer accuracy,

(vii) Date and time in the unit's computer, and

(viii) Decayed source or sources activity in the unit's computer;

(E) If the results of the checks required in subparagraph (D) of this subdivision indicate the malfunction of any system, lock the control console in the off position and not use the unit except as may be necessary to repair, replace or check the malfunctioning system; and

(F) Retain a record of each check required by subparagraph (D) of this subdivision in accordance with subsection (jj)(23) of this section.

(12) Periodic spot-checks for gamma stereotactic radiosurgery units. Each licensee or registrant shall:

(A) If authorized to use a gamma stereotactic radiosurgery unit for medical use, perform spot-checks of each gamma stereotactic radiosurgery facility and on each unit:

(i) Monthly,

(ii) At the beginning of each day of use, and

(iii) After each source installation;

(B) Have the authorized medical physicist:

(i) Establish written procedures for performing the spot-checks required in subparagraph (A) of this subdivision, and

(ii) Review the results of each spot-check required by subparagraph (A)(i) of this subdivision within fifteen (15) days of the check. The authorized medical physicist need not actually perform the spot-check measurements.

The authorized medical physicist shall notify the registrant or licensee as soon as possible, in writing, of the results of the spot check;

(C) To satisfy the requirements of subparagraph (A)(i) of this subdivision spot-checks shall, at a minimum:

(i) Assure proper operation of:

(I) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off,

(II) Helmet microswitchs,

(III) Emergency timing circuits, and

(IV) Stereotactic frames and localizing devices (trunnions), and

(ii) Determine:

(I) The output for one typical set of operating conditions measured with the dosimetry system described in subdivision (6)(B) of this subsection,

(II) The difference between the measurement made in subparagraph (C)(ii)(I) of this subdivision and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay),

(III) Source output against computer calculation,

(IV) Timer accuracy and linearity over the range of use,

(V) On-off error, and

(VI) Trunnion centricity;

(D) To satisfy the requirements of subparagraphs (A)(ii) and (A)(iii) of this subdivision, spot-checks shall assure proper operation of:

(i) Electrical interlocks at each gamma stereotactic radiosurgery room entrance,

(ii) Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility,

(iii) Viewing and intercom systems,

(iv) Timer termination,

(v) Radiation monitors used to indicate room exposures, and

(vi) Emergency off buttons;

(E) Arrange for prompt repair of any system identified in subparagraph (C) of this subdivision that is not operating properly;

(F) If the results of the checks required in subparagraph (D) of this subdivision indicate the malfunction of any system, lock the control console in the off position and not use the unit except as may be necessary to repair, replace or check the malfunctioning system; and

(G) Retain a record of each check required by subparagraphs (C) and (D) of this subdivision in accordance with subsection (jj)(24) of this section.

(13) Additional technical requirements for mobile remote afterloader units. Each registrant or licensee shall:

(A) If providing mobile remote afterloader service:

(i) Check survey instruments for consistent response before medical use at each address of use or on each day of use, whichever is more frequent, and

(ii) Account for all sources before departure from a client's address of use;

(B) In addition to the periodic spot-checks required by subdivision (11) of this subsection, if authorized to use mobile afterloaders for medical use, perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks shall be made to verify the operation of:

(i) Electrical interlocks on treatment area access points,

(ii) Source exposure indicator lights on the remote afterloader unit, on the control console and in the facility,

(iii) Viewing and intercom systems,

(iv) Applicators, source transfer tubes and transfer tube-applicator interfaces,

(v) Radiation monitors used to indicate room exposures,

(vi) Source positioning accuracy, and

(vii) Radiation monitors used to indicate whether the source has returned to a safe shielded position;

(C) In addition to the requirements for checks in subparagraph (B) of this subdivision, ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use;

(D) If the results of the checks required in subparagraph (B) of this subdivision indicate the malfunction of any system, lock the control console in the off position and not use the unit except as may be necessary to repair, replace or check the malfunctioning system; and

(E) Retain a record of each check required by subparagraph (B) of this subdivision in accordance with subsection (jj)(25) of this section.

(14) Radiation surveys. Each registrant or licensee shall:

(A) In addition to the survey requirements in section 22a-153-2(h) of the Regulations of Connecticut State Agencies, perform surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source or sources in the shielded position does not exceed the levels stated in the Sealed Source and Device Registry;

(B) Make the survey required by subparagraph (A) of this subdivision at installation of a new source and following repairs to the source or sources shielding, the source or sources driving unit or other electronic or mechanical component that could expose the source, reduce the shielding around the source or sources or compromise the radiation safety of the unit or the source or sources; and

(C) Retain a record of the radiation surveys required by subparagraph (A) of this subdivision in accordance with subsection (jj)(26) of this section.

(15) Five-year inspection for teletherapy and gamma stereotactic radiosurgery units. Each registrant or licensee shall:

(A) Have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement or at intervals not to exceed five (5) years, whichever comes first, to assure proper functioning of the source exposure mechanism;

(B) Assure that inspection and servicing required by subparagraph (A) of this subdivision shall only be performed by persons specifically licensed to do so by the Commissioner, an Agreement State, a Licensing State or the Nuclear Regulatory Commission; and

(C) Record the inspection and servicing in accordance with subsection (jj)(27) of this section.

(16) Therapy-related computer systems. Each registrant or licensee shall perform acceptance testing on the treatment planning system in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

(A) The source-specific input parameters required by the dose calculation algorithm;

(B) The accuracy of dose, dwell time and treatment time calculations at representative points;

(C) The accuracy of isodose plots and graphic displays;

(D) The accuracy of the software used to determine radioactive source positions from radiographic images; and

(D) The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

(17) Training for use of remote afterloader units, teletherapy units and gamma sterotactic radiosurgery units. Except as provided in subsection (o) of this section, each registrant or licensee shall require an authorized user of a sealed source for a use authorized under subsection (hh)(1) of this section to be a physician who:

(A) Is certified by a medical specialty board whose certification process includes all of the requirements in subparagraph (B) of this subdivision and whose certification has been recognized by an Agreement State or the Nuclear Regulatory Commission; or

(B) Meets the following requirements:

(i) 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 two hundred (200) hours of classroom and laboratory training in the areas of radiation physics and instrumentation; radiation protection; mathematics pertaining to the use and measurement of radioactivity; and radiation biology,

(ii) Five hundred (500) hours of work experience, under the supervision of an authorized user who meets the requirements in this subdivision or equivalent Agreement State or Nuclear Regulatory Commission requirements at a medical institution, involving:

(I) Reviewing full calibration measurements and periodic spot checks,

(II) Preparing treatment plans and calculating treatment doses and times,

(III) Using administrative controls to prevent a medical event 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,

(V) Checking and using survey meters, and

(VI) Selecting the proper dose and how it is to be administered,

(iii) Three (3) years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in this subdivision or equivalent Agreement State or Nuclear Regulatory Commission requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by subparagraph (B)(ii) of this subdivision, and

(iv) Has obtained written certification, signed by a preceptor authorized user, who meets the requirements in this subdivision, equivalent Agreement State or Nuclear Regulatory Commission requirements, that the individual has satisfactorily completed the requirements in (B)(i) and (B)(ii) of this subdivision and has achieved a level of competency sufficient to function independently as an authorized user of the therapeutic medical unit for which the individual is requesting authorized user status.

(ii) Other medical uses of radioactive material or radiation from radioactive material. A registrant or licensee may use radioactive material or a radiation source approved for medical use that is not otherwise specifically addressed in this section if:

(1) The applicant, registrant or licensee has submitted the information required by subsection (c)(4) of this section; and

(2) The applicant, registrant or licensee has received written approval from the Nuclear Regulatory Commission, an Agreement State or Licensing State in a registration or license and uses the material in accordance with the applicable regulations and registration or license, specific conditions, the Nuclear Regulatory Commission, Agreement State or Licensing State considers necessary for the medical use of the material.

(jj) Records.

(1) Unless otherwise specified in this subsection, each registrant or licensee shall maintain any record required by this section for a period of five (5) years.

(2) Records of authority and responsibilities for radiation protection programs. Each registrant or licensee shall:

(A) Retain a record of actions taken by the registrant or licensee's management in accordance with subsection (e)(1) including a summary of the actions taken and a signature of licensee management;

(B) Retain a current copy of the authorities, duties and responsibilities of the Radiation Safety Officer as required by subsection (e)(4) of this section, and a signed copy of the Radiation Safety Officer's agreement to be responsible for implementing the radiation safety program, as required by subsection (e)(2) of this section with the signature of the Radiation Safety Officer and licensee management; and

(C) The minutes of each Radiation Safety Committee meeting held in accordance with subsection (e)(7) of this section shall include:

(i) The date of the meeting,

(ii) Members present,

(iii) Members absent, and

(iv) Summary of deliberations and discussions.

(3) Records of radiation protection program safety changes. Records made in accordance with subsection (f)(1) of this section shall include a copy of the old and new procedures, the effective date of the change and the signature of the licensee management that reviewed and approved the change.

(4) Records of medical events. Each registrant or licensee shall retain a record of any medical event reported in accordance with subsection (kk)(1) of this section and shall include the following information:

(A) The registrant or licensee's name;

(B) Names of the individuals involved;

(C) The social security number or other identification number if one has been assigned, of the individual who is the subject of the medical event;

(D) A brief description of the event indicating its cause;

(E) The effect, if any, on the individual; the actions, if any, taken, or planned, to prevent recurrence; and,

(F) Whether the licensee 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.

(5) Record of a dose to an embryo, fetus or a nursing child. A record of a dose to an embryo, fetus or a nursing child reported in accordance with subsection (kk)(2) of this section shall include the licensee's name, names of all the individuals involved, social security number or other identification number if one has been assigned to the pregnant individual or nursing child who is the subject of the event; a brief description of the event including the cause; the effect, if any, on the embryo, fetus or nursing child; the actions, if any, taken, or planned, to prevent recurrence; and whether the licensee notified the pregnant individual or mother or the mother's or child's responsible relative or guardian and, if not, whether such failure to notify was based on guidance from the referring physician.

(6) Records of calibrations of instruments used to measure the activity of unsealed radioactive material. Records of instrument calibrations required by subsection (q) of this section shall include the model and serial number of the instrument, the date of the calibration, the results of the calibration and the name of the individual who performed the calibration.

(7) Records of survey instrument calibrations. Records of survey instrument calibrations required by subsection (r) of this section shall include the model and serial number of the instrument, the date of the calibration, the results of the calibration and the name of the individual who performed the calibration.

(8) Records of dosages of unsealed radioactive material for medical use. Records of dosage determinations required by subsection (s) of this section shall include the radioactive drug; the patient's or human research subject's name, or identification number if one has been assigned; prescribed dosage; the determined dosage, or a notation that the total activity is less than 1.1 megabecquerel (30 μCi); the date and time of the dosage determination; and the name of the individual who determined the dosage.

(9) Records of possession of sealed sources and brachytherapy sources. Records of the semi-annual physical inventory of sealed sources and brachytherapy sources required by subsection (u)(4) of this section shall include the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its nominal activity, the location of each source, and the name of the individual who performed the inventory.

(10) Records of surveys for ambient radiation exposure rate. Records of each survey required by subsection (x) of this section shall include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

(11) Records of surveys for ambient radiation exposure rate. Records of each survey required by subsection (x) of this section shall include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

(A) Retain a record, signed by the authorized user, of the basis for authorizing the release of an individual, for five (5) years after the date of release; and

(B) Retain a record, for five (5) years after the date of release, that the instructions required by subsection (y) of this section were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 1 millisievert (0.1 rem).

(12) Records of decay-in-storage. Records of the disposal of licensed materials, as required by subsection (bb) of this section, shall include the date of the disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container and the name of the individual who performed the survey.

(13) Records of radionuclide purity. Records of the radionuclide contaminant concentration tests required by subsection (dd)(2) of this section shall include, for each measured elution of radionuclide used to prepare a radioactive drug, the ratio of the measures expressed as kilobecquerel of contaminant per megabecquerel of desired radionuclide (microcuries/millicurie), or microgram of contaminant per megabecquerel of desired radionuclide (microgram/millicurie), the time and date of the measurement and the name of the individual who made the measurement.

(14) Records of safety instruction and training. Records of safety instructions and training required by subsections (ee)(2), (ff)(4) and (t)(4) of this section shall include a list of the topics covered, the date of the instruction or training, the name or names of the attendee or attendees and the name or names of the individual or individuals who provided the instruction.

(15) Records of radiation surveys of patients and human research subjects. Records of the surveys required by subsections (ff)(2) and (hh)(2) of this section shall include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey.

(16) Records of brachytherapy source inventory. Records of brachytherapy source accountability required by subsection (ff)(3) of this section shall include:

(A) For temporary implants:

(i) The number and activity of sources removed from storage, the time and date they were removed from storage, the name of the individual who removed them from storage and the location of use; and

(ii) The number and activity of sources not implanted, the time and date they were returned to storage, and the name of the individual who returned them to storage; and

(B) For permanent implants:

(i) The number and activity of sources removed from storage, the date they were removed from storage, and the name of the individual who removed them from storage;

(ii) The number and activity of sources returned to storage, the date they were returned to storage, and the name of the individual who returned them to storage; and

(iii) The number and activity of sources permanently implanted in the patient or human research subject.

(17) Records of calibration measurements on brachytherapy sources. Records of the calibrations on brachytherapy sources required by subsection (ff)(6) of this section shall include the date of the calibration; the manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source; the source output or activity; source positioning accuracy within applicators; and the signature of the authorized medical physicist.

(18) Records of decay of strontium-90 sources for ophthalmic treatments. Records of the activity of a strontium-90 source required by subsection (ff)(6) of this section shall be maintained for the life of the source and shall include:

(A) The date and initial activity of the source as determined under subsection (ff)(6) of this section; and

(B) For each decay calculation, the date, the source activity and the signature of the authorized medical physicist.

(19) Records of installation, maintenance, adjustment and repair. Records of the installation, maintenance, adjustment and repair of remote afterloader units, teletherapy units and gamma stereotactic radiosurgery units required by subsection (hh)(3) of this section shall include the date, description of the service and name or names of the individual or individuals who performed the work.

(20) Records of dosimetry equipment.

(A) Records of the calibration, intercomparison and comparisons of dosimetry equipment done in accordance with subsection (hh)(6) of this section shall be retained for the duration of the registration or license; and

(B) For each calibration, intercomparison or comparison, each record shall include:

(i) The date,

(ii) The manufacturer's name, model numbers and serial numbers of the instruments that were calibrated, intercompared or compared as required by subsections (hh)(6)(A) and (B) of this section,

(iii) The correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison, and

(iv) The names of the individuals who performed the calibration, intercomparison or comparison.

(21) Records of teletherapy remote afterloader and gamma stereotactic radiosurgery full calibrations. Records of the teletherapy, remote afterloader and gamma stereotactic radiosurgery full calibrations required by subsections (hh)(7), (hh)(8) and (hh)(9) of this section shall include:

(A) The date of the calibration;

(B) The manufacturer's name, model number and serial number for the teletherapy, remote afterloader and gamma stereotactic radiosurgery unit(s), the source(s), and instruments used to calibrate the unit;

(C) The results and assessments of the full calibrations;

(D) The results of the autoradiograph required for low dose-rate remote afterloader units; and

(E) The signature of the authorized medical physicist who performed the full calibration.

(22) Records of periodic spot-checks for teletherapy units. Records of each periodic spot-check for teletherapy units required by subsection (hh)(10) of this section shall include:

(A) The date of the spot-check;

(B) The manufacturer's name, model number, and serial number for the teletherapy unit, source and instrument used to measure the output of the teletherapy unit;

(C) An assessment of timer linearity and constancy;

(D) The calculated on-off error;

(E) A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;

(F) The determined accuracy of each distance measuring and localization device;

(G) The difference between the anticipated output and the measured output;

(H) Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each source exposure indicator light, and the viewing and intercom system and doors; and

(I) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(23) Records of periodic spot-checks for remote afterloader units. Records of each spot-check for remote afterloader units required by subsection (hh)(11) of this section shall include, as applicable:

(A) The date of the spot-check;

(B) The manufacturer's name, model number and serial number for the remote afterloader unit and source;

(C) An assessment of timer accuracy;

(D) Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems and clock and decayed source activity in the unit's computer; and

(E) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(24) Records of periodic spot-checks for gamma stereotactic radiosurgery units. Records of each spot-check for gamma stereotactic radiosurgery units required by subsection (hh)(12) of this section shall include, as applicable:

(A) The date of the spot-check;

(B) The manufacturer's name, model number and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit;

(C) An assessment of timer linearity and accuracy;

(D) The calculated on-off error;

(E) A determination of trunnion centricity;

(F) The difference between the anticipated output and the measured output;

(G) An assessment of source output against computer calculations;

(H) Notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism and stereotactic frames and localizing devices (trunnions); and

(I) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(25) Records of additional technical requirements for mobile remote afterloader units. Records of each check for mobile remote afterloader units required by subsection (hh)(13) shall include:

(A) The date of the check;

(B) The manufacturer's name, model number and serial number of the remote afterloader unit;

(C) Notations accounting for all sources before the licensee departs from a facility;

(D) Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators and source transfer tubes, and source positioning accuracy; and

(E) The signature of the individual who performed the check.

(26) Records of surveys of therapeutic treatment units.

(A) Records of radiation surveys of treatment units made in accordance with subsection (hh)(14) of this section shall be maintained for the duration of use of the unit; and

(B) Each record shall include:

(i) The date of the measurements,

(ii) The manufacturer's name, model number and serial number of the treatment unit, source and instrument used to measure radiation levels,

(iii) Each dose rate measured around the source while the unit is in the off position and the average of all measurements, and

(iv) The signature of the individual who performed the test.

(27) Records of 5-year inspection for teletherapy and gamma stereotactic surgery units.

(A) Records of the 5-year inspections for teletherapy and gamma stereotactic radiosurgery units required by subsection (hh)(15) of this section shall be maintained for the duration of use of the unit; and

(B) Each record shall include:

(i) The inspector's radioactive materials license number,

(ii) The date of inspection,

(iii) The manufacturer's name and model number and serial number of both the treatment unit and source,

(iv) A list of components inspected and serviced, and the type of service, and

(v) The signature of the inspector.

(kk) Reports.

(1) Reports and notifications of medical events. Each licensee or registrant shall:

(A) Other than events that result from intervention by a patient or human research subject, report any event in which the administration of radioactive material or radiation from radioactive material results in:

(i) A dose that differs from the prescribed dose by more than 0.05 Sievert (5 rem) effective dose equivalent, 0.5 Sievert (50 rem) to an organ or tissue, or 0.5 Sievert (50 rem) shallow dose equivalent to the skin; and either:

(I) The total dose delivered differs from the prescribed dose by 20 percent or more,

(II) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range, or

(III) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more,

(ii) A dose that exceeds 0.05 Sievert (5 rem) effective dose equivalent, 0.5 Sievert (50 rem) to an organ or tissue or 0.5 Sievert (50 rem) shallow dose equivalent to the skin from any of the following:

(I) An administration of a wrong radioactive drug,

(II) An administration of a radioactive drug containing radioactive material by the wrong route of administration,

(III) An administration of a dose or dosage to the wrong individual or human research subject,

(IV) An administration of a dose or dosage delivered by the wrong mode of treatment, or

(V) A leaking sealed source, and

(iii) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sievert (50 rem) to an organ or tissue and 50 percent of the dose expected from the administration defined in the written directive, excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site;

(B) Report any event resulting from intervention of a patient or human research subject in which the administration of radioactive material or radiation from radioactive material results, or will result in, unintended permanent functional damage to an organ or a physiological system, as determined by a physician;

(C) Notify the Commissioner by telephone no later than the next calendar day after discovery of the medical event;

(D) Submit a written report to the Commissioner within fifteen (15) days after discovery of the medical event, as follows:

(i) The written report shall include:

(I) The licensee's name,

(II) The name of the prescribing physician,

(III) A brief description of the event,

(IV) Why the event occurred,

(V) The effect, if any, on the individual who received the administration,

(VI) Actions, if any, that have been taken, or are planned, to prevent recurrence, and

(VII) Certification that the registrant or licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not, and

(ii) The report shall not contain the individual's name or any other information that could lead to identification of the individual,

(E) Provide notification of any medical event not caused by the individual who is the subject of the medical event to the referring physician and also notify the individual who is the subject of the medical event no later than twenty four (24) hours after its discovery, unless the referring physician personally informs the registrant or licensee either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The registrant or licensee 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 or licensee shall notify the individual as soon as possible thereafter. The registrant or licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of this paragraph, the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the registrant or licensee shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the registrant or licensee upon request. The registrant or licensee shall provide such a written description if requested;

(F) Aside from the notification requirement, nothing in this section affects any rights or duties of registrants, licensees and physicians in relation to each other, to individuals affected by the medical event or to that individual's responsible relatives or guardians; and

(G) Retain a record of a medical event in accordance with subsection (jj)(4) of this section. A copy of the record required under subsection (jj)(4) of this section shall be provided to the referring physician if other than the registrant or licensee, within fifteen (15) days after discovery of the medical event.

(2) Report and notification of a dose to an embryo, fetus or a nursing child. Each licensee or registrant shall:

(A) Report any dose to an embryo or fetus that is greater than 5 millisievert (500 mrem) dose equivalent that is a result of an administration of radioactive material

or radiation from radioactive material to a pregnant individual unless the dose to the embryo or fetus was specifically approved, in advance, by the authorized user;

(B) Report any dose to a nursing child that was not specifically approved, in advance, by the authorized user, that is a result of an administration of radioactive material to a breast feeding individual that:

(i) Is greater than 5 millisievert (500 mrem) total effective dose equivalent, or

(ii) Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician;

(C) Notify the Commissioner by telephone no later than the next calendar day after discovery of a dose to the embryo, fetus or nursing child that requires a report in subdivision (2)(A) or (2)(B) of this subsection;

(D) The licensee shall submit a written report to the Commissioner within fifteen (15) days after discovery of a dose to the embryo, fetus or nursing child that requires a report in subdivision (2)(A) or (2)(B) of this subsection:

(i) The written report shall include:

(I) The registrant or licensee's name,

(II) The name of the prescribing physician,

(III) A brief description of the event,

(IV) Why the event occurred,

(V) The effect on the embryo, fetus or the nursing child,

(VI) What actions, if any, have been taken, or are planned, to prevent recurrence, and

(VII) Certification that the registrant or licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not, and

(ii) The report shall not contain the individual's or child's name or any other information that could lead to identification of the individual or child;

(E) Notify the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than twenty four (24) hours after discovery of an event that would require reporting under subdivision (2)(A) or (2)(B) of this subsection, unless the referring physician personally informs the

registrant or licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. The registrant or licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within twenty four (24) hours, the registrant or licensee shall make the appropriate notifications as soon as possible thereafter. The registrant or licensee may not delay any appropriate medical care for the embryo, fetus or the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this paragraph, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother, when appropriate. If a verbal notification is made, the registrant or licensee shall inform the mother, or the mother's or child's responsible relative or guardian that a written description of the event can be obtained from the registrant or licensee upon request. The registrant or licensee shall provide such a written description if requested; and

(F) Retain a record of a dose to an embryo, fetus or a nursing child in accordance with subsection (jj)(5) of this section. A copy of the record required under subsection (jj)(5) of this section shall be provided to the referring physician, if other than the registrant or licensee, within fifteen (15) days after discovery of the event.

(3) Reports of leaking sources. A registrant or licensee shall file a report with the Commissioner within five (5) days if a leakage test required by subsection (u) of this section reveals the presence of 185 Becquerel (0.005 μCi) or more of removable contamination. The written report shall include the model number and serial number if assigned, of the leaking source; the radionuclide and its estimated activity; the results of the test; the date of the test; and the action taken.

(4) Reports of patient departure prior to authorized release. Each registrant or licensee shall:

(A) Notify the Commissioner by telephone immediately upon discovery that a patient or human research subject has departed from the registrant or licensee's facility without authorization under subsection (y) of this section; and

(B) Submit a written report to the Commissioner within thirty (30) days after discovery of the unauthorized departure. The written report shall include:

(i) The registrant or licensee's name,

(ii) The date and time of the unauthorized departure,

(iii) The projected date and time when release would have occurred,

(iv) The radionuclide, chemical and physical form and calculated activity at time of release, and

(v) The apparent reason or reasons for the departure prior to authorized release.

(5) Notification of deceased patients or human research subjects containing radioactive material. Each registrant or licensee shall:

(A) Notify the Commissioner by telephone immediately upon discovery that a patient or human research subject containing radioactive material has died, when it is possible that any individual could receive exposures in excess of section 22a-153-2(f) of the Regulations of Connecticut State Agencies as a result of the deceased's body; and

(B) Submit a written report to the Commissioner within 30 days after discovery that the patient or human research subject referenced in subdivision (2)(A) of this subsection has died. The written report shall include:

(i) The registrant or licensee's name,

(ii) The date of death, and

(iii) The radionuclide, chemical and physical form and calculated activity at time of death.

The Regulations of Connecticut State Agencies are amended by adding section 22a-153-9, as follows:

(NEW)

Sec. 22a-153-9. Decommissioning

(a) Definitions. For the purposes of this section:

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

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

(3) "Decommissioning plan" means a written document that includes the licensee's planned procedures and activities for decommissioning of the facility or site.

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

(5) "Facility" means the location within one building, vehicle, or under one roof and under the same administrative control (1) at which the possession, use, processing or storage of radioactive material is or was authorized or (2) at which one or more radiation-producing machines or radioactivity-inducing machines are installed or located. "Facility" may also mean multiple such locations at a site or part of a site.

(6) "Final radiation survey" means the survey of the facility or site after decommissioning activities have been completed during which the determination is made by the licensee that the facility or site meets the department's release criteria.

(7) "Licensee" means any person who is licensed by the department. For purposes of this section, the term "Licensee" also means any person who is responsible for decommissioning by being registered with the department, being subject to a record of possession of a radiation source or device or being otherwise legally obligated to conduct decommissioning activities in accordance with these regulations.

(8) "Principal activity" means an activity authorized by the license which is essential to achieving the purpose(s) for which the license was issued or amended. Storage during which no licensed material is accessed for use or disposal and activity incidental to decontamination or decommissioning are not principal activities.

(9) "Residual radioactivity" means radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the license's control. This includes radioactivity

from all licensed and unlicensed sources used by the licensee, but excludes background radiation. It also includes radioactive materials remaining at the site as a result of routine or accidental releases of radioactive material at the site and previous burials at the site.

(10) "Restricted use" means that a limit or control has been placed on future use of the facility and the facility is no longer under the control of the licensee, registrant, of holder of the record of possession.

(11) "Unrestricted use" means that the facility or area may be used by individuals for any purpose without limits or controls. The facility or area is no longer under the control of the licensee, registrant, or holder of the record of possession.

(b) Decommissioning timeliness.

(1) Each licensee or person in possession of a non-exempt source of radiation who decides to terminate all activities involving that source of radiation shall notify the department immediately, in writing.

(2) Each licensee or person responsible for a facility or site which includes a non-exempt source of radiation or which may be contaminated by residual radioactivity shall, no less than 30 days before vacating or relinquishing possession or control of the facility or site, notify the department in writing of the intent to vacate.

(3) The licensee shall notify the department in writing within 60 days of the occurrence of any of the following:

(A) The licensee has decided to permanently cease principal activities at the entire site or in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with these regulations;

(B) No principal activities under the license have been conducted for a period of 24 months; or,

(C) No principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with these regulations.

(4) From the date of notification of the department required in subdivision (1) and (2) of this subsection, the licensee shall either:

(A) Begin decommissioning activities; or

(B) Within 12 months of notification, submit a decommissioning plan, if required by subsection (b) of this section, and begin decommissioning upon department approval of that plan.

(5) The department may approve an alternate schedule for the submission of plans and for the completion of decommissioning as required pursuant to subdivision (1) and (2) of this subsection if the department determines that the alternate schedule (1) is necessary to effectively conduct decommissioning, (2) presents no undue risks to public health and safety, and (3) is otherwise in the public interest. The schedule for decommissioning may not commence until the department has made a determination on the request.

(c) Decommissioning plan.

(1) A licensee shall submit a decommissioning plan if:

(A) the licensee intends to terminate the license using radiological criteria specified in subsection (f) of this section or subsection (g) of this section;

(B) otherwise required by these regulations;

(C) required by license condition; or

(D) the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area have not been previously approved by the department and these procedures could increase potential health and safety impacts to workers or to the public, such as in any of the following cases:

(i) Procedures would involve techniques not applied routinely during cleanup or maintenance operations;

(ii) Workers would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during the operation for which the license was issued;

(iii) Procedures could result in significantly greater airborne concentrations of radioactive materials than are present during operation; or

(iv) Procedures could result in significantly greater releases of radioactive material to the environment than those associated with the operation for which the license was issued.

(2) Procedures with potential health and safety impacts shall not be carried out prior to approval of the decommissioning plan.

(3) The proposed decommissioning plan for the facility or site (or separate building or outdoor area) shall include:

(A) A description of the conditions of the facility or site sufficient to evaluate the acceptability of the plan;

(B) A description of planned decommissioning activities;

(C) A description of methods used to ensure protection of workers and the environment against radiation hazards during decommissioning;

(D) A description of the radiation survey planned to demonstrate compliance with subsection (d)(4) and subsection (e)(1) of this section (or if applicable, subsection (f) of this section or subsection (g) of this section); and,

(E) An updated detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and a plan for assuring the availability of adequate funds for completion of decommissioning.

(4) For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, the plan shall include a justification for the delay. The proposed decommissioning plan shall be approved by the department if the information therein demonstrates that the decommissioning will be completed as soon as practicable and that the health and safety of workers and the public will be adequately protected.

(d) Completion of decommissioning.

(1) The licensee shall complete decommissioning of the facility or site as soon as practicable but no later than 24 months following the initiation of decommissioning, unless an alternate schedule addressing the factors in subdivision (3) of this subsection is requested with written justification and approved by the department.

(2) When decommissioning involves the entire site, the licensee shall request license termination upon completion of decommissioning activities.

(3) For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, the plan shall include a justification for the decommissioning schedule warranted by consideration of the following:

(A) Whether it is technically feasible to complete decommissioning within the allotted 24-month period;

(B) Whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 24-month period;

(C) Whether a significant volume reduction in wastes requiring disposal will be achieved by allowing short-lived radionuclides to decay;

(D) Whether a significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay; and,

(E) Other site-specific factors which the department may consider appropriate on a case-by-case basis, such as the regulatory requirements of other government agencies, lawsuits, groundwater treatment activities, monitored natural ground-water restoration, actions that could result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensee.

(4) As the final step in decommissioning, the licensee shall:

(A) Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey unless the licensee demonstrates that the premises are suitable for release in some other manner. The licensee shall, as appropriate:

(i) Report levels of gamma radiation in units of millisieverts (or microroentgens) per hour at one meter from surfaces, and report levels of radioactivity, including alpha and beta, in units of megabecquerels (or disintegrations per minute or microcuries) per 100 square centimeters - removable and fixed - for surfaces, megabecquerels (or microcuries) per milliliter for water, and becquerels (or picocuries) per gram for solids such as soils or concrete; and

(ii) Specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.

(B) Certify the disposition of all licensed material including accumulated wastes, by submitting a completed department Form T or equivalent information.

(e) Termination of a license without restriction.

(1) A site shall be considered acceptable for unrestricted use if the residual radioactivity that is distinguishable from background radiation results in a TEDE to an average member of the critical group that does not exceed 0.19 millisievert (19 mrem) per year, including that from groundwater sources of drinking water, and the residual radioactivity has been reduced to levels that are as low as reasonably achievable (ALARA). Determination of the levels which are ALARA must take into account consideration of any detriments, such as deaths from transportation accidents, expected to potentially result from decontamination and waste disposal.

(2) Licenses or registrations shall be terminated upon written notice to the licensee when the department determines that:

(A) Radioactive material has been properly disposed;

(B) Reasonable effort has been made to eliminate residual radioactive contamination, if present; and

(C) Documentation is provided to the department that:

(i) A radiation survey has been performed which demonstrates that the premises are

suitable for release in accordance with department requirements; or

(ii) Other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with department requirements.

(f) License termination under restricted conditions. No decommissioning plan for restricted use shall be accepted by the department unless it can be demonstrated that the requirements in subsection (e) of this section cannot be met. A site shall be considered acceptable for license termination under restricted conditions if:

(1) The licensee can demonstrate that further reductions in residual radioactivity necessary to comply with the provisions of subsection (e)(1) of this section would result in net public or environmental harm or were not being made because the residual levels associated with restricted conditions are ALARA. Determination of the levels which are ALARA must take into account consideration of any detriments, such as traffic accidents, expected to potentially result from decontamination and waste disposal;

(2) The licensee has made provisions for legally enforceable institutional controls that provide reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 0.19 millisievert (19 mrem) per year, including that from groundwater sources of drinking water;

(3) 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:

(A) Funds placed into an account segregated from the licensee's assets and outside the licensee's administrative control as described in 10 CFR 30.35(f)(1);

(B) Surety method, insurance, or other guarantee method as described in 10 CFR 30.35(f)(2);

(C) A statement of intent in the case of Federal, State, or local Government licensees, as described in 10 CFR 30.35(f)(4); or

(D) When a governmental entity is assuming custody and ownership of a site, an arrangement that is deemed acceptable by such governmental entity;

(4) The licensee has submitted a decommissioning plan to the department indicating the licensee's intent to decommission in accordance with section 22a-153-9 and specifying that the licensee intends to decommission by restricting use of the site. The licensee shall document in the decommissioning plan how the advice of individuals and institutions in the community who may be affected by the decommissioning has been sought and incorporated, as appropriate, following analysis of that advice;

(A) Licensees proposing to decommission by restricting use of the site shall seek advice from

such affected parties regarding the following matters concerning the proposed decommissioning:

(i) Whether provisions for institutional controls proposed by the licensee:

(I) Will provide reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group will not exceed the applicable limit in section 22a-153-2 of these regulations;

(II) Will be enforceable; and

(III) Will not impose undue burdens on the local community or other affected parties; and

(ii) Whether 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; and

(B) In seeking advice on the issues identified in subsection (f)(4)(A) of this section, the licensee shall provide for:

(i) Participation by representatives of a broad cross section of community interests who may be affected by the decommissioning;

(ii) An opportunity for a comprehensive, collective discussion on the issues by the participants represented; and

(iii) A publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues;

(5) Residual radioactivity at the site shall be reduced so that if the institutional controls were no longer in effect, there is reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group is as low as reasonably achievable and would not exceed either:

(A) 1 millisievert (100 mrem) per year; or

(B) 5 millisievert (500 mrem) per year provided the licensee:

(i) Demonstrates that further reductions in residual radioactivity necessary to comply with the 1 millisievert/year (100 mrem/y) value of subsection (f)(5)(A) of this section are not technically achievable, would be prohibitively expensive, or would result in net public or environmental harm;

(ii) Makes provisions for durable institutional controls; and

(iii) Provides sufficient financial assurance to enable a responsible government entity or independent third party, including a governmental custodian of a site, both to carry out periodic rechecks of the site no less frequently than every 5 years to assure that the institutional controls remain in place as necessary to meet the criteria of subsection (f)(2) of this section and to assume and carry out responsibilities for any necessary control and maintenance of those controls. Acceptable financial assurance mechanisms are those in subsection (f)(3) of this section.

(g) Alternate criteria for license termination.

(1) The department may terminate a license using alternate criteria greater than the dose criteria of subsection (f)(2) of this section and subsection (f)(4)(A)(i)(I) of this section, if the licensee:

(A) Provides assurance that public health and safety would continue to be protected, and that it is unlikely that the dose from all man-made sources combined, other than medical, could be more than the 1 millisievert/year (100 mrem/y) limit of section 22a-153-2 of these regulations, by submitting an analysis of possible sources of exposure;

(B) Has employed, to the extent practical, restrictions on site use according to the provisions of subsection (f) of this section in minimizing exposures at the site;

(C) Reduces doses to ALARA levels, taking into consideration any detriments such as traffic accidents expected to potentially result from decontamination and waste disposal; and

(D) Has submitted a decommissioning plan to the department indicating the licensee's intent to decommission in accordance section 22a-153-9 and specifying that the licensee proposes to decommission by use of alternate criteria. The licensee shall document in the decommissioning plan how the advice of individuals and institutions in the community who may be affected by the decommissioning has been sought and addressed, as appropriate, following analysis of that advice. In seeking such advice, the licensee shall provide for:

(i) Participation by representatives of a broad cross section of community interests who may be affected by the decommissioning;

(ii) An opportunity for a comprehensive, collective discussion on the issues by the participants represented; and

(iii) A publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues.

(2) The use of alternate criteria to terminate a license requires the approval of the department after consideration of the staff's recommendations that will address any comments provided by federal, state and local governments and any public comments submitted pursuant to subsection (h) of this section.

(h) Public notification and public participation. Upon the receipt of a decommissioning plan from the licensee, or a proposal by the licensee for release of a site pursuant to subsection (f) or (g) of this section, or whenever the department deems such notice to be in the public interest, the department shall:

(1) Notify and solicit comments from:

(A) Local and state governments in the vicinity of the site and any Indian Nation or other indigenous people that have treaty or statutory rights that could be affected by the decommissioning; and

(B) The Environmental Protection Agency for cases where the licensee proposes to release a site pursuant to subsection (g) of this section.

(2) Publish a notice in a forum, such as local newspapers, letters to state or local organizations, or other appropriate forum, that is readily accessible to individuals in the vicinity of the site, and solicit comments from affected parties.

(i) Applicability of decommissioning criteria following license termination. After a site has been decommissioned and the license terminated in accordance with the criteria in section 22a-153-9, the department will require additional cleanup only if, based on new information, the department determines that the criteria of this section were not met and residual radioactivity remaining at the site could result in significant threat to public health and safety.

Statement of Purpose: This proposed new regulation adopts rules for the use, production, transportation, possession, storage and disposal of ionizing radiation. These proposed changes are based upon model regulations from the Conference of Radiation Control Program Directors. They ensure consistency and standardization of work practices surrounding ionizing radiation. Furthermore, they make the state and federal regulations substantially the same, allowing the regulated community one set of standards to comply with.

The Department's ionizing radiation regulations haven't been revised since the early 1970's. The technology changes that have occurred since then are addressed in this proposal protecting public health and the environment from the deleterious effects of ionizing radiation.

Currently, the Department registers users of ionizing radiation. These proposed regulatory amendments have been written to support our current framework for the control of ionizing radiation and can also be used to support the Nuclear Regulatory Commission's Agreement State Program for licensing radioactive material.