SUMMARY OF EXPRESS TERMS

The regulatory proposal would repeal and replace all sections within Part 16 of Title 10 of the New York Codes, Rules and Regulations (NYCRR), as described in more detail below.

Section 16.1 is updated to correct references to other agencies and persons exempted under Title 10 of the Code of Federal Regulations (CFR) Part 30.

Section 16.2 is updated to include numerous new definitions used in 10 CFR Part 30, as well as other definitions related to new technologies, updated units and clarification of terms.

Section 16.4 updates appendix references, including changing the reference from 10 NYCRR Part 16 to application sections within 10 CFR Part 30.

Section 16.5 updates responsibilities for radiation safety to include acceptance testing and annual program review requirements.

Section 16.6 makes updates to the requirements for evaluating prior occupational doses and removes provisions on planned special exposures. The term “eye dose” is replaced by “lens dose.”

Section 16.7 updates dose limits for members of the public to reflect current Title 10 CFR references and outdated language is removed or updated.

Section 16.10 is amended to update inspection schedules, add Certified Radiation Equipment Safety Officer (CRESO) program requirements, and update requirements for surveys and testing of sealed sources.

Section 16.11 is updated to reflect changes in terminology for personnel monitoring and to clarify dose limits.

Sections 16.12, 16.13 and 16.15 are all updated to reflect 10 CFR Part 30 references instead of references to 10 NYCRR Part 16, as well as to clarify the actual language and phrasing used within these sections.

Section 16.14 is updated to require recording of high patient doses from fluoroscopy and notification of referring physician and instructions to patient.

Sections 16.16 and 16.17 are updated for compatibility with 10 CFR Part 30 requirements.

Section 16.19, concerning limitations on application of radiation to humans, is updated to reflect changes in the use of radioactive materials especially therapeutic sources.

Section 16.22 is updated to remove the requirement for mammography screening programs to teach breast self-examination.

Section 16.23 is updated to require quality assurance (QA) programs for advanced modality dental and podiatry, to require radiation safety policies regarding patient fluoroscopy doses and neonatal imaging, to update specifications for modern imaging modalities, and to update breast imaging QA requirements.

Section 16.24 is updated to reflect updates to QA requirements and verification of radiation therapy treatments.

Section 16.26 is updated to incorporate by reference the current federal regulation from the U.S. Nuclear Regulatory Commission (NRC).

Sections 16.40 and16.41 are updated to reflect new fee schedules and to incorporate NYS Department of Labor (DOL) fee categories.

Section 16.50 is updated to correctly reference the New York City Department of Health and Mental Hygiene (NYC DOHMH), change registration periods to allow more flexibility, and include commercial requirements previously listed within DOL regulations.

Section 16.51 is updated to include several items in the prohibited uses of radiation equipment, and half-value layer tables were updated to be current with federal manufacturing requirements (21 CFR Part 1020) for equipment listed in sections 16.52 through 16.70 of Title 10 of the NYCRR.

Sections 16.52, 16.54 and 16.55 are updated to include specifications for hand-held units and Cone Beam Computed Tomography (CBCT) as well as updates to filtration requirements. Requirements for gonadal shielding have also been removed.

Section 16.53 is updated to include changes for handheld intra-oral radiographic equipment.

Section 16.58 is updated to include new specifications for display of air kerma and minimum source to skin distance, to be consistent with federal manufacturing requirements (21 CFR Part 1020).

Sections 16.60 and 16.61 are updated to reflect current technologies and therapy equipment operated at potentials over and below 60 kV.

Section 16.65 is a new section regarding CBCT quality assurance, physicist testing, and accreditation requirements.

Section 16.101, concerning licensure, is updated to incorporate references to the CFR. Although no additional requirements are being added, elements of 10 CFR Part 31 and the Appendices to Part 16 are now included herein.

Section 16.102 is updated to add a paragraph on authorizing the Department to inspect a facility prior to the issuance of a license and adds a paragraph requiring an emergency plan for licensees that possess large amounts of dispersible radioactive material. This was previously codified in DOL regulations under 12 NYCRR Part 38. This section also adds conditions for consortiums to share accelerator produced isotopes.

Section 16.103, concerning licensing requirements for radioactive materials, incorporates by reference various provisions within 10 CFR Parts 30, 40, and 70 for licensing requirements. Currently these requirements are only incorporated into license conditions but not NYS regulations.

Section 16.104 adds requirements on portable gauge security, consortiums, and breakthrough limits for generators.

Section 16.109 adds reciprocity agreement provisions with other Agreement States, which were previously codified in DOL regulations within 12 NYCRR Part 38. This new section will also allow a licensee to pay a fee to work in New York for up to 180 days each year, instead of only allowing licensees to work 30 days each year but at no charge.

Section 16.112 is updated to add requirements for increased security for certain amounts of radioactive material, as required by 10 CFR Part 37.

Sections 16.113 and 16.114 add requirements for decommissioning and financial assurance.

Section 16.123 updates medical use requirements for specific licenses for certain medical uses of byproduct materials, to be compatible with Federal regulations.

Section 16.124 is a new section that adds manufacturing requirements for licenses to manufacture or transfer certain items containing radioactive material.

Section 16.125 is a new section that adds additional requirements for the manufacture, preparation or transfer for commercial distribution of medical drugs containing radioactive material.

Section 16.126 adds a new requirement for sealed source and device registration.

Section 16.127 adds a new section governing licenses for industrial radiography as well as radiation safety requirements for industrial radiographic operations.

Section 16.128 adds a new section for well logging.

Section 16.129 adds a new section for panoramic irradiators.

Pursuant to the authority vested in the Commissioner of Health by section 7 of Part B of Chapter 58 of the Laws of 2006, Part 38 of Title 12 (Labor) of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) is hereby repealed, and pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by Section 225 of the Public Health Law, sections 16.0 through 16.200 of Part 16 of Title 10 (Health) of the NYCRR are hereby repealed and replaced, to be effective upon filing a Notice of Adoption in the New York State Register, to read as follows:

Part 16 - Ionizing Radiation

Section 16.0 Introductory note.

This Part applies to all radiation equipment and radioactive material within the jurisdiction of the New York State Department of Health. Sections of this Part set forth under the heading "General Provisions" (sections 16.1-16.26) contain provisions applicable to radiation equipment operators and persons in possession of radioactive materials, including general radiation protection requirements.

Sections of this Part set forth under the heading "Radiation Equipment" (sections 16.50-16.63) contain the registration provisions for radiation equipment and general and additional radiation protection requirements applicable only to specific radiation equipment.

Sections of this Part set forth under the heading "Licensing of Radioactive Materials" (sections 16.100-16.123) contain the licensing provisions for radioactive materials, i.e., byproduct

material, source material, special nuclear material in quantities not sufficient to form a critical mass, naturally occurring radioactive materials, and accelerator-produced radioactive material. Section 16.150, "Radon testing and reporting", contains provisions applicable to firms performing radon measurements and mitigations in the State of New York.

Section 16.200, "Material incorporated by reference," provides a list of federal rules and regulations also related to the regulation of ionizing radiation.

GENERAL PROVISIONS

16.1 Applicability and inapplicability of this Part.

(a) Applicability. Except as otherwise provided in subdivision (b) of this section, this Part applies to any person who transfers, receives, possesses or uses any radiation source in this State. The types of installations to which this Part is generally applicable are described in the definition of "radiation installation" in section 16.2 of this Part.

(b) Inapplicability.

(1) This Part does not apply to any common or contract carrier operating within this State to the extent that such carrier is subject to regulation as provided for by law by the United States Department of Transportation or other agencies of the United States or agencies of the State of New York, other than the Department of Health, having jurisdiction.

(2) The licensure requirements contained in sections 16.100 through 16.110 and sections 16.120 through 16.123 of this Part shall not apply in a county, part-county or city health district having a population of more than 2,000,000 people, provided that such health district has established its

own substitute licensure requirements with respect to radiation sources located within such health district and transferred, received, possessed or used by persons other than the State and its institutions or other facilities and provided that such substitute licensure requirements are submitted to the State Department of Health prior to their effective date and are acceptable to the State Department of Health as consistent with the corresponding requirements of this Part.

(3) Persons described in 10 CFR 30.12 & 30.13, are exempt from this Part to the same extent provided for in 10 CFR 30, as revised and implemented in full on October 16, 2020.

(4) All discharges of wastes to the environment are subject to the provisions of the Environmental Conservation Law with particular reference to Article 17 (water pollution control), Article 19 (air pollution control) and Article 27 (collection, treatment and disposal of refuse and other solid waste) thereof, and to all pertinent rules and regulations of the State Department of Environmental Conservation, including its permit requirements.

(c) Communications. Except as otherwise provided for in this Part or authorized by the department, all applications, notifications or other communications filed pursuant to this Part shall be addressed to the New York State Department of Health, Bureau of Environmental Radiation Protection, Empire State Plaza, Albany, NY 12237, by telephone (518) 402-7550, facsimile (518) 402-7554 or email to berp@health.ny.gov. Registrants and licensees that are authorized to operate pursuant to Article 28 of the Public Health Law may comply with adverse event reporting required by this Part by electronic filing with the department via the New York Patient Occurrence and Tracking System (NYPORTS).

16.2 Definitions.

(a) As used in this Part, unless the context indicates otherwise, the terms below shall have the following meanings:

(1) "A_1" means the maximum activity of special form radioactive material permitted in a Type A package. "A_2" means the maximum activity of radioactive material, other than special form radioactive material, permitted in a Type A package. These values are either listed or may be derived in accordance with the procedure prescribed in 10 CFR 71 appendix A, as revised and implemented in full on November 30, 2021.

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

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

(4) "Acceptance Test" is an evaluation of medical equipment and software to verify proper function prior to clinical use. Acceptance testing includes but is not limited to image quality, radiation dose, and radiation protection.

(5) "Accessible surface" means surface of equipment or of an equipment part that can be easily or accidentally touched by persons without the use of a tool.

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

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

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

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

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

(11) "Airborne radioactivity area" means a room, enclosure, or area in which airborne radioactive materials, composed wholly or partly of licensed material, exist in concentrations:
(i) in excess of the derived air concentrations (DACs) specified in appendix B to 10 CFR 20, as revised and implemented in full on December 19, 2002, or
(ii) 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.

(12) “Air kerma” or “AK” means kerma in air (see definition of Kerma (under paragraph (99) of this subdivision.)

(13) “Air kerma rate” or “AKR” means the air kerma (see definition of Kerma (under paragraph (99) of this subdivision) per unit time.

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

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

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

(17) "Aluminum equivalent" means the thickness of aluminum affording the same attenuation, under specified conditions, as the material in question.

(18) "Annual limit on intake" or “ALI” means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent of 0.05 Sv (5 rem) or a committed dose equivalent of 0.5 Sv (50 rem) to any individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are given in appendix B to 10 CFR 20, as revised and implemented in full on December 19, 2002.

(19) "Annually" means either at intervals not to exceed 1 year or, once per year at about the same time each year (plus or minus 1 month).

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

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

(22) “Authorized licensing authority” means the New York State Department of Health, the New York City Department of Health and Mental Hygiene, an Agreement State, or the United States Nuclear Regulatory Commission.

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

(24) "Becquerel" or “Bq” means the SI unit of activity. One becquerel is equal to one disintegration or transformation per second (s^{-1}).

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

(26) "Bone densitometer" means a device intended for medical purposes to measure bone density and mineral content by x-ray or gamma ray transmission measurements through the bone and

adjacent tissues. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(27) “Broad scope license” or “specific license of broad scope” means a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of the radioactive material specified in the license, but not exceeding quantities specified in the license, for any authorized purposes. This type of license is subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee’s radiation safety committee.

(28) “Byproduct material” means:

(i) 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;

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

(iii) any discrete source of radium-226 produced, extracted, or converted for extraction for use for a commercial, medical, or research activity;

(iv) any material that has been made radioactive by use of a particle accelerator and is produced, extracted, or converted after extraction for use for a commercial, medical, or research activity;

(v) any discrete source of naturally occurring radioactive material, other than source material, that is extracted or converted after extraction for use in a commercial medical or research activity that the Nuclear Regulatory Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security is extracted or converted after extraction for use in a commercial, medical, or research activity.

(29) "Calendar quarter" means not less than 12 consecutive weeks or more than 14 consecutive weeks. The first calendar quarter of each year shall begin in January and subsequent calendar quarters shall be so arranged such that no day is included in more than one calendar quarter and no day in any one year is omitted from inclusion within a calendar quarter. No licensee or registrant shall change the method used to determine calendar quarters for purposes of this Part except at the beginning of a calendar year.

(30) “Calibration” means the determination of:

(i) the response or reading of an instrument relative to a series of known radiation values over the range of the instrument; or

(ii) the strength of a source of radiation relative to a standard.

(31) "C-arm fluoroscope" means a fluoroscopic x-ray system in which the image receptor and the x-ray tube housing assembly are connected or coordinated to maintain a spatial relationship.

Such a system allows a change in the direction of the beam axis with respect to the patient without moving the patient.

(32) “Certified radiation equipment safety officer" or “CRESO” means an individual who meets the requirements in section 16.10(d) of this Part and who holds an unexpired certificate as a radiation equipment safety officer issued by the department.

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

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

(35) "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.

(36) "Collimator" means a device or mechanism by which the x-ray or gamma-ray beam is restricted in size.

(37) “Commissioner" means the Commissioner of Health of the State of New York.

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

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

(40) "Cone" means a device used to indicate beam direction and to establish a minimum source-surface distance. It may or may not incorporate a collimator.

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

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

(43) “Controlled area” means any area the access to which is controlled for the purpose of protecting individuals from exposure to radiation and radioactive material but shall not mean any area used as residential quarters.

(44) "Controlled area" as used in this Part is synonymous with "restricted area."

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

(46) "Curie" means a unit of activity. One curie (Ci) is that quantity of radioactive material which decays at the rate of 3.7×10^{10} disintegrations per second (2.22×10^{12} disintegrations per minute).

(47) "Declared pregnant worker" means a person who has voluntarily informed the licensee or registrant, in writing, of their pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant worker withdraws the declaration in writing or is no longer pregnant.

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

(49) "Decommissioning plan" means a written document that includes the licensee's planned procedures and activities for decommissioning of the facility or site.

(50) "Deep dose equivalent" or "H_d" which applies to external whole body exposure, means the dose equivalent at a tissue depth of 1 centimeter (1000 mg/cm^2).

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

(52) "Department" means the New York State Department of Health and includes its duly authorized representatives, except for the reference to 10 CFR 30.12, as revised and implemented on November 30, 2021, in section 16.1 of this Part, for which Department means the U.S. Department of Energy.

(53) "Depleted uranium" means the source material uranium in which the isotope uranium-235 is less than 0.711 percent by weight of the total uranium present.

(54) "Derived air concentration" or "DAC" means the concentration of a given radionuclide in air which, if breathed by the reference man for a working year of 2,000 hours under conditions of light work, results in an intake of one ALI. For purposes of this Part, the condition of light work is an inhalation rate of 1.2 cubic meters of air per hour for 2,000 hours in a year. DAC values are given in table 1, column 3, of appendix B to 10 CFR 20, as revised and implemented in full on December 19, 2002.

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

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

(57) "Diagnostic type protective tube housing" means x-ray tube housing so constructed that the leakage radiation at a distance of one meter from the source does not exceed 1 millisievert (100 milliroentgens) in one hour when the tube is operated at its maximum continuous rated current for the maximum rated tube potential.

(58) "Diaphragm" means a device or mechanism by which the x-ray or gamma-ray beam is restricted in size.

(59) “Disposable respirator” means a respirator for which maintenance is not intended and that is designed to be discarded after excessive breathing resistance, sorbent exhaustion, physical damage, or end-of-service-life renders it unsuitable for use. Examples of this type of respirator

are a disposable half-mask respirator or a disposable escape-only self-contained breathing apparatus (SCBA).

(60) “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.

(61) "Dose" is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent. For purposes of this Part, "radiation dose" is an equivalent term.

(62) “Dose area product” or “DAP” is the absorbed dose multiplied by the area irradiated. Units are expressed as $Gy \cdot cm^2$.

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

(64) "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.

(65) "Dose limits" means the permissible upper bounds of radiation doses established in accordance with this Part. For purposes of this Part, "limits" is an equivalent term.

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

(67) "Dosimetry processor" means a person that processes and evaluates individual monitoring devices in order to determine the radiation dose delivered to the monitoring devices.

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

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

(70) "Entrance or access point" means any location through which 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.

(71) “Explosive materials” means any chemical compound, mixture, or device which produces substantial instantaneous release of gas and heat spontaneously or by contact with sparks or flame.

(72) “Exposure” means either:

(i) being exposed to ionizing radiation or to radioactive materials; or

(ii) the quotient of dQ by dm where “dQ” is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass “dm” are completely stopped in air. The special unit of exposure is the roentgen R. One roentgen is equal to 0.000258 coulomb per kilogram of air.

(73) “Exposure rate” means the exposure per unit of time, such as roentgen per minute and milliroentgen per hour.

(74) “External dose” means that portion of the dose equivalent received from any source of radiation outside the body.

(75) “Extremity” means hand, elbow, arm below the elbow, foot, knee and leg below the knee.

(76) "Facility" means the location within one building, vehicle, or under one roof and under the same administrative control:

(i) at which the possession, use, processing or storage of radioactive material is or was authorized; or

(ii) 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.

(77) "Filter" means material placed in the useful beam to change beam quality in radiation producing equipment.

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

(79) "Final status 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.

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

(81) "Fit Test" means the use of a protocol to qualitatively evaluate the fit of a respirator on an individual.

(82) “Former U.S. Atomic Energy Commission (AEC) or U.S. Nuclear Regulatory Commission (NRC) licensed facilities” means nuclear reactors, nuclear fuel reprocessing plants, uranium

enrichment plants, or critical mass experimental facilities where AEC or NRC licenses have been terminated.

(83) “General License” means a license issued pursuant to the terms and conditions of sections 16.101 or 16.103 of this Part. General licenses are effective without the filing of an application with or the issuance of a licensing document by the department.

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

(85) “Half value layer” or “HVL” means the thickness of a specified substance which, when introduced into the path of a given beam of radiation, reduces the exposure rate by one-half.

(86) “Health officer having jurisdiction” means the commissioner or the commissioner’s designee, or the chief executive officer of the appropriate county or part-county health department or the New York City Department of Health and Mental Hygiene, or the director of a state, regional, area or district office of public health.

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

(88) "High radiation area" means any area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving a dose

equivalent in excess of 1 mSv (0.1 rem) in 1 hour at 30 centimeters from any source of radiation or 30 centimeters from any surface that the radiation penetrates. For purposes of this Part, rooms or areas in which diagnostic x-ray systems are used for healing arts purposes are not considered high radiation areas.

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

(90) “Human use” as used in this Part is equivalent to “medical use”.

(91) “Image receptor” means any device which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformation. Image receptors may include but are not limited to radiographic film with or without cassette, a phosphorescent screen, a computed radiography system (CR), a direct digital radiography system (DR), or scintillation camera.

(92) “Individual” means any human being.

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

(i) dose equivalent:

(*a*) by the use of individual monitoring devices or

(*b*) by the use of survey data; or

(ii) committed effective dose equivalent:

(*a*) by bioassay or

(*b*) by determination of the time-weighted air concentrations to which an individual has been exposed, that is, DAC-hours.

(94) "Individual monitoring devices" means devices designed to be worn by a single individual for the assessment of dose equivalent. For purposes of this Part, "personnel dosimeter" and "dosimeter" are equivalent terms. Examples of individual monitoring devices are film badges, thermoluminescence dosimeters (TLDs), optically stimulated luminescent dosimeters (OSLDs), pocket ionization chambers, and personal (lapel) air sampling devices.

(95) “Inherent filtration” means the filtration permanently in the useful beam: it includes the window of the x-ray tube and any permanent tube or source enclosure.

(96) “Inspection” means an official examination or observation including, but not limited to, reviews of records, tests, surveys, and monitoring to determine compliance with rules, regulations, orders, requirements, and conditions of the department.

(97) “Interlock” means a mechanical, electrical or software barrier or device, arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.

(98) “Internal dose” means that portion of the dose equivalent received from radioactive material taken into the body.

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

(100) "Kerma Area Product" or "KAP" is the air kerma multiplied by the corresponding X-ray beam cross-sectional area. Units are expressed as $Gy \cdot cm^2$.

(101) "Kilovolt" or "kV" means a unit of electrical potential equal to 1000 volts. "Kilovolt peak" or "kVp" means the crest value in kilovolts of the potential difference of a pulsating generator. When only one-half of the wave is used, the value refers to the useful half of the wave.

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

(103) "Leakage radiation" means all radiation coming from within the source or tube housing except the useful beam.

(104) "Lens dose equivalent" or "LDE" applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm2).

(105) "License" means a radioactive material license issued by the department in accordance with the regulations adopted by the department. There are two types of licenses: general and specific. Unless otherwise specified, the type of license referred to in this Part will be a specific license

(106) “Licensed material” means radioactive material received, possessed, used, transferred or disposed of under a general or specific license issued by an authorized licensing authority.

(107) “Licensed Medical Physicist” or “LMP” means an individual who is authorized to practice medical physics in the appropriate subspecialty pursuant to article 166 of the Education Law. In addition, an “Authorized Medical Physicist” or “AMP” means a licensed medical physicist who meets the requirements of paragraph 16.123(b)(1) of this Part.

(108) “Licensee” means any person who is licensed by the department in accordance with this Part or one who possesses any radioactive material that is subject to the licensure requirements of this Part.

(109) “Limits” has the same meaning as dose limits as defined in paragraph (65) of this subdivision.

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

(111) “Lost or missing licensed material” means licensed material whose location is unknown by the licensee. This definition includes licensed material that has been shipped but has not reached its planned destination and whose location cannot by readily traced in the transportation system.

(112) “Lot Tolerance Percent Defective” means, expressed in percent defective, the poorest quality in an individual inspection lot that should be accepted.

(113) “Medical use” means the intentional internal or external administration of ionizing radiation to human beings under the order or direction and supervision of individuals specified in section 16.19 of this Part.

(114) “Member of the public” means any individual except when that individual is receiving an occupational dose.

(115) “Minor” means an individual less than 18 years of age.

(116) “Monitoring” means the measurement of radiation levels, concentrations, surface area concentrations or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses. For purposes of this Part, radiation monitoring and radiation protection monitoring are equivalent terms.

(117) “Monitor Unit” has the same meaning as Dose Monitor Unit as defined in paragraph (66) of this subdivision.

(118) “Natural radioactivity” means radioactivity of naturally occurring nuclides.

(119) “Nationally tracked source” is a sealed source containing a quantity equal to or greater than Category 1 or Category 2 levels of any radioactive material listed in appendix E of 10 CFR 20, as revised and implemented in full on December 19, 2002. In this context a sealed source is defined as radioactive material that is sealed in a capsule or closely bonded, in a solid form and which is not exempt from regulatory control. It does not mean material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet. Category 1 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 1 threshold. Category 2 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 2 threshold but less than the Category 1 threshold.

(120) "Negative pressure respirator (tight fitting) " means a respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside the respirator.

(121) “Nonstochastic effect” means health effects, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect. For purposes of this Part, a “deterministic effect” is an equivalent term.

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

(123) “Nuclear Regulatory Commission” or “NRC” means the U.S. Nuclear Regulatory Commission or its duly authorized representatives.

(124) “Occupational dose” means the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation or to radioactive material from licensed and unlicensed sources of radiation, whether in the possession of the licensee or other person. Occupational dose does not include doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released under 10 CFR 35.75, as revised and implemented on August 14, 2007, from voluntary participation in medical research programs, or as a member of the public.

(125) “Operator” means any person conducting the business or activities carried on within the radiation installation or having by law the administrative control of a radiation source whether as owner, lessee, contractor or otherwise.

(126) “Package” means the packaging, together with its radioactive contents, as presented for transport.

(127) "Particle 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 as energies usually in excess of 1 MeV. For purposes of this definition, "accelerator" is an equivalent term.

(128) “Person” means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of the State, any other state or political subdivision or agency thereof, and any legal successor, representative, agent or agency of the foregoing, but shall not include federal government agencies.

(129) “Personnel monitoring equipment” has the same meaning as individual monitoring devices, as defined in paragraph (94) of this subdivision.

(130) "Phantom" means an object behaving in essentially the same manner as components of human anatomy, in both material and shape appropriate for the purpose, with respect to absorption or scattering of the ionizing radiation in question.

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

(132) "Possess" means to acquire or take responsibility for radiation sources without regard for ownership.

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

(134) "Professional practice" means the practice of medicine, dentistry, podiatry, osteopathy or chiropractic.

(135) "Professional practitioner" means any individual licensed or otherwise authorized under State Education Law to practice a profession.

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

(137) "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.

(138) "Principal individual" means a person primarily or ultimately liable.

(139) "Protective apron" means an apron made of radiation attenuating material(s), used to reduce exposure to radiation.

(140) “Protective barrier” means a barrier of radiation attenuating materials(s) used to reduce useful beam and/or stray radiation to the degree required to assure compliance with sections 16.6 and 16.7 of this Part.

(141) “Protective glove” means a glove made of radiation attenuating material(s) used to reduce radiation exposure.

(142) "Public dose" means the dose received by a member of the public from exposure to sources of radiation released by the licensee or registrant, or to any other source of radiation under the control of the licensee or registrant. Public dose does not include occupational dose, dose received from background radiation from any medical administration the individual has received, from exposure to individuals administered radioactive material and released under 10 CFR 35.75, as revised and implemented on August 13, 2007, or equivalent, or dose from voluntary participation in medical research programs.

(143) "Qualitative fit test” or “QLFT” means a pass/fail fit test to assess the adequacy of respirator fit that relies on the individual’s response to the test agent.

(144) “Quality factor” or “Q” means the modifying factor (listed in tables 1004(b).1 and 1004(b).2 of 10 CFR 20.1004, as revised and implemented on May 21, 1991) that is used to derive dose equivalent from absorbed dose.

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

(146) "Quarter" has the same meaning as Calendar Quarter, as defined in paragraph (29) of this subdivision.

(147) "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). One millirad equals 0.001 rad.

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

(149) "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 1 hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates.
(150) "Radiation equipment" means any equipment or device that can emit radiation by virtue of the application thereto of high voltage.

(151) "Radiation installation" means a place, facility or mobile unit where radiation equipment, in operable condition or intended to be used, is located or used, or where radioactive material is

transferred, received, possessed or used including generally a hospital; medical, dental, chiropractic, podiatry, or veterinarian institution, clinic or office; industrial facility; educational institution; commercial, private or research laboratory performing diagnostic procedures or handling equipment or material for medical use; or any trucking, storage, messenger or delivery service establishment. Radiation installation shall include, whether or not it is specially stated above, any place, facility or mobile unit where radiation is applied intentionally to a human. The limits of the contiguous radiation installation area shall be as designated by the operator.

(152) “Radiation safety officer” shall mean a principal individual who, under the authorization of the operator of a radiation installation, administers a radiation protection program in accordance with section 16.5 of this Part and who is qualified by training and experience in radiological health to evaluate the radiation hazards of such installation and administer such radiation protection program.

(i) For human use radiation equipment installations, the radiation safety officer (RSO) shall be:

(*a*) a professional practitioner as defined in section 16.2 of this Part, practicing within their professional practice as defined in this section; or,

(*b*) a physicist certified by the American Board of Health Physics or the American Board of Radiology in a branch of physics related to the type of radiation sources in the installation, or, an individual with equivalent training and experience as determined by the department.

(ii) For non-human use radiation equipment installations, the radiation safety officer shall be:

(*a*) a veterinarian for veterinary installations; or,

(*b*) a physicist certified by the American Board of Health Physics, the American Board of Radiology, or, an individual with equivalent training and experience as determined by the department; or,

(*c*) a researcher determined by the institution as qualified by training and experience for installations using only x-ray diffraction and fluorescence analysis equipment.

(iii) For licensed non-human use radioactive materials installations, the radiation safety officer shall be:

(*a*) an authorized user named on the radioactive materials license issued by this department; or,

(*b*) a physicist certified by the American Board of Health Physics or the American Board of Radiology in a branch of physics related to the type of use of radioactive material in the installation, or, an individual with equivalent training and experience as determined by the department; or

(*c*) an individual who, under the authorization of the operator of a radiation installation, administers a radiation protection program in accordance with section 16.5 of this Part and who is qualified by training and experience in radiological health to evaluate the radiation hazards of such installation and administer such radiation protection program.

(iv) For a license that authorizes human use, the radiation safety officer shall be

(*a*) an individual that meets the training and experience requirements in paragraph 16.123(b)(10) of this Part; and

(*b*) an individual who is also:

(*1*) an authorized user named on the radioactive materials license issued by this department or;

(*2*) a physicist certified by the American Board of Health Physics or the American Board of Radiology in a branch of physics related to the type of use of radioactive material in the installation; or

(*3*) an individual with equivalent training and experience as determined by the department.

(153) “Radiation source” means any radioactive material or any radiation equipment.

(154) “Radioactive material” means any solid, liquid, or gas that emits radiation spontaneously.

(155) “Radioactivity” means the transformation of unstable atomic nuclei by the emission of radiation.

(156) “Radiobioassay” has the same meaning as bioassay, as defined in paragraph (25) of this subdivision.

(157) "Radon" means the radioactive noble gas radon 222.

(158) “Reference man” means a hypothetical aggregation of human physical and physiological characteristics determined by international consensus. These characteristics may be used by researchers and public health workers to standardize results of experiments and to relate biological insult to a common base.

(159) “Registrant” means any person who is registered with the department or is legally obligated to register with the department pursuant to this Part.

(160) “Registration” means registration with the department in accordance with this Part.

(161) “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 sievert).

(162) “Research and development” means:

(i) theoretical analysis, exploration, or experimentation; or

(ii) the extension of investigative findings and theories of 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.

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

(164) “Respiratory protective device” means an apparatus, such as a respirator, used to reduce an individual’s intake of airborne radioactive material.

(165) “Restricted area” means any area, access to which is limited by the licensee or registrant for the purpose of protecting individuals against undue risks from exposure to sources of radiation. A restricted area does not include areas used as residential quarters. "Restricted area" as used in this Part is synonymous with "controlled area."

(166) “Roentgen” means the special unit of exposures. One roentgen R equals 2.58×10^{-4} coulombs per kilogram of air (see definition of Exposure (under paragraph (72) of this subdivision)).

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

(168) “Scattered radiation” means radiation whose direction has been altered during passage through matter. (It may have been modified also by a decrease in energy.)

(169) “Sealed source” means radioactive material that is permanently bonded or fixed in a capsule or matrix designed to prevent release and dispersal of the radioactive material under the

most severe conditions which are likely to be encountered in normal use and handling.

(170) "Sealed Source and Device Registry" or "SSDR" means the national registry that contains the registration certificates, maintained by the Nuclear Regulatory Commission (NRC), that summarize the radiation safety information for sealed sources and devices, and describe the licensing and use conditions appropriate for the product.

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

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

(173) "Shutter" means an adjustable device fixed to the radiation source housing to intercept or collimate the useful beam.

(174) "SI" means an abbreviation of the International System of Units.

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

(176) "Site" means the area contained within the boundary of a location under the control of persons generating or storing radioactive materials.

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

(178) “Site boundary” means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee or registrant.

(179) “Source material” means:

(i) uranium or thorium, or any combination thereof, in any physical or chemical form; or

(ii) 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.

(180) “Source of radiation” means any radioactive material or any device or equipment emitting, or capable of producing, radiation.

(181) “Source-skin distance” or “source-surface distance” means the distance measured along the central ray from the center of the front surface of the source (x-ray focal spot or sealed radioactive source) to the surface of the irradiated object.

(182) “Special form radioactive material” means radioactive material which satisfies the following conditions:

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

(ii) the piece or capsule has at least one dimension not less than 5 millimeters (0.197 inch); and

(iii) it satisfies the additional requirements specified in section 71.4, Special form radioactive material, of 10 CFR 71, as revised and implemented in full on November 30, 2021 (see section 16.200 of this Part).

(183) “Special nuclear material” means:

(i) plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material that the U.S. 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

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

(184) “Special nuclear material in quantities not sufficient to form a critical mass” means uranium enriched in the isotope U-235 in quantities not exceeding 350 grams of contained U-235; uranium-233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams; or any combination of them in accordance with the following formula: For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum

of such ratios for all of the kinds of special nuclear material in combination shall not exceed 1. For example, the following quantities in combination would not exceed the limitation and are within the formula:

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

(185) "Specific License" means a license for byproduct material issued pursuant to sections 102 through 123 of this Part. A specific license also means a similar license issued by the New York City Department of Health and Mental Hygiene, the United States Nuclear Regulatory Commission or any Agreement State.

(186) “State” means the State of New York, unless the context of this Part clearly indicates that a different meaning is intended.

(187) “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 function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects. For purposes of this Part, probabilistic effect is an equivalent term.

(188) “Stray radiation” means the sum of leakage and scattered radiation.

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

(190) "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 or calculations of levels of radiation or concentrations of radioactive material present.

(191) "Therapeutic type protective tube housing" means:

(i) for x-ray therapy equipment not capable of operating at 500 kVp or above, an x-ray tube housing so constructed that the leakage radiation at one meter from the source does not exceed one roentgen in an hour when the tube is operated at its maximum rated continuous current for the maximum rated tube potential; or

(ii) for x-ray therapy equipment capable of operation at 500 kVp or above, an x-ray tube housing so constructed that leakage radiation at one meter from the source does not exceed 0.1 percent of the useful beam dose rate at one meter from the source for any of its operating conditions.

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

(193) “Total effective dose equivalent” or “TEDE” means the sum of the effective dose equivalent for external exposures and the committed effective dose equivalent for internal exposures.

(194) “Unrestricted area” means an area, access to which is neither limited nor controlled by the licensee or registrant.

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

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

(197) “Use” as used in radioactive materials licenses means to employ or apply radioactive materials for the licensed purpose. It shall include instruction of, and responsibility for, technical

and support staff members. It does not include training others in the techniques of use of radioactive materials for the purpose of qualifying for licensure. In licenses authorizing human use of radioactive materials “use” will also include:

(i) ordering or directing the administration of radiation of radioactive materials to humans, including the method or route of administration;

(ii) actual use of, or direction of, technologists or other paramedical personnel in the use of, radioactive material;

(iii) regular review of the progress of patients receiving therapy and modification of the originally prescribed dose as warranted by the patient's reaction to radiation therapy.

(198) “Useful beam” means the radiation that passes through the source or tube-housing port and the aperture of the collimating device when the exposure switch or timer is activated.

(199) "User seal check" means an action conducted by the respirator user to determine if the respirator is properly seated to the face. Examples include negative pressure check, positive pressure check, irritant smoke check, or isoamyl acetate check. For purposes of this Part “fit check” is an equivalent term.

(200) "Very high radiation area" means any area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving an absorbed dose in excess of 5 Gy (500 rad) in 1 hour at 1 meter from a radiation source or 1 meter from any surface that the radiation penetrates. (Note: At very high doses received at high dose

rates, units of absorbed dose (e.g., rads and grays) are appropriate, rather than units of dose equivalent (e.g., rems and sieverts)).

(201) "Waste" means those low-level radioactive wastes containing source, special nuclear, or byproduct material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level radioactive waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in subparagraphs (ii), (iii), and (iv) of the definition of byproduct material set forth in this section.

(202) "Waste handling licensees" means persons licensed to receive and store radioactive wastes prior to disposal and/or persons licensed to dispose of radioactive wastes.

(203) "Week" means 7 consecutive days starting on Sunday.

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

Organ or Tissue	W_T
Gonads	0.25
Breast	0.15
Red bone marrow	0.12

Lung	0.12
Thyroid	0.03
Bone surfaces	0.03
Remainder	0.30[1]
Whole Body	1.00[2]

[1] 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.

[2] 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.

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

(206) "Worker" means an individual engaged in activities under a license or registration issued by the department and controlled by a licensee or registrant but does not include the licensee or registrant.

(207) “Working level” or “WL” means any combination of short-lived radon daughters in 1 liter of air that will result in the ultimate emission of 130,000 MeV of potential alpha particle energy.

The short-lived radon daughters are, for radon-222: polonium-218, lead-214, bismuth-214, and polonium-214; and for radon-220: polonium-216, lead-212, bismuth-212, and polonium-212.

(208) “Working level month” or “WLM” means an exposure to 1 working level for 170 hours. (2,000 working hours per year divided by 12 months per year is approximately equal to 170 hours per month.)

(209) “Year” means the period of time beginning in January used to determine compliance with the provisions of this Part. The licensee or registrant may change the starting date of the year used to determine compliance by the licensee or registrant provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

16.3 Granting exemptions or variations. The department may upon either the application of any interested person or the department's own initiative, grant an exemption or variation from any requirement of this Part when the department finds that such exemption or variation will not result in an undue danger to life and property from radiation hazards.

16.4 Exemption of certain radiation sources from the requirements of this Part. Any person is hereby exempted from the requirements of this Part to the extent that such person transfers, receives, possesses, installs, operates or uses:

(a) Any of the radioactive materials~~,~~ or items containing radioactive material in accordance with the provisions in 10 CFR 30.14, 30.15, 30.18, 30.19, 30.20, 30.21(a), (b) and (d), 30.22(a), , all

as revised and implemented in full on October 16, 2020, and 10 CFR 40.13, as revised and implemented in full on January 14, 1961.

(b) Radiation equipment constructed so that it cannot emit radiation at a level greater than 0.005 mGy (0.5 milliroentgen) per hour, measured two inches or five centimeters from the surface, and averaged over an area of 1.55 square inches or 10 square centimeters as certified by the manufacturer of the device; provided, however, that such exemption shall not apply to the testing or servicing of such equipment during its production.

(c) Radiation equipment during its storage, shipment, retail sale or other similar use during which such equipment is not connected to a voltage source and does not emit radiation.

16.5 Responsibility for radiation safety. No person shall operate or permit the operation of a radiation installation, nor shall the person operate, transfer, receive, possess, or use or permit the operation, transfer, receipt, possession or use of any radiation source unless that person:

(a) achieves occupational doses and doses to members of the public as low as is reasonably achievable (ALARA). Such effort shall include, to the extent practicable, the use of procedures and engineering controls which are based on sound radiation protection principles;

(b) develops, documents, and implements a radiation protection program commensurate with the scope and extent of the radiation activities engaged in by the radiation installation. This program shall be designed to ensure compliance with the provisions of this Part;

(c) provides a radiation safety officer as described in section 16.2 of this Part. The radiation safety officer shall be delegated authority to ensure the implementation of this radiation protection program and shall be responsible for the day-to-day conduct of the program;

(d) provides for a radiation safety committee to administer the radiation protection program in hospitals, and broad scope licensees and in accordance with section 16.123(d) of this Part. The committee shall include the facility operator or a person with the authority to act on behalf of the facility operator, and representation from departments within the facility where radiation sources are used. The committee shall approve all uses of radiation-producing equipment and radioactive materials within the facility, shall review the activities of the radiation safety officer annually, and shall review the radiation protection program at least annually. The committee, or a subcommittee, shall also oversee the administration of a quality assurance program, as required by subdivision (e) of this section;

(e) provides a quality assurance program for diagnostic and therapeutic uses of radiation producing equipment and radioactive materials pursuant to sections 16.23, 16.24 and other applicable sections of this Part;

(f) ensures that all personnel involved in planning for or administering radiation doses to humans, or in the use of radiation producing equipment or radioactive materials for other purposes, are supervised, and are instructed as described in subdivision (c) of section 16.13 of

this Part, and are competent to safely use such radiation equipment or other radiation sources and services;

(g) ensures that radiation equipment is used only for those procedures for which it is designed;

(h) ensures that acceptance testing of all medical and chiropractic diagnostic equipment, and treatment and planning equipment for radiation therapy, and all associated software, is performed before first use of such equipment on humans by an individual competent to perform such testing and approved by a licensed medical physicist. Such testing will also be performed following reassembly or major upgrade; and

(i) conducts, or causes to be conducted, an annual review of the radiation protection program content and implementation.

16.6 Occupational dose limits.

(a) Occupational dose limits for adults

(1) No person shall transfer, receive, possess, or use any radiation source so as to cause any individual adult to receive an occupational dose from all sources of radiation that exceeds any of the following limits:

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

(*a*) The total effective dose equivalent being equal to 0.05 Sv (5 rem); or

(*b*) The sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 0.50 Sv (50 rem).

(ii) The annual limits to the lens of the eye, to the skin of the whole body, and to the skin of the extremities which are: [note that any reference to eye dose is equivalent to lens dose]

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

(*b*) A shallow dose equivalent of 0.50 Sv (50 rem) to the skin of the whole body or to the skin of any extremity.

(2) When the external exposure is determined by measurement with an external personal monitoring device, the deep-dose equivalent must be used in place of the effective dose equivalent, unless the effective dose equivalent is determined by a dosimetry method approved by the department. The assigned deep dose equivalent must be for the part of the body receiving the highest exposure. The assigned shallow dose equivalent must be the dose averaged over the contiguous 10 square centimeters of the skin receiving the highest exposure.

(i) The deep dose equivalent, lens dose equivalent and shallow dose equivalent may be assessed from surveys or other radiation measurements for the purposes 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 the individual monitoring are unavailable.

(ii) When a protective apron is worn pursuant to section 16.58 of this Part, by physicians during x-ray fluoroscopic procedures and monitoring is conducted as specified in section 16.11(b)(1) of this Part, the effective dose equivalent for external radiation may be determined for these individuals as follows:

(*a*) When only one individual monitoring device is used and it is located at the neck outside the protective apron, the reported deep dose equivalent value multiplied by 0.3 shall be the effective dose equivalent for external radiation; or

(*b*) When individual monitoring devices are worn, both under the protective apron at the waist and outside the protective apron at the neck, the effective dose equivalent for external radiation shall be assigned the value of the sum of the deep dose equivalent reported for the individual monitoring device located at the waist under the protective apron multiplied by 1.5 and the deep dose equivalent reported for the individual monitoring device located at the neck outside the protective apron multiplied by 0.04.

(3) Derived air concentration (DAC) and annual limit on intake (ALI) values are presented in table 1 of appendix B to 10 CFR 20, as revised and implemented in full on December 19, 2002, and may be used to determine the individual's dose and to demonstrate compliance with the occupational dose limits.

(4) Notwithstanding the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to 10 milligrams in a week. (*See* footnote 3 of appendix B to 10 CFR 20, as revised and implemented in full on December 19, 2002).

(5) The licensee or registrant shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person. The licensee or registrant shall determine the occupational radiation dose received during the current year. In complying with this requirement, a licensee or registrant may accept a record of the occupational dose that the individual received during the current year, or from the individual's employer(s) for work involving radiation exposure during the past year, that discloses the nature and the amount of any occupational dose that the individual received during the current year.

(b) Compliance with requirements for summation of external and internal dose.

(1) If the licensee or registrant is required to monitor pursuant to both subdivisions (a) and (d) of section 16.11 of this Part, the licensee or registrant shall demonstrate compliance with the dose limits by summing external and internal doses. If the licensee or registrant is required to monitor only pursuant to subdivisions (a) or (d) of section 16.11 of this Part, then summation is not required to demonstrate compliance with the dose limits. The licensee or registrant may demonstrate compliance with the requirements for summation of external and internal doses by meeting one of the conditions specified in paragraph (2), and the conditions in paragraphs (3) and (4) 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.

(2) 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; or

(ii) the total number of derived air concentrations-hours (DAC-hours) for all radionuclides divided by 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_{50}, that is, $W_T H_{T,50}$ per unit intake for any organ or tissue.

(3) Intake by oral ingestion. If the occupationally exposed individual also receives an intake of radionuclides by oral ingestion greater than 10 percent of the applicable oral ALI, the licensee or registrant shall account for this intake and include it in demonstrating compliance with the limits.
(4) Intake through wounds or absorption through skin. The licensee or registrant shall evaluate and 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 paragraph.

(c) Determination of external dose from airborne radioactive material.
(1) Licensees shall, when determining the dose from airborne radioactive material, include the contribution to the deep dose equivalent, lens dose equivalent, and shallow dose equivalent from external exposure to the radioactive cloud (*See* 10 CFR 20 appendix B, footnotes 1 and 2, as revised and implemented in full on March 14, 2023).
(2) Airborne radioactivity measurements and DAC values shall not be used as the primary means to assess the deep dose equivalent when the airborne radioactive material includes radionuclides other than noble gases or if the cloud of airborne radioactive material is not relatively uniform. The determination of the deep dose equivalent to an individual shall be based upon measurements using instruments or individual monitoring devices.

(d) Determination of internal exposure.
(1) For purposes of assessing dose used to determine compliance with occupational dose equivalent limits, the licensee shall, when required under section 16.11 of this Part, take any of

the following measurements as may be necessary for timely and appropriate detection and assessment of intake of radioactivity by individuals:

(i) concentrations of radioactive materials in air in work areas; or

(ii) quantities of radionuclides in the body; or

(iii) quantities of radionuclides excreted from the body; or

(iv) combinations of these measurements.

(2) Unless respiratory protective equipment is used, as provided in section 16.26 of this Part, or the assessment of intake is based on bioassays, the licensee or registrant shall assume that an individual inhales radioactive material at the airborne concentration in which the individual is present.

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

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

(ii) upon prior approval of the department, 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 (*See* 10 CFR 20, appendix B, as revised and implemented in full on March 14, 2023) to the committed effective dose equivalent.

(4) If the licensee chooses to assess intakes of Class Y material using the measurements given in subparagraphs (ii) or (iii) of paragraph (1) of this subdivision, the licensee or registrant may

delay the recording and reporting of the assessments for periods up to 7 months, unless otherwise required by sections 16.15(b) or 16.15(c) of this Part. This delay permits the licensee or registrant to make additional measurements basic to the assessments.

(5) 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 10 CFR 20, appendix B, as revised and implemented in full on March 14, 2023, 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.

(6) 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.

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

(i) the licensee uses the total activity of the mixture in demonstrating compliance with the dose limits in subdivision (a) of this section and in complying with the monitoring requirements in section 16.11(d) of this Part; and

(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.

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

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

(ii) For an ALI and the associated DAC is determined by the nonstochastic organ dose limit of 0.50 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 10 CFR 20, appendix B, table 1, as revised and implemented in full on March 14, 2023. The licensee or registrant may, as a simplifying assumption, use the stochastic ALIs to determine committed effective dose equivalent. However, if the licensee or registrant uses the stochastic ALIs, the licensee or registrant shall also demonstrate that the limit in clause (a)(1)(i)(b) of this section, is met.

(e) Occupational dose limits for minors. The annual occupational dose limits for minors are 10 percent of the annual occupational dose limits specified for adult workers in subdivision (a) of this section.

(f) Dose equivalent to an embryo/fetus.

(1) The licensee or registrant shall ensure that the dose equivalent to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant worker, does not exceed 5 mSv (0.5 rem). (*See* section 16.14(d) of this Part for recordkeeping requirements).

(2) The licensee or registrant shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant worker so as to satisfy the limit in paragraph (1) of this subdivision.

(3) The dose equivalent to an embryo/fetus shall be taken as the sum of:

(i) the deep dose equivalent to the declared pregnant worker; and

(ii) the dose equivalent to the embryo/fetus resulting from radionuclides in the embryo/fetus and radionuclides in the declared pregnant worker during the entire pregnancy period.

(4) If by the time the worker declares pregnancy to the licensee or registrant, the dose to the embryo/fetus exceeded 5 mSv (0.5 rem), the licensee or registrant shall be deemed to be in compliance with paragraph (1) of this subdivision if the additional dose equivalent to the embryo/fetus does not exceed 0.5 mSv (0.05 rem) during the remainder of the pregnancy.

16.7 Radiation dose limits for individual members of the public.

(a) Dose limits for individual members of the public.

(1) Each licensee or registrant shall conduct operations so that:

(i) the dose in any unrestricted area from external sources, exclusive of the dose contributions from patients administered radioactive material and released in accordance with 10 CFR 35.75, as revised and implemented on August 13, 2007, does not exceed 0.02 mSv (0.002 rem) in any one hour; and

(ii) the total effective dose equivalent to individual members of the public from the licensed operation, or registered equipment operation, does not exceed 1 mSv (0.1 rem) in a year, exclusive of dose contribution from background radiation, from any administration the individual has received, from exposure to individuals administered radioactive material and released under

10 CFR 35.75, as revised and implemented on August 13, 2007, from voluntary participation in medical research programs, and from the licensee's or registrant's disposal of radioactive material into sanitary sewerage in accordance with section 16.8 of this Part.

(2) If the licensee permits members of the public to have access to controlled areas, the limits for members of the public continue to apply to those individuals.

(3) Notwithstanding subparagraph (ii) of paragraph (1) this subdivision, a licensee may permit visitors to an individual who cannot be released, in accordance with 10 CFR 35.75, as revised and implemented on August 13, 2007, to receive a radiation dose greater than 0.1 rem (1 mSv), but not exceeding 0.5 rem (5 mSv) if the authorized user, as defined in section 16.123 of this Part, has determined before the visit that it is appropriate.

(4) A licensee or license applicant may apply for prior department authorization to operate up to an annual dose limit for an individual member of the public of 0.5 rem (5 mSv). The licensee or license applicant shall include the following information in this application:

(i) demonstration of the need for and the expected duration of operations in excess of the limit in subdivision (a) of this section;

(ii) the licensee's program to assess and control dose within the 0.5 rem (5 mSv) annual limit;

(iii) the procedures to be followed to maintain the dose as low as is reasonably achievable; and

(iv) any additional information requested by the department.

(5) The department may impose additional restrictions on radiation levels in unrestricted areas and on the total quantity of radionuclides that a licensee may release in effluents in order to restrict the collective dose.

(6) If radioactive materials are released into the air or water by any person in such a manner that the radioactive materials may be reconcentrated in the environment or may be added to any other

radioactive materials released to the environment, the department may restrict the release by such person to assure that the limits set forth in this Part are not exceeded.

(b) Compliance with dose limits for individual members of the public.

(1) The licensee or registrant shall make or cause to be made, as appropriate, surveys of radiation levels in unrestricted and controlled areas and radioactive materials in effluents released to unrestricted and controlled areas to demonstrate compliance with the dose limits for individual members of the public in subdivision (a) of this section.

(2) A licensee or registrant shall maintain records of measurements and calculations used to demonstrate compliance with the annual dose limit in subdivision (a) of this section.

(3) A licensee shall show compliance with the annual dose limits in subdivision (a) of this section by;

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

(ii) demonstrating that:

(*a*) the annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in 10 CFR 20, appendix B, table 2, as revised and implemented in full on March 14, 2023; and

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

16.8 Waste disposal. Disposal and transportation of radioactive waste shall be governed by the New York State Department of Environmental Conservation as set forth in 6 NYCRR Parts 380 and 381.

16.9 Professional practitioners and related provisions.

(a) Nothing in sections 16.6 through 16.16 of this Part shall limit any human use of radiation in diagnostic or therapeutic procedures pursuant to section 16.19 of this Part, provided that with respect to use on humans of radioactive material, such use is in accordance with a specific or general license issued under this Part, or an exemption therefrom.

(b) Each professional practitioner who administers, inserts, or implants an amount of radioactive material into a patient in such quantities that the patient cannot be released under 10 CFR35.75, as revised and implemented on August 13, 2007, shall require that the patient wear a wrist band. The wrist band shall bear the radiation symbol, the quantity and type of radioactive material administered, inserted or implanted and the date on which such quantity was measured.

(c) Radioactive cadavers.

(1) If any patient containing radioactive material, which was administered for therapeutic purposes, dies it shall be the responsibility of the physician who pronounces such patient as dead to notify immediately the physician in charge of the case or their designated representative.

(2) No person shall commence any autopsy on any cadaver that contains radioactive material in a quantity that exceeds five millicuries, which was administered for therapeutic purposes, without first having consulted with and being advised by the radiation safety officer for the licensee or, if

they are not available, the physician responsible for the administration of the radioactive material. If neither is available, their designated representative may serve.

(3) A radioactivity report on every cadaver containing more than five millicuries of radioactive material which was administered for therapeutic purposes, shall be completed by the radiation safety officer or the physician responsible for the administration of the radioactive material or their designated representatives. The report must include: the name and address of the hospital; the name of the deceased; the name, address and telephone number of the next of kin; the name, address and telephone number of the funeral home to which the deceased will be sent; the radionuclide involved, the approximate activity on the day of the report and the physical form; the location of the radioactive materials in the body and the external rate at the body surface closest to the source; the precautions to be observed during autopsy or handling of the body by the funeral director; and the name of the person who prepared the form. This report shall accompany the body (whether autopsied or not) when it is surrendered to the funeral director. The licensee shall retain a copy of the radioactivity report for a period of three years for review by the department.

(d) Provide notification of suspected radiation related illness as required by section 16.15(f) of this Part.

16.10 Inspections, surveys, checks and tests; vacating installations; securing radiation sources.

(a) Each person who possesses any radiation source shall make, or cause to be made, the applicable surveys required under this section and such additional surveys as may be necessary for them to comply with other sections in this Part, to determine the magnitude and extent of

radiation levels and concentrations or quantities of radioactive material in areas including the subsurface, and as the department may direct in order to evaluate the extent of the radiation hazard or potential radiation hazards of the radiation levels and residual radioactivity detected that may be present. Each person who possesses any radioactive material not in a sealed source for which surveys are required shall provide or have available appropriate calibrated and operable instruments capable of detecting and measuring radiation and radioactive contamination. Records of surveys describing the location and amount of subsurface residual radioactivity identified at the site must be kept with records important for decommissioning in accordance with this Part.

(1) Any radiation installation subject to the registration requirements of section 16.50(a) of this Part shall be inspected periodically to assure compliance with this Part and the maintenance of radiation exposures as far below the limits set forth in this Part as is reasonably achievable. Inspections shall be made at a frequency as specified in subparagraph (i) of this paragraph, The inspection shall be performed in a manner, and reported in writing on a form, prescribed by the department. The person who makes the inspection shall include in such report all recommendations necessary to accomplish compliance with this Part, and to reduce radiation exposure as far below the limits set forth in this Part as reasonably achievable. The inspection shall be made by the department, the New York City Department of Health and Mental Hygiene or, as the department shall direct, by the appropriate county or part-county health officer having jurisdiction or by a certified radiation equipment safety officer. Such county or part-county health officer or the New York City health commissioner shall make the inspection only under an inspection program that is certified by the department in writing as approved and in effect. They may make the inspection or have it made by a duly authorized representative approved for

such purpose by both such health officer and the department. The operator of an installation required to be inspected by a certified radiation equipment safety officer, shall be solely responsible for having all such required inspections made.

(i) The department shall establish a schedule of inspection frequencies and make this available to regulated entities and other interested parties. This schedule may be adjusted for cause or administrative purposes by the department. Initial inspections should occur within the first year of operations.

(ii) The CRESO (certified radiation equipment safety officer), or the health officer having jurisdiction, as the case may be, shall furnish the inspection report, signed by the person who made the inspection, to the operator of the installation and a copy thereof to the department in accordance with the instructions of the prescribed form.

(2) Radiation installations wherein radioactive materials are handled or installed which will have any readily accessible area in which there is reasonable expectation that a radiation level will exist in excess of two millirems in any one hour shall be surveyed during the initial operation and whenever any change is made in the installation or its use that might increase the radiation level to which a person could be exposed.

(3) Accessible areas and equipment within radiation installations wherein radioactive material not contained in a sealed source is handled or installed shall be surveyed at least once a month for radioactive contamination unless a shorter interval is specified in a license issued pursuant to this part. Radioactive contamination of surfaces shall be kept ALARA using Appendix 16-A, Table 7 of Part 16 of Title 10 (Health) of the NYCRR.

(4) Depleted uranium components, and each sealed or plated sources, containing radioactive material other than Hydrogen-3, with a half- life greater than 30 days and in any form other than

gas, shall be tested for leakage prior to initial use and at successive intervals thereafter not to exceed six months or a longer interval as specified in the sealed source and device registry, except as noted below:

(i) That each source designed for the purpose of emitting alpha particles shall be tested at intervals not to exceed three months or as specified in the sealed source and device registry.

(ii) Notwithstanding the periodic leak test required by this paragraph, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less of beta, neutron, and/or gamma emitting material or 10 microcuries or less of alpha emitting material.

(iii) Except for alpha sources, the periodic leak test required by this paragraph shall not apply to sealed sources that are stored and not being used. The sources excepted from this test shall be tested for leakage prior to any use or transfer to another person unless they have been leak tested within six months prior to the date of use or transfer. In the absence of the delivery of a certificate by the transferor to the transferee indicating that a test pursuant to the applicable provisions of this Part was made within six months prior to the transfer, the source shall not be used until tested for leakage.

(5) Additional requirements for leak tests:

(i) If there is reason to suspect that a sealed source might have been damaged, or might be leaking, such source shall be tested for leakage before further use.

(ii) The test sample shall be taken from selected accessible surfaces of the sealed source or from the surfaces of the device in which the sealed source is permanently mounted or stored. For teletherapy and/or irradiator sources, the selected accessible surfaces should be those surfaces on which one might expect contamination (if there were to be leakage) to accumulate and shall include the inner surface of the most frequently used treatment cone or beam collimating device.

The test sample shall be taken with the source in the "off" position the leak test technique shall be capable of detecting:

(*a*) the escape of radon at the rate of 37,000 Bq (0.001 microcuries) or more per 24 hours for sealed radium sources; or

(*b*) 185,000 Bq (0.005) microcurie or more of removable radioactivity from all other sealed sources and depleted uranium shields, collimators, etc. Detection of a leak in any sealed source in excess of the sensitivity levels set forth in this paragraph shall result in immediate suspension in the use of such source until such source is decontaminated and repaired or disposed of in accordance with section 16.8 of this Part. Records of leak test results shall be kept in units of microcuries per test sample and maintained for inspection by the department.

A leaking source report shall be submitted to the department for each source found to be leaking in excess of the above sensitivity levels within five days of detection of the leak and shall describe the equipment involved, the test results, and the corrective action taken. The reporting requirements are listed in section 16.15(e) of this Part.

(6) Protective devices such as interlocks, safety switches, fume hoods, filters and trapping devices for radioactive gases, shall be tested regularly and maintained in good repair and proper operating condition.

(b) Each person shall perform surveys of the area wherein radioactive material is or has been stored as necessary to demonstrate to the department that the area of the licensee’s facility meets the criteria in section 16.28 of this Part for unrestricted release. This does not apply to decommissioning of buildings or license termination.

(c) Each person who possesses any radiation source shall secure such source against its unauthorized removal from its place of storage or use. The following additional restrictions apply to noncontrolled areas:

(1) Radiation sources stored in a noncontrolled area shall be stored in a locked facility in the original shipping container, or a container providing equivalent radiation protection. Such a facility may be a cabinet, a safe or a room, providing the facility is locked at all times when no activities are in progress relating to the use of the radiation sources.

(2) Radiation sources in a noncontrolled area and not in storage shall be tended under the constant surveillance and immediate control of the licensee or registrant.

(3) Security requirements for portable moisture density gauges. Each portable gauge licensee shall use a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal, whenever portable gauges are not under the control and constant surveillance of the licensee.

(d) Certified Radiation Equipment Safety Officer (CRESO). A certification as a radiation equipment safety officer shall be issued by the department. Eligibility for renewal of a certificate shall be based on a work record as a certified radiation equipment safety officer that is in conformance with the regulations of the department. The certificate may be revoked for cause by the department on due notice.

(1) The requirements for certification as a radiation equipment safety officer are as follows:

(i) at least 18 years of age at the time of application; and

(ii) good moral character; and

(iii) graduation from a regionally accredited college or university, or one recognized by New York State, with a bachelor's degree in physical or natural science, mathematics or engineering; or four years of satisfying full-time paid experience in radiation protection or control; or an equivalent combination of the education and experience specified in this clause; and

(iv) successful completion, after meeting the requirements of subparagraphs (i), (ii), and (iii) of this paragraph, of an examination prescribed by the department; and

(v) at least three years of satisfactory full-time paid experience in radiation protection or control including at least one year of experience dealing with radiation equipment, with the provision that up to two years of graduate training in physical or natural science, mathematics or engineering, may be substituted on a year for year basis for the required experience except for the one year of experience in radiation protection or control dealing with radiation equipment. Verification of employment, experience, and education must be provided upon department request.

(vi) Individuals must have available calibrated test equipment appropriate for the types of equipment inspected. Records of calibration must be submitted to the department as requested.

(2) The department may accept in lieu of the requirements of subparagraphs (iii) and (iv) of paragraph (1) of this subdivision a certificate in radiation protection or control issued by the American Board of Health Physics, the American Board of Radiology or the American Board of Medical Physics.

(3) A person meeting all requirements of paragraph (1) of this subdivision except the experience or experience substitute requirement of subparagraph (v) of paragraph (1) may be certified as a radiation equipment safety officer with the restriction that they perform surveys only under the

supervision of a certified radiation equipment safety officer who meets the requirements of subparagraph (v).

(4) The Radiation Safety Officer for a facility may not act as CRESO for the same facility.

(e) Instrumentation. Each person required to perform a survey by this Part shall be provided with or have available appropriate calibrated and operable instruments capable of detecting and measuring radiation.

(f) Radiation equipment-surveys. Every installation and mobile source wherein radiation equipment is to be used shall be surveyed during the initial operation of such equipment and whenever any change is made in such installation or mobile source or in its use that might increase the radiation level to which an individual could be exposed. When vibrations or other physical conditions exist in such installations or mobile sources which may cause changes in the protective features, surveys shall be made at least every six months.

16.11 Personnel monitoring.

(a) External radiation sources. Each licensee and registrant shall monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee or registrant. Each person who possesses any radiation source shall supply and require the proper use of appropriate, calibrated and operable individual monitoring devices by:

(1) adults likely to receive, in one year from sources external to the body, a dose in excess of 10 percent of the limits in paragraph (1) of section 16.6(a) of this Part; and

(2) minors likely to receive, in 1 year, from radiation sources external to the body, a deep dose equivalent in excess of 1 mSv (0.1 rem), a lens dose equivalent in excess of 1.5 mSv (0.15 rem), or a shallow dose equivalent to the skin or to the extremities in excess of 0.5 rem (5 mSv); 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 section 16.6 of this Part; and

(3) declared pregnant worker likely to receive during the entire pregnancy, from radiation sources external to the body, a deep dose equivalent in excess of 1 mSv (0.1 rem) (Note: All of the occupational doses in section 16.6 of this Part continue to be applicable to the declared pregnant worker as long as the embryo/fetus dose limit is not exceeded.); and

(4) individuals entering a high or very high radiation area, or operating fluoroscopy equipment; and

(5) as required by section 16.119 of this Part for individuals conducting industrial radiography operations (10 CFR 34.47, as revised and implemented on March 18, 2020) and as required by section 16.120 of this Part for irradiator operators (10 CFR36.55, as revised and implemented on March 18. 2020)

(b) A person supplying personnel monitoring devices to individuals as required by subdivision (a) of this section shall ensure that the individuals wear such devices as follows:

(1) 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.

(2) An individual monitoring device used for monitoring the dose to an embryo/fetus of a declared pregnant woman, pursuant to section 16.6(h)(1) of this Part, shall be located at the waist under any protective apron worn by the woman.

(3) An individual monitoring device used for monitoring the lens dose equivalent shall be located at the neck outside any protective apron worn by the individual, or at an unshielded location closer to the eye.

(4) An individual monitoring device used for monitoring the dose to the extremities shall be worn on the extremity likely to receive the highest exposure. The device shall be oriented to measure the highest dose to the extremity being monitored.

(c) All personnel monitoring devices, except for direct and indirect reading dosimeter and those dosimeters used to measure the dose to any extremity, that require processing to determine the radiation dose and which are supplied pursuant to subdivision (a) of this section, or with conditions specified in a license or registration shall be processed and evaluated by a dosimetry processor:

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

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

(d) Intake of radioactive material. Each licensee shall perform all appropriate measurements of those specified in section 16.6(d)(1) of this Part which will enable them to determine the

occupational intake of radioactive material by and assess the committed effective dose equivalent to:

(1) Adults likely to receive, in one year, an intake in excess of 10 percent of the applicable ALI(s) in 10 CFR 20, appendix B, table 1, columns 1 and 2, as revised and implemented in full on March 14, 2023.

(2) Minors likely to receive, in one year, a committed effective dose equivalent in excess of 0.50 mSv (0.05 rem).

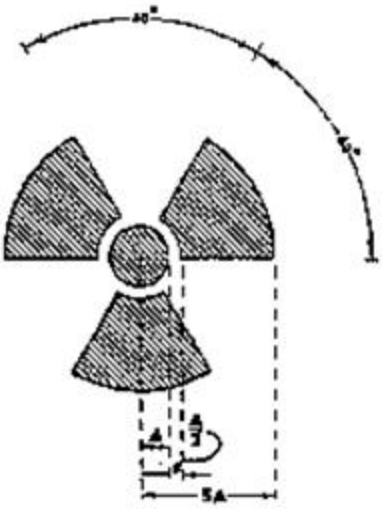
(3) Declared pregnant worker likely to receive, during the entire pregnancy, a committed effective dose equivalent in excess of 0.50 mSv (0.05 rem).

16.12 Radiation symbol, signs, labels, and control devices.

(a) Standard radiation symbol. Unless otherwise authorized by the department, the symbol prescribed by this section shall use the colors magenta, or purple, or black on yellow background. The symbol prescribed is the three-bladed design and shall be as illustrated below:

(1) Cross-hatched area is to be magenta, or purple, or black.

(2) The background is to be yellow.



(3) Exception to color requirements for standard radiation symbol. Notwithstanding the requirements of subdivision (a) of this section, licensees or registrants are authorized to label sources, source holders, or device components containing sources of radiation that are subjected to high temperatures, with conspicuously etched or stamped radiation caution symbols and without a color requirement.

(4) Additional information on signs and labels. In addition to the contents of signs and labels prescribed in this Part, the licensee or registrant shall provide, on or near the required signs and labels, additional information, as appropriate, to make individuals aware of potential radiation exposures and to minimize the exposures.

(b) (1) Posting requirements.

(i) Posting of radiation areas. The licensee or registrant shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIATION AREA".

(ii) Posting of high radiation areas. The licensee or registrant shall post each high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, HIGH RADIATION AREA" or "DANGER, HIGH RADIATION AREA".

(iii) Posting of very high radiation areas. The licensee or registrant shall post each very high radiation area with a conspicuous sign or signs bearing the radiation symbol and words "GRAVE DANGER, VERY HIGH RADIATION AREA".

(iv) Posting of airborne radioactivity areas. The licensee or registrant shall post each airborne radioactivity area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, AIRBORNE RADIOACTIVITY AREA" or "DANGER, AIRBORNE RADIOACTIVITY AREA".

(v) Posting of areas or rooms in which licensed material is used or stored. The licensee shall post each area or room in which there is used or stored an amount of licensed material exceeding 10 times the quantity of such material specified in 10 CFR 20, appendix C, as revised and implemented in full on March 14, 2023, with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)".

(2) Exceptions to posting requirements.

(i) A licensee or registrant is not required to post caution signs in areas or rooms containing sources of radiation for periods of less than eight hours, if each of the following conditions is met:

(*a*) the sources of radiation are constantly attended during these periods by an individual who takes the precautions necessary to prevent the exposure of individuals to sources of radiation in excess of the limits established in this Part; and

(*b*) the area or room is subject to the licensee's or registrant's control.

(ii) Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs pursuant to paragraph (1) of this subdivision provided that the patients that could be released from licensee control pursuant to section 16.123 of this Part.

(iii) A room or area is not required to be posted with a caution sign because of the presence of a sealed source provided the radiation level at 30 centimeters from the surface of the sealed source container or housing does not exceed 0.05 mSv (0.005 rem) per hour.

(iv) A room or area is not required to be posted with a caution sign because of the presence of a diagnostic x-ray system used solely for healing arts purposes.

(c) Labeling of containers and radiation equipment.

(1) The licensee or registrant shall ensure that each container of licensed material bears a durable, clearly visible label bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL". The label shall also provide information, such as the radionuclides present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, kinds of materials, and mass enrichment, to permit individuals handling or using containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures.

(2) Each licensee shall, prior to removal or disposal of empty uncontaminated containers to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials.

(3) Each registrant shall ensure that radiation equipment is labeled in a conspicuous manner which cautions individuals that radiation is produced when it is energized.

(4) Exemptions to labeling requirements. A licensee or registrant is not required to label:

(i) containers holding licensed material in quantities less than the quantities listed in 10 CFR 20, appendix C, as revised and implemented in full on March 14, 2023; or

(ii) containers holding licensed material in concentrations less than those specified in 10 CFR 20, appendix B, table 3, as revised and implemented in full on March 14, 2023; or

(iii) containers attended by an individual who takes the precautions necessary to prevent the exposure of individuals in excess of the limits established by this Part, (e.g., laboratory containers, such as beakers, flasks, and test tubes, used transiently in laboratory procedures (i.e., for a period of a few hours) in the presence of an authorized user); or

(iv) containers when they are in transport and packaged and labeled in accordance with the regulations of the United States Department of Transportation; or

(v) containers that are accessible only to individuals authorized to handle or use them, or to work in the vicinity of the containers, if the contents are identified to these individuals by a readily available written record. Examples of containers of this type are containers in locations such as water-filled canals, storage vaults, or hot cells. The record shall be retained as long as the containers are in use for the purpose indicated on the record; or

(vi) installed manufacturing or process equipment, such as chemical process equipment, piping, and tanks.

(d) Control of access to high radiation areas.

(1) The licensee or registrant shall ensure that each entrance or access point to a high radiation area has one or more of the following features:

(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 1 hour at 30 centimeters from the source of radiation from any surface that the radiation penetrates; or

(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.

(2) In place of the controls required by paragraph (1) of this subdivision for a high radiation area, the licensee or registrant may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry.

(3) The licensee or registrant may use alternative methods for controlling access to high radiation areas found by the department to be effective at accomplishing such control.

(4) The licensee or registrant shall establish the controls required by paragraphs (1) and (3) of this subdivision in a way that does not prevent individuals from leaving a high radiation area.

(5) The licensee or registrant is not required to control each entrance or access point to a room or other area that is a high radiation area solely because of the presence of radioactive materials prepared for transport and packaged and labeled in accordance with section 16.17 of this Part, provided that:

(i) the packages do not remain in the area longer than 3 days; and

(ii) the dose rate at 1 meter from the external surface of any package does not exceed 0.1 mSv (0.01 rem) per hour.

(6) The licensee 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 Part and to operate within the ALARA provisions of the licensee's or registrant's radiation protection program.

(7) 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 this paragraph if the registrant has met all the specific requirements for access and control specified in other applicable sections of this Part, such as those regulating x-ray equipment in the healing arts and particle accelerators.

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

(1) In addition to the requirements in paragraph (2) of this subdivision, the licensee or registrant shall institute additional 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 5 Gy (500 rad) or more in 1 hour at 1 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 irradiators as described in subdivision (f) of this section.

(2) 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 paragraph (1) of this subdivision if the registrant has met all the specific requirements for access and control specified in other applicable sections of this Part, such as those regulating radiation equipment in the healing arts or particle accelerators.

(f) Control of access to very high radiation areas -- irradiators.

(1) This subdivision applies to licensees or registrants with sources of radiation in non-self-shielded irradiators. This subdivision does not apply to sources of radiation that are used in teletherapy, in industrial radiography, or in completely self-shielded irradiators in which the source of radiation is both stored and operated within the same shielding radiation barrier and, in the designed configuration of the irradiator, is always physically inaccessible to any individual and cannot create a radiation level of 5 Gy (500 rad) or more in 1 hour at 1 meter in an area that is accessible to any individual.

(2) Each area in which there may exist radiation levels in excess of 5 Gy (500 rad) in 1 hour at 1 meter from a source of radiation that is used to irradiate materials shall meet the following requirements:

(i) Each entrance or access point shall be equipped with entry control devices which:

(*a*) function automatically to prevent any individual from inadvertently entering a very high radiation area; and

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

(*c*) prevent operation of the source of radiation if it would produce radiation levels in the area that could result in a deep dose equivalent to an individual in excess of 1 mSv (0.1 rem) in 1 hour.

(ii) Additional control devices shall be provided so that, upon failure of the entry control devices to function as required by subparagraph (2)(i) of this subdivision:

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

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

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

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

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

(iv) When the shield for stored sealed sources is a liquid, the licensee or registrant shall provide means to monitor the integrity of the shield and to signal, automatically, loss of shielding to 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 1 hour.

(v) Physical radiation barriers that comprise permanent structural components, such as walls, that have no credible probability of failure or removal in ordinary circumstances need not meet the requirements of subparagraphs (iii) and (iv) of this paragraph.

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

(vii) Each area shall be controlled by use of such procedures and devices as are necessary to ensure that the area is cleared of personnel prior to each use of the source of radiation.

(viii) Prior to the first individual's entry into each very high radiation area after any use of the source of radiation, the area shall be checked by a radiation measurement. The area may not be used unless 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 1 hour.

(ix) The entry control devices required in subparagraph (i) of paragraph (2) of this subdivision shall have been tested for proper functioning. (*See* section 16.14(f) of this Part for recordkeeping requirements).

(*a*) Testing shall be conducted prior to initial operation with the source of radiation on any day, unless operations were continued uninterrupted from the previous day; and

(b) Testing shall be conducted prior to resumption of operation of the source of radiation after any unintentional interruption; and

(c) The licensee or registrant shall submit and adhere to a schedule for periodic tests of the entry control and warning systems.

(x) The licensee or registrant shall not conduct operations, other than those necessary to place the source of radiation in safe condition or to effect repairs on controls, unless control devices are functioning properly.

(xi) Entry and exit portals that are used in transporting materials to and from the irradiation area, and that are not intended for use by individuals, shall be controlled by such procedures and devices as are necessary to physically protect and warn against inadvertent entry by any individual through these portals. Exit portals for irradiated materials shall be equipped to detect and signal the presence of any loose radioactive material that is carried toward such an exit and to automatically prevent loose radioactive material from being carried out of the area.

(3) Licensees, registrants, or applicants for licenses or registrations for sources of radiation within the purview of paragraph (2) of this subdivision which will be used in a variety of positions or in locations, such as open fields or forests, that make it impracticable to comply with certain requirements of paragraph (2) of this subdivision, such as those for the automatic control of radiation levels, may apply to the department for approval of alternative safety measures. Alternative safety measures shall provide personnel protection at least equivalent to those specified in paragraph (2) 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 the absence of high radiation levels before an individual can gain access to the area where such sources of radiation are used.

(4) The entry control devices required by paragraph (2) and (3) of this subdivision shall be established in such a way that no individual will be prevented from leaving the area.

(g) Unnecessary use of signs and labels. Cautionary signs and labels shall not be used except as required by subdivisions (b) and (c) of this section.

16.13 Notices, instructions and reports to workers; inspections.

(a) Purpose and scope. This section establishes requirements for notices, instructions and reports by radioactive materials licensees or radiation-producing equipment registrants to individuals engaged in work under a license or registration, and options available to such individuals in connection with inspections of the activities and facilities of licensees or registrants by the department or health officer having jurisdiction to ascertain compliance with the provisions of this Part, orders and licenses issued thereunder regarding radiological working conditions.

(b) Posting of notices to workers.

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

(i) the regulations of this Part;

(ii) the radioactive materials license and conditions or documents incorporated into the license by reference and amendments thereto, or the certificate of registration;

(iii) the operating procedures (including emergency procedures) applicable to work under the license or registration; and

(iv) any notice of violation involving radiological working conditions, proposed imposition of civil penalty or order issued pursuant to the provisions of the Public Health Law, and any response from the licensee or registrant.

(2) If posting of a document specified in paragraph (1) of this subdivision is not practicable, the licensee or registrant may post a notice which describes the document and states where it may be examined.

(3) A current copy of "Notice to Employees" shall be posted by each licensee or registrant wherever individuals work in or frequent any portion of a restricted area.

(4) Documents, notices or forms posted pursuant to this section shall be conspicuous, be replaced if defaced or altered, and appear in a sufficient number of places to permit individuals engaged in work under the license or registration to observe them on the way to or from assigned work locations to which the document applies.

(5) Department documents shall be posted within two working days after receipt of the documents from the department; the licensee's or registrant's response, if any, shall be posted within two working days after dispatch from the licensee or registrant. Such documents shall remain posted for a minimum of five working days or until action correcting violations, if any, has been completed, whichever is later.

(c) Instructions. All individuals likely to receive an occupational dose or frequenting any portion of a restricted area shall be provided instruction as specified in this subdivision. In determining those individuals subject to the requirements of this subdivision, licensees and registrants must take into consideration assigned activities during normal and abnormal situations involving exposure to radiation and/or radioactive material which can reasonably be expected to occur during the life of a licensed and/or registered facility. The extent of these instructions must be commensurate with potential radiological health protection problems present in the workplace. Individuals described under this Part shall be:

(1) kept informed of the storage, transfer or use of radioactive material, of radiation-producing equipment or of radiation in such portions of the restricted area;

(2) instructed in the operating procedures applicable to work under the license or registration and the health protection problems associated with exposure to such radioactive material,

radiation equipment, or radiation, in precautions or procedures to minimize exposure, in the purposes and functions of protective devices employed, and required to demonstrate familiarity with such precautions, procedures and devices;

(3) instructed in, and required to observe, to the extent within the worker's control, the applicable provisions of this Part and licenses and/or registrations for the protection of personnel from exposures to radiation, radiation equipment, or radioactive material occurring in such areas;

(4) instructed of their responsibility to report promptly to the licensee or registrant any condition which may lead to or cause a violation of the department regulations and licenses or unnecessary exposure to radiation or radioactive material;

(5) instructed in the appropriate response to warnings made in the event of any unusual occurrence of malfunction that may involve exposure to radiation or radioactive material; and

(6) advised as to the radiation exposure reports which workers must be given or may request pursuant to subdivision (d) of this section.

(7) The extent of these instructions required under this subdivision shall be commensurate with the nature and level of the likely exposure and with potential radiological health problems in the restricted area. Instruction shall be given before an individual begins work likely to result in receiving an occupational dose or before an individual begins work in a restricted area and at least annually thereafter. Records documenting individual worker instruction shall be maintained for inspection by the department for a period of three years.

(d) Notification and reports to individuals.

(1) Radiation exposure data for an individual and the results of any measurements, analyses and calculations of radioactive material deposited or retained in the body of an individual shall be reported to the individual as specified in this subdivision. The information reported shall include

data and results as shown in records maintained by the licensee or registrant pursuant to subparagraphs (i) through (vi) of paragraph (1) of subdivision (d) of section 16.14 of this Part. Each notification and report shall be in writing and include appropriate data, such as the name of the licensee or registrant, the name of the individual, the individual's identifying information together with the individual's exposure information and contain the following statement: "This report is furnished to you under the provisions of Part 16, New York State Sanitary Code, and should be preserved for further reference."

(2) Each licensee or registrant shall advise each worker annually of the worker's exposure to radiation or radioactive material as shown in records maintained by the licensee or registrant pursuant to subparagraphs (i) through (vi) of paragraph (1) of subdivision (d) of section 16.14 of this Part.

(3) At the request of a worker formerly engaged in work controlled by the licensee or the registrant, each licensee or registrant shall furnish to the worker a report of the worker's exposure to radiation or radioactive material. Such report shall:

(i) be furnished within 30 days from the time the request is made, or within 30 days after the exposure of the individual has been determined by the licensee or registrant, whichever is later;

(ii) cover, within the period of time specified in the request, each calendar year in which the worker's activities involved exposure to radiation from radioactive material licensed by, or radiation producing equipment registered with the department;

(iii) contain the results of any dose to the embryo/fetus and include any calculations and analysis of radioactive material deposited in such individual's body, including any bioassay or other medical evaluation services of which records are required by subparagraphs (ii) through (vi) of paragraph (1) of subdivision (d) of section 16.14 of this Part; and

(iv) include the dates and locations of work under the license or registration in which the worker participated during this period.

(4) When a licensee or registrant is required pursuant to section 16.15 of this Part to report to the department any exposure of an individual to radiation or radioactive material, the licensee or the registrant shall also provide to the individual a report on his exposure data included therein. Such reports shall be transmitted at a time not later than the transmittal to the department.

(5) At the request of any worker who has been engaged in a work assignment in an area restricted by a licensee or registrant for purposes of radiation protection, and who is terminating employment in such work assignment in the current year, the licensee or registrant shall provide a written report of the radiation dose received by that worker from operations of the licensee or registrant during that specifically identified current year. The report shall be provided to the worker or the worker's designee at termination, and if the final determined personnel monitoring results are not available at that time, a written estimate of that dose shall be provided in the interim. Estimated doses shall be clearly indicated as such.

(e) Inspections; presence of representatives of licensees or registrants and workers during inspection.

(1) Each licensee or applicant for a license or registrant, shall afford the department or health officer having jurisdiction during hours of operation the opportunity to inspect:

(i) the radiation source and the installation, institution, establishment, premises or facilities at which such source is located, possessed, stored or used;

(ii) each record required to be maintained by this Part.

(2) During an inspection, the licensee or registrant shall conduct, or permit the department or health officer having jurisdiction to conduct, such tests as the department or health officer may require, including but not limited to tests of:

(i) any radiation source and the installation, institution, establishment, premises or facilities at which such radiation source is located, possessed, stored or used; and

(ii) the personnel monitoring equipment referred to in section 16.11 of this Part and any other equipment, instrument or devices used in connection with the location, possession, storage or use of such radiation source.

(3) During an inspection, the department or health officer having jurisdiction may consult privately with workers as specified in subdivision (f) of this section. The licensee or registrant may accompany department inspectors or health officer having jurisdiction during other phases of an inspection.

(4) If, at the time of inspection, an individual has been authorized by the workers to represent them during inspections, the licensee or registrant shall notify the inspectors of such authorization and shall give the worker's representative an opportunity to accompany the inspectors during the inspection of physical working conditions.

(5) Each workers' representative shall be routinely engaged in work under control of the licensee or registrant and shall have received instructions as specified in subdivision (c) of this section.

(6) Different representatives of licensees or registrants and workers may accompany the inspectors during different phases of an inspection if there is no resulting interference with the conduct of the inspection. However, only one workers' representative at a time may accompany the inspectors.

(7) 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 inspectors during the inspection of physical working conditions.

(8) Notwithstanding the other provisions of this section, inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection. With regard to any area containing proprietary information or radioactive materials quantities of concern, the workers' representative for that area shall be an individual previously authorized by the licensee or registrant to enter that area.

(f) Consultation with workers during inspections.

(1) Inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of department regulations, registrations and licenses to the extent the inspectors deem necessary for the conduct of an effective and thorough inspection.

(2) During the course of an inspection any worker may privately bring to the attention of the inspectors, either orally or in writing, any past or present condition which he has reason to believe may have contributed to or caused any violations of this Part, or license condition, or an unnecessary exposure of an individual to radiation from licensed radioactive material or registered radiation equipment under the licensee's or registrant's control. Any such notices in writing shall comply with the requirements of paragraph (1) of subdivision (g) of this section.

(3) The provisions of paragraph (2) of this subdivision shall not be interpreted as authorization to disregard instructions provided pursuant to subdivision (c) of this section.

(g) Requests by workers for inspections.

(1) Any worker or representative of workers who believes that a violation of this Part or of 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. Any such notice shall:

(i) be in writing;

(ii) set forth the specific grounds for the notice; and

(iii) be signed by the worker or representative of the workers. A copy shall be provided to the licensee or registrant by the department no later than at the time of inspection, except that, upon the request of the worker giving such notice, their 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 department, except for good cause shown.

(2) If, upon receipt of such notice, the department determines that the complaint meets the requirements set forth in paragraph (1) of this subdivision and that there are reasonable grounds to believe that the alleged violation exists or has occurred, the licensee or registrant shall afford the department or health officer having jurisdiction, during routine hours of operation or at other reasonable times, opportunity to conduct an inspection. Inspection pursuant to this section need not be limited to matters referred to in the complaint or allegation.

(3) No 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 this Part or has testified or is about to testify in any such proceeding, or because of the exercise by such worker on behalf of himself or others of any option afforded by this Part.

(h) Inspections not warranted; informal review.

(1) If the department determines, with respect to a complaint under subdivision (g) of this section, that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, the department shall notify the complainant in writing of such determination. The complainant may obtain an informal review of such a determination by submitting a written statement of position with the department who will provide the licensee or registrant with a copy of such statement by certified mail, excluding, at the request of the complainant, the name of the complainant. The licensee or registrant may submit an opposing written statement of position with the department, who will provide the complainant with a copy of such statement by certified mail. Upon the request of the complainant, the department may hold an informal conference in which the complainant and the licensee or registrant may orally present their views. An informal conference may also be held at the request of the licensee or registrant, but disclosure of the identity of the complainant will be made only following receipt of written authorization from the complainant. After considering all written or oral views presented, department shall affirm, modify or reverse the initial determination of the department and furnish the complainant and the licensee or registrant a written notification of the decision and the reason therefore.

(2) If the department determines that an inspection is not warranted because the requirements of paragraph (1) of subdivision (g) of this section have not been met, it shall notify the complainant in writing of such determination. Such determination shall be without prejudice to the filing of a new complaint meeting the requirements of paragraph (1) of subdivision (g) of this section.

(i) Each person who possesses any radiation source shall, when necessary or desirable in order to aid in determining the extent of any individual's occupational exposure to a radiation source, comply with orders from the department directing such person to make available to such

individual bioassay services or other appropriate medical evaluations and to furnish to the department and the health officer having jurisdiction a copy of the reports of such services.

16.14 Records

(a) General provisions.

(1) Each licensee or registrant shall use the SI units: becquerel, gray, sievert and coulomb per kilogram, or the special units: curie, rad, rem, and roentgen, including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by this Part, with the exception that information on shipment manifests as required by 10 CFR20.2006(b), as revised and implemented on October 1, 2007, shall be recorded in the SI units.

(2) The licensee or registrant shall make a clear distinction among the quantities entered on the records required by this Part, such as, total effective dose equivalent, shallow dose equivalent, lens dose equivalent, deep dose equivalent, or committed effective dose equivalent.

(3) Form of records. Each record required by this Part shall be legible throughout the specified retention period. The record shall be the original or the record may also be stored in electronic media with the capability for producing retrievable, legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications shall include pertinent information, such as stamps, initials, and signatures.

(4) The discontinuance of or curtailment of activities does not relieve any person who possesses any radiation source of responsibility for retaining all records required by this Part.

(b) Records of radiation protection programs. Unless otherwise specified in license condition or regulation, records shall be maintained for a minimum of three years.

(1) Each licensee or registrant shall 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.

(2) The licensee or registrant shall retain the records required by subparagraph (i) of paragraph (1) of subdivision (b) of this section until the department terminates each pertinent license or registration requiring the record. The licensee or registrant shall retain the records required by subparagraph (ii) of paragraph (1) of subdivision (b) of this section for three years after the record is made.

(3) The licensee or registrant shall maintain safeguards sufficient to prevent tampering with and loss of records and shall have adequate procedures or systems in place to ensure the security and integrity of all data and records and have plans to recover from events of data tampering and ensure continuity of care.

(c) Records of surveys.

(1) Each licensee or registrant shall maintain records showing the results of surveys and calibrations required by sections 16.10(a) and 16.16(b) and (c) of this Part. The licensee or registrant shall retain these records for three years after the record is made.

(2) The licensee or registrant shall retain each of the following records until the department authorizes the disposition of these records:

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

(ii) records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose; and

(iii) records showing the results of air sampling, surveys, and bioassays required pursuant to section 16.26(c)(1)(iii)(a) and (b) of this Part; and

(iv) records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment.

(3) Upon termination of the license or registration, the licensee or registrant shall ensure that all occupationally monitored employees are provided their most recent and final exposure reports.

(4) Records of tests for leakage or contamination of sealed sources. Records of tests for leakage or contamination of sealed sources required by section 16.10(a)(4) of this Part shall be kept in units of becquerel or microcuries and maintained for inspection by the department.

(d) Records of individual monitoring results.

(1) Recordkeeping requirement. Each licensee or registrant shall maintain records of doses received by all individuals for whom monitoring was required pursuant to section 16.11 of this Part, and records of doses received during accidents and emergency conditions. Assessments of dose equivalent and records made using units in effect before the effective date of this Part need not be changed. These records shall include, when 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; and

(ii) the estimated intake or body burden of radionuclides, see section 16.6(b) of this Part; and

(iii) the committed effective dose equivalent assigned to the intake or body burden of radionuclides; and

(iv) the specific information used to assess the committed effective dose equivalent pursuant to section 16.6(d) of this Part; and

(v) the total effective dose equivalent when required by section 16.6(b) of this Part; and

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

(2) Recordkeeping frequency. The licensee or registrant shall make entries of the records specified in this subdivision at least annually.

(3) Recordkeeping format. The licensee or registrant shall maintain the records specified in this subdivision on US NRC's "Occupational Radiation Exposure Record for a Monitoring Period", or in clear and legible records containing all the information required by such form.

(4) The licensee or registrant shall maintain the records of dose to an embryo/fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy, including the estimated date of conception, shall also be kept on file, but may be maintained separately from the dose records.

(5) The licensee or registrant shall retain each required form or record until disposition is authorized by the department.

(6) Upon termination of the license or registration, the licensee or registrant shall provide dosimetry records and/or bioassay data to the individuals who were monitored.

(e) Records of dose to individual members of the public:

(1) Each licensee or registrant shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public. (*See* section 16.7(a) of this Part).

(2) The licensee or registrant shall retain the records required by this subdivision until disposition is authorized by the department.

(f) Records of testing entry control devices for very high radiation areas.

(1) Each licensee or registrant shall maintain records of tests made pursuant to section 16.12(f)(2)(ix) of this Part on entry control devices for very high radiation areas. These records must include the date, time, and results of each such test of function.

(2) The licensee or registrant shall retain the records required by this subdivision for three years after the record is made.

(g) Records of transfer, or receipt of radioactive materials.

(1) Each licensee shall maintain accurate and complete written records for each transfer or receipt of radioactive materials including radioactive waste.

(i) The licensee shall retain each record of receipt of radioactive material as long as the material is possessed and for three years or as directed by the department, following transfer or disposal of the material.

(ii) The licensee who transferred the material shall retain each record of transfer for three years after each transfer unless a provision of this Part, or other applicable regulations, dictates otherwise.

(iii) The licensee who disposed of the material shall retain each record of disposal of radioactive material until the department terminates each license that authorizes disposal of the material.

(2) The licensee shall retain each record that is required by this or by license condition for the period specified by the appropriate regulation or license condition. If a retention period is not otherwise specified by regulation or license condition, the record must be retained until the department terminates each license that authorizes the activity that is subject to the recordkeeping requirement.

(3) Prior to license termination, each licensee authorized to possess radioactive material with a half-life greater than 120 days, in an unsealed form, shall forward records of disposal of licensed material made under section 16.8 of this Part to the department.

(4) If licensed activities are transferred each licensee authorized to possess radioactive material, with a half-life greater than 120 days, in an unsealed form, shall transfer disposal records to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated:

(5) Prior to license termination, each licensee shall forward the records required by the Part for decommissioning to the department.

(h) Records of Patient Fluoroscopy Doses

(1) When a patient's skin dose from a fluoroscopic procedure exceeds 2 Gy (200 rad), the facility will record the dose in the patient's medical record along with an unambiguous identification of those areas of the patient's skin that received the dose. Such identification may be through diagram or narrative description.

(2) When a patient skin dose from a fluoroscopic procedure is equal to or greater than 3 Gy (300 rad):

(i) The facility will monitor the patient for skin reactions for at least 1 year.

(ii) The patient's referring physician will be notified and provided information regarding management of skin reactions.

(iii) The patient will receive written follow-up instructions that informs them how to identify skin reactions, how to notify the facility, how to arrange for follow-up.

(iv) The patient should have sufficient knowledge to alert providers.

16.15 Reports.

(a) Reports of stolen, lost, or missing licensed or registered sources of radiation.

(1) Telephone reports. Each licensee or registrant shall report to the department by telephone as follows:

(i) Immediately after its occurrence becomes known to the licensee or registrant, stolen, lost, or missing licensed radioactive material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in 10 CFR 20, appendix C, as revised and implemented in full on March 14, 2023.

(ii) Within 7 calendar days after its occurrence becomes known to the licensee, lost, stolen, or missing licensed radioactive material in an aggregate quantity greater than 10 times the quantity specified in 10 CFR 20, appendix C, as revised and implemented in full on March 14, 2023, that is still missing.

(iii) Immediately after its occurrence becomes known to the registrant, a stolen, lost, or missing radiation equipment.

(iv) Immediately after the discovery of an event that prevents immediate protective action necessary to avoid exposures to radiation or radioactive materials which could exceed the regulatory limits, or releases of radioactive material which could exceed regulatory limits; due to an event such as an explosion, or toxic gas release.

(2) Written reports. Each licensee or registrant required to make a report pursuant to this subdivision shall, within 30 days after making the telephone report, make a written report to the department setting forth the following information:

(i) A description of the licensed or registered source of radiation involved, including, for radioactive material, the kind, quantity, and chemical and physical form, manufacturer, model

and serial number for the device and/or source, and the estimated current activity of the source; and, for radiation equipment, the manufacturer, model and serial number, type and maximum energy of radiation emitted; and other pertinent information as requested by the department.

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

(iii) A statement of disposition, or probable disposition, of the licensed or registered 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.

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

(3) After filing the written report, the licensee or registrant shall also report any additional substantive information on the loss or theft within 30 days after the discovery of such information.

(4) The names of individuals who may have received exposure to radiation must be stated only in a separate and detachable portion of the report.

(b) Notification of incidents.

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

(i) an individual to receive:

(a) a total effective dose equivalent of 0.25 Sv (25 rem) or more; or

(b) a lens dose equivalent of 0.75 Sv (75 rem) or more; or

(c) a shallow dose equivalent to the skin or extremities 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.

(2) Twenty-four hour notification. Each licensee or registrant shall, within 24 hours of discovery of the event, report 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); or

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

(c) a shallow dose equivalent to the skin or extremities 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 hotcells or process enclosures.

(3) The licensee or registrant shall prepare each report filed with the department pursuant to this subdivision so that names of individuals who have received exposure to sources of radiation are stated in a separate and detachable portion of the report.

(4) Licensees or registrants shall make the reports required by paragraphs (1) and (2) of this subdivision by means indicated in section 16.1(c) of this Part.

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

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

(i) incidents for which notification is required by section 16.15(b) of this Part;

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

(*a*) the occupational dose limits for adults in section 16.6(a) of this Part;

(*b*) the occupational dose limits for a minor in section 16.6(e) of this Part;

(*c*) the limits for an embryo/fetus of a declared pregnant worker in section 16.6(f) of this Part;

(*d*) the limits for an individual member of the public in section 16.7(a) of this Part;

(*e*) any applicable limit in the license or registration;

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

(*a*) a restricted area in excess of applicable limits in the license or registration;

(*b*) an unrestricted area in excess of 10 times the applicable limit set forth in this Part or in the license or registration, whether or not involving exposure of any individual in excess of the limits in section 16.7(a) of this Part.

(2) Contents of reports.

(i) Each report required by this subdivision shall describe the extent of exposure of individuals to radiation and radioactive material, including, as appropriate:

(*a*) estimates of each individual's dose; and

(*b*) the levels of radiation and concentrations of radioactive material involved; and

(*c*) the cause of the elevated exposures, dose rates, or concentrations; and

(*d*) corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, and associated license or registration conditions.

(ii) Each report filed pursuant to paragraph (1) of this subdivision shall include for each individual exposed: the name and status as minor or adult. With respect to the limit for the embryo/fetus in section 16.6(f) of this Part, the identifiers should be those of the declared pregnant worker. The report shall be prepared so that this information is stated in a separate and detachable portion of the report.

(3) All licensees or registrants who make reports pursuant to this subdivision shall submit the report in writing to the department.

(d) Notifications and reports to individuals.

(1) Requirements for notification and reports to individuals of exposure to radiation or radioactive material are specified in section 16.13 of this Part.

(2) When a licensee or registrant is required pursuant to section 16.15(c) of this Part to report to the department 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 department and shall comply with the provisions of section 16.13 of this Part.

(e) Reports of leaking or contaminated sealed sources. If a sealed source is determined to be leaking or contaminated, a report shall be filed within five days with the department describing the equipment involved, the test results and the corrective action taken. The information must include device make and model, source make, model, serial number, isotope, and the activity and date for which the activity was determined and other information as requested by the department.

(f) Each professional practitioner who treats or diagnoses any suspected radiation illness shall report in writing to the department within seven days after such treatment or diagnoses, the fact thereof and the full name, address and age of the individual. Included in this reporting requirement are patients who have developed clinical symptoms as a result of contact with radioactive jewelry or other consumer products.

(g) Radioactive materials licensees and general license registrants shall report events described in 10 CFR 30.50(a), (b), (c)(1) and (c)(2), as revised and implemented on October 16, 2020; 10 CFR40.60(a), (b), (c)(1) and (c)(2), as revised and implemented on October 16, 2020; and 10 CFR70.50(a) and (b), as revised and implemented on October 16, 2020, to the department instead of to the NRC.

(h) Licensees and registrants authorized for medical use shall furnish reports of medical events as required by sections 16.25 and 16.123 of this Part.

(i) Reports of transactions involving nationally tracked sources.

(1) Each licensee who manufactures, transfer, receive, disassemble, or dispose of a nationally tracked source shall comply with 10 CFR 20.2207, as revised and implemented in full on August 9, 2021.

(j) Immediately report to the department any exceedance of external radiation standards for packages, as specified in section 16.16(d) of this Part.

16.16 Procedures for picking up, receiving, and opening packages.

(a) Each licensee who expects to receive a package containing quantities of radioactive material in excess of the Type A(2) quantities specified in 10 CFR71.4 as revised and implemented on

November 30, 2021, and appendix A of 10 CFR 71 as revised and implemented in full on November 30, 2021, shall make arrangements:

(1) to receive the package when the carrier offers it for delivery; or

(2) to receive notification of the arrival of the package at the carrier's terminal and to pick up the package expeditiously.

(b) Each licensee shall:

(1) Monitor the external surfaces of a package Labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in U.S. Department of Transportation regulations, 49 CFR 172.403 as revised and implemented on July 11, 2014, and 172.436-440 as revised and implemented on December 20, 1991, for radioactive contamination unless the package contains only radioactive material in the form of a gas or in special form as defined in 10 CFR71.4 as revised and implemented on November 30, 2021.

(2) Monitor the external surfaces of a package Labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in U.S. Department of Transportation regulations, 49 CFR 172.403 as revised and implemented on July 11, 2014, and 172.436-440 as revised and implemented on December 20, 1991, for radiation levels unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, as defined in 10 CFR71.4 as revised and implemented on November 30, 2021, and appendix A to 10 CFR 71 as revised and implemented on November 30, 2021.

(c) Each licensee, upon receipt of a package containing radioactive material in quantities described in subdivision (a) of this section, or any package that shows evidence of damage or leaking shall monitor the external surfaces of the package for radioactive contamination, shall survey all packages for radiation levels and shall make other surveys as may be required by

section 16.10 of this Part. The licensee shall perform the monitoring as soon as practical after receipt of the package, but not later than three hours after the package is received during the licensee's normal working hours, or not later than three hours from the beginning of the next working day if it is received after working hours.

(d) The licensee shall immediately notify the final delivery carrier and the department, by telephone, if packages, other than those transported by exclusive use vehicle, are found to have any of the conditions in paragraphs (1) and (2) of this subdivision. Notification to the department shall be made by means indicated in section 16.1(c) of this Part.

(1) Removable radioactive contamination in excess of the limits specified in 49 CFR173.443 as revised and implemented on July 11, 2014, [0.01 microcuries (22,000 dpm) (0.37 KBq) per 100 square centimeters on the external surfaces of the package]; or

(2) External radiation levels [at 1 meter from the external surface of the package in excess of 0.01 rem (10 mrem) (0.1mSV) per hour] in excess of the limits in 10 CFR71.47 as revised and implemented on September 28, 1995.

(e) Each licensee shall:

(1) Establish and maintain written procedures for the safe opening of packages in which radioactive material is received that include consideration given to special instructions for the type of package being opened.

(2) Ensure that the procedures are followed.

16.17 Packaging and Transportation of Radioactive Material.

(a) Any person performing packaging, preparation for shipment, and transportation of radioactive material shall comply with the provisions of the following federal regulations, which

are hereby incorporated by reference, with the same force and effect as if fully set forth at length herein: 10 CFR 71, Packaging and Transportation of Radioactive Material, as revised and implemented in full on November 30, 2021, except as follows:

(1) Sections 71.0, 71.1, 71.2, 71.6, 71.7, 71.9, 71.10, 71.11, 71.12, 71.14(b), 71.19, 71.31, 71.33 through 71.36, 71.38, 71.39, 71.41, 71.51 -71.81, 71.85(a)-(c), 71.91(b), 71.93, 71.95, 71.99, 71.100, 71.101(c)(2), 71.101(d)-(f), and 71.107-71.125 are excluded.

(2) Any reference to the "Commission", "NRC", "NRC Regional Office" or any other organizational unit thereof shall be deemed to be a reference to the New York State Department of Health, except for when used in 71.5(b), 71.17(b), (c)(3), and (e), 71.85(c), 71.88(a)(4), 71.93(c), 71.95, 71.97(c)(1)(iii), (c)(3)(ii) and (iii), and (f), and 71.101(c)(1).

(3) In section 71.89 "10 CFR 20.1906(e)" is replaced with "10 NYCRR 16.16".

16.18 Surrender of radioactive material; sealing of radiation equipment.

Notwithstanding any exemption set forth in this Part:

(a) The department may, by rule, regulation, license condition or order, impose upon any person possessing a radiation source such requirements, in addition to those set forth in this Part, as it deems appropriate or necessary to protect the public health and safety and to minimize danger to life and property from radiation hazards.

(b) The department may by order require the removal through an authorized transferee or the surrender to the department of any radioactive material by any person who is not able or equipped, or who fails, to observe with regard to such radioactive material such radiation protection standards as are established by the department, or who uses such radioactive material in violation of law or this Part or order of the department or in a manner other than as set forth in

a license issued therefor by the department. Such person shall decontaminate any premises which may have been contaminated with radioactive material as a result of his activities to such radiation levels as the department may specify. The expenses incidental to such transfer, surrender, and/or decontamination shall be borne by such person responsible for the source.

(c) The department may by order require radiation equipment sealed, with an official New York State Department of Health seal or other suitable method, when such equipment is used by any person who is not able or equipped, or fails to observe with regard to such radiation equipment such radiation protection standards as are established by the department, or who uses such radiation equipment in violation of law or this Part or order of the department. Radiation equipment sealed by the department pursuant to this subdivision shall not be unsealed without prior authorization by the department.

16.19 Limitations on application of radiation to humans.

(a) Diagnostic x-ray equipment. No individual other than a professional practitioner, as defined in section 16.2(a) of this Part; a physician's assistant working under the authority of a physician in accordance with article 37 of the Public Health Law; or, a certified nurse practitioner working in accordance with article 139 of the Education Law, within a practice agreement with a physician, or under the authority of a Medical Director or Medical Board in an article 28 facility, shall direct or order the application of radiation from radiation equipment to a human being. No individual other than a professional practitioner; or an individual licensed and registered or exempted under article 35 of the Public Health Law, and operating within their scope of practice or, a student currently enrolled in an approved program of study in radiologic technology, and under direct supervision by a professional practitioner or licensed and registered radiographer;

shall position patients, set techniques or apply such radiation to a human being. Such direction or order to apply, or application of, radiation shall be in the course of the practitioner's professional practice and shall comply with the applicable provisions of Part 89 of this Title and article 35 of the Public Health Law.

(1) Dental assistants may operate dental radiographic equipment for dental x-ray procedures only under the supervision of a licensed dentist pursuant to the applicable provisions of section 89.30 of this Title and of section 3516 of the Public Health Law.

(b) Radiation therapy (external beam and brachytherapy) equipment. No individual other than a qualified physician shall direct or order the application of radiation from therapy equipment to a human being. No individual other than an Authorized User, named on a radioactive materials license for uses specified in 10 CFR sections 35.400, 35.600 and 35.1000, as revised and implemented in full on November 14, 2022, shall direct or order the application of radioactive material or radiation from radioactive material for therapeutic purposes to a human being. Nor shall any individual other than a qualified physician, or a licensed and registered radiation therapist or a student currently enrolled in an approved program of study in radiation therapy technology, and under direct supervision of a qualified physician or licensed radiation therapist; position patients, set techniques or apply radiation therapy to a human being. Such direction or order to apply, or application of, radiation shall be in compliance with the applicable provisions of Part 89 of this Title and article 35 of the Public Health Law.

(c) Radioactive materials. No individual other than a physician who is an Authorized User, named in a radioactive materials license issued pursuant to section 16.100 of this Part, or a physician under the Authorized User’s supervision shall direct or order the use of radioactive materials specified in 10 CFR sections 35.100, 35.200, 35.300 or 35.1000 or sealed sources for

diagnosis specified in 10 CFR 35.500 to a human being, as revised and implemented in full on November 14, 2022. Nor shall anyone other than these individuals, or an individual working under their direction or order, or a licensed and registered nuclear medicine technologist, as defined in article 35 of the Public Health Law, or student currently enrolled in an approved program of study in nuclear medicine technology, and under direct supervision by a professional practitioner or licensed and registered nuclear medicine technologist; administer radioactive materials to a human being. Such direction or order, or administration of radioactive materials or radiation shall be in the course of the physician's practice and shall comply with the practitioner's professional practice and shall comply with the applicable provisions of Part 89 of this Title and article 35 of the Public Health Law.

(d) The use of body scanning equipment for security screening. No individual, except as described in article 35 of the Public Health Law and section 16.70 of this Part, shall apply radiation to humans for purposes of security screening.

16.20 Hearings.

(a) On disapproval of applications. If the department disapproves any application for license filed pursuant to section 16.102 of this Part:

(1) The department will conduct a hearing if the applicant files with the department a written petition within 30 days after receipt of such notice of disapproval, and the petition:

(i) asserts that such disapproval was, and the respect in which it was, improper; and

(ii) requests a hearing.

(2) Having determined to conduct a hearing on the issues raised in an applicant's petition, the department will give written notice by personal delivery or by certified or registered mail to the

applicant at least 20 days prior to such hearing, informing that person that they may be present and heard at the hearing.

(b) On amendment, suspension or revocation of licenses; imposition of additional requirements; transfer or surrender of radioactive material. Except in any case of willfulness or in which the public health or safety requires otherwise, or in which an administrative correction is required, the department shall not amend, suspend or revoke any license pursuant to section 16.107 of this Part, or impose additional requirements on the possessor of a radiation source or require the transfer or surrender of radioactive material pursuant to section 16.18 of this Part without first:

(1) notifying in writing such licensee or person of the facts or conduct which may warrant such amendment, suspension, revocation, additional requirement, transfer or surrender, and giving such licensee or person a reasonable opportunity to demonstrate or achieve compliance with all lawful requirements; and

(2) conducting a hearing if the licensee or person files with the department a written petition within 30 days after receipt of such notice, and the petition:

(i) asserts that such amendment, suspension, revocation, additional requirement, transfer or surrender would be, and the respects in which it would be improper; and

(ii) requests a hearing.

(3) giving written notice by personal delivery or by certified or registered mail to the licensee or person at least 20 days prior to any hearing ordered pursuant to paragraph (2) of this subdivision. Such notice will inform the licensee or person that they may be present and heard at the hearing. The requirements in subdivision (b) of this section may be waived upon consent of the licensee or their authorized representative.

16.21 RESERVED.

16.22 X-ray screening; general requirements; mammography.

(a) General requirements. This applies to each person or operator that provides x-ray screening to a target population when there is no individual order for each procedure.

(1) All screening shall be performed under the supervision of a licensed practitioner pursuant to section 89.2(a) of this Title.

(2) The screening program operator shall establish and maintain a referral system for communicating findings to the patient's primary care provider in a timely fashion.

(3) The screening program operator shall establish and maintain a referral system for patients with suspicious findings or disease when the patient does not report having a primary care provider.

(4) The screening program operator shall annually review the program to determine the appropriateness of continuing screening and report the findings of that review to the department.

(5) A prospective screening program operator shall apply to the department and submit information prior to operation indicating how the operator will comply with paragraphs (1) through (4) of this subdivision.

(6) The screening program operator shall prepare and submit to the department within 15 days of a request, a report that includes the following information for a requested time period:

(i) the total number of patients screened by diagnosis;

(ii) the total number of suspicious findings or disease;

(iii) the total number of patients referred for follow-up for each suspicious finding or disease diagnosed.

(b) Mammography. The following requirements for mammography screening are in addition to those in paragraphs (1) through (5) of subdivision (a) of this section.

(1) All mammographic images shall be interpreted by a qualified physician.

(2) Baseline mammography images shall be maintained for ten years.

(3) The screening program operator shall perform an annual analysis of false positive and false negative findings for cases where the data can be obtained.

(4) The facility shall prepare and submit to the department an annual report including:

(i) total number of individuals screened by age group;

(ii) total number of patients referred for follow-up by age group; and

(iii) results of the analysis of false-positive findings.

16.23 Quality assurance programs for diagnostic facilities.

(a) A quality assurance program is a system of plans, actions, reviews, reports and records whose purpose is to ensure that diagnostic facilities achieve consistent high-quality imaging and other diagnostic results, while maintaining radiation output and personnel doses within limits prescribed by the department.

(1) Each radiation facility conducting diagnostic x-ray, fluoroscopy, cone beam CT, CT and/or radioactive materials procedures, excepting intraoral dental, panoramic dental, podiatric x-ray, and veterinary facilities, shall implement a quality assurance program including at a minimum:

(i) the adoption of a manual containing written policies and procedures for radiation protection and describing the facility's quality assurance program. Policies and procedures must be consistent with the types of equipment and services provided, including but not limited to, use of gonad or scoliosis shielding; personnel monitoring; protection of pregnant workers and patients;

and holding of patients. The quality assurance manual must describe the various processing, generator and systems quality control tests appropriate for the types of equipment and services provided in sufficient detail to ensure that they will be performed properly;

(ii) the performance of quality control tests and the correction of deficiencies as specified in the quality assurance manual;

(iii) the maintenance of equipment records for each diagnostic imaging system, containing test results, records of equipment repairs and other pertinent information;

(iv) the provision of a formalized in-service training program for employees, including, but not limited to, quality assurance and radiation safety procedures;

(v) the measurement of radiation output at the point of skin entry for common X-ray examinations;

(vi) the measurement of the amount of activity of each dose of a radiopharmaceutical administered to a patient;

(vii) the calculated absorbed dose for diagnostic procedures involving radioactive materials;

(viii) the recording of patient doses from fluoroscopy;

(ix) patient dose management in fluoroscopically guided procedures in conformance with the ACR-AAPM Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures (ACR Resolution 44 – 2013), NCRP Report 168, or equivalent standard.

(x) the provision of the information described in subparagraphs (v), (vi), and (vii) of this paragraph to any patient upon request; and

(xi) the conduct of an ongoing analysis of repeated, rejected or misadministered diagnostic studies which is designed to identify and correct problems and to optimize quality.

(xii) Each radiation facility conducting medical imaging studies and storing the imaging data electronically, shall implement a quality assurance program that includes written policies and procedures to ensure continuity of care for electronic images that is consistent with that provided for hardcopy imaging studies including assessment of backup of images and at least an annual testing of the system.

(2) Quality Assurance for Digital Imaging Acquisition Systems. Each radiation facility using digital imaging systems, excepting dental, podiatric and veterinary facilities, shall follow quality assurance (QA) and quality control (QC) protocols for image processing in addition to section 16.23(a)(1) of this Part. Acceptance testing and the radiation safety survey shall be completed and documented before first human use.

(i) Equipment Test Records shall be maintained for each unit in operation. Exposure indicator numbers for typical exams and image retakes shall be trended and kept for three years. If the manufacturer does not provide target numbers and tolerances, QC numbers for tests shall be trended to establish control limits.

(ii) Quality Control Records for Equipment. Test Records shall be maintained and available for review for quality control test equipment that requires calibration. Quality Control Records may be maintained in either hardcopy or softcopy format but shall be available for review during inspections.

(iii) Equipment Monitoring.

(*a*) All automated tests recommended by the manufacturer shall be run at the recommended frequency.

(*b*) The following tests shall be performed and documented on non-cassette based (also referred to as direct read or DR) systems using the manufacturer's phantom or a phantom acceptable to the department:

(*1*) Characterization of the beam (kVp, thickness and type of attenuation, mAs, other necessary information).

(*2*) Exposure index number calibration verification.

(*3*) Establish exposure index target values (for anatomic regions or exam type).

(*4*) Low contrast test.

(*5*) Contrast scale test.

(*6*) Spatial resolution test.

(7) Uniformity test.

(*8*) Geometric accuracy test.

(*9*) Artifact test.

(*10*) Signal-to-noise ratio (on raw images).

(*11*) Contrast-to-noise ratio (on raw images).

(*12*) Number of bad pixels test (if the system is capable).

(*13*) Automatic Exposure Control (AEC) verification.

(*c*) The following tests shall be performed and documented on cassette based (also referred to as computed radiography or CR) systems using the manufacturer's phantom or a phantom acceptable to the department:

(*1*) Characterization of the beam (kVp, thickness and type of attenuation, mAs, other necessary information).

(*2*) Establish exposure index target values (for anatomic regions or exam type).

(*3*) Low contrast test.

(*4*) Contrast scale test.

(*5*) Spatial resolution test.

(*6*) Uniformity test.

(*7*) Geometric accuracy test.

(*8*) Signal-to-noise ratio (on raw images).

(*9*) Contrast-to-noise ratio (on raw images).

(*10*) Image plate (IP) artifact test.

(*11*) IP dark noise test.

(*12*) Laser jitter.

(*13*) Primary erasure.

(*14*) Automatic Exposure Control (AEC) verification.

(*15*) System Linearity & Sensitivity.

(iv) Primary Diagnostic Monitors (PDM). Each primary diagnostic monitor shall be tested per the manufacturer's quality control requirements. At a minimum the following tests shall be performed and documented:

(*a*) Visual test pattern evaluation (TG-18QC, SMPTE, or equivalent).

(*b*) DICOM calibration of the Grayscale Standard Display Function (GSDF).

(*c*) Maximum luminance output.

(*d*) Minimum luminance output.

(*e*) Luminance ratio of maximum to minimum.

(*f*) Evaluation of viewing conditions.

(v) Laser Printers. Each printer, if used for primary interpretation or for patient records or referral, shall be tested per the manufacturer's quality control requirements and shall be of diagnostic quality. At a minimum the following tests shall be performed and documented.

(*a*) Download and print the SMPTE pattern.

(*b*) Measure the density of the 10%, 40%, and 90% patches.

(*c*) Determine and plot the Mid-density using the density at the 40% patch (MD) and Lower-density (LD) using the density at the 90% patch.

(*d*) Determine and plot Density Difference (DD) subtract the density at the 40% patch from the density of the 10% patch.

(vi) Neonatal imaging. Neonatal intensive care units must develop a QA program which includes the following protocols:

(*a*) establishing a technique chart for neonatal imaging including, at a minimum, specific techniques for chest and abdomen, along with corresponding direct or indirect determination of entrance skin dose; and

(*b*) an annual training program for Licensed Radiographic Technologists (LRTs) for conducting neonatal imaging; and

(*c*) a protocol for the proper use of neonatal collimation; and

(*d*) each facility must conduct an annual report on the compliance with the facility's neonatal QA program and forward such report to the facility radiation safety committee for review.

(vii) Imaging of children. Each registrant that conducts x-ray imaging of children must establish specific techniques at least for 1-year old, 5-year-old and 10-year-old children, specific to PA chest and abdomen x-ray studies. Additionally, the entrance skin exposure must be directly or

indirectly determined for the latter studies and posted in the facility along with the technique chart wherever it is reasonable to expect that children of such an age group can be x-rayed.

(b) Breast imaging quality assurance. Each facility performing breast imaging examinations that are not regulated by the U.S. Food and Drug Administration's Mammography Quality Standards Act, shall ensure that the breast imaging system is optimized to provide consistent, high-quality imaging. A breast imaging system includes the x-ray control, x-ray generator, x-ray tube, image receptor and all components of the imaging process. The facility shall use a breast equivalent phantom approved by the department to monitor image resolution. The breast phantom contains test objects which represent low density areas and microcalcifications which are related to the imaging of breast lesions. A test object is either a mass, fiber, or speck set.

(1) No breast imaging shall be performed unless the minimum manufacturer specifications and or the minimum criteria established by the American College of Radiology (ACR) for breast phantom imaging are met.

(2) All facilities shall optimize the breast imaging systems used and determine the breast phantom test object resolution of the system prior to performing breast imaging. The number of test objects resolved is the reference image the facility shall use for comparison during periodic testing. Under any conditions, if during the testing required under subdivision (a) of this section, the system is found to have lost the ability to resolve two test objects previously visible in the reference image, the facility shall investigate the reason and optimize the system.

(3) Diminished phantom test object resolution and facility follow-up.

(i) Whenever the phantom image indicates that the breast imaging system fails to meet the minimum test object resolution defined in paragraph two of this subdivision the facility shall

investigate the reason. Correction to achieve the minimum level shall be completed prior to performance of breast imaging.

(ii) In addition, if it is found that breast imaging has been performed while minimum requirements were not met the investigation shall include:

(*a*) a review of phantom images to determine at which point the image resolution fell below the minimum; and

(*b*) a review, by a panel of physicians selected by the department for this review, of breast images performed since the last phantom image that was identified as meeting the minimum level. Physicians selected for the panel must be certified in diagnostic radiology by the American Board of Radiology or the American Osteopathic Board of Radiology or have equivalent qualifications and will be selected for addition to this panel in consultation with the New York State Radiological Society. Members of the panel are deemed volunteers in service to the department within the meaning of paragraph (a) of subdivision one of section 17 of the Public Officers Law and, in lieu of expenses, shall be compensated by the department at the prevailing departmental per diem rate. The cases chosen for review shall include images from the range of studies performed by the facility which the panel ascertains to be sufficient to determine that the clinical images are of diagnostic quality. A record of the review and findings shall be maintained for inspection.

(iii) If images are identified by the physician conducting the review as nondiagnostic, the facility shall, within 5 business days, notify:

(*a*) the referring physician, or other authorized referring practitioner as defined in subdivision (a) of section 16.19 of this Part, or the patient, if not referred by a practitioner, of the need for follow-up; and

(*b*) the department of the results of the investigation and follow-up contacts.

(iv) A record of the results of the investigation and actions taken to correct any deficiency shall be maintained for review by the department for a period of three years.

16.24 Quality assurance programs for the use of radiation for therapy in humans.

(a) External beam therapy and brachytherapy. Each licensee or registrant authorized to administer external beam therapy or brachytherapy to human beings shall implement a quality assurance program to systematically monitor, evaluate, and document radiation therapy services to ensure consistent and safe fulfillment of the dose prescription to the target volume, with minimal dose to normal tissues, minimal exposure to personnel, and adequate patient monitoring aimed at determining the end result of the treatment. Each such licensee or registrant shall meet or exceed all quality assurance criteria described in this subdivision.

(1) Each licensee or registrant shall adopt, maintain, and implement a quality assurance manual that includes policies and procedures that ensure quality of patient care and safety of patients and other personnel. The manual must include procedures to ensure the following:

(i) Each patient's medical record shall be complete, accurate, legible, and shall include the patient's initial clinical evaluation, treatment planning data, treatment execution data, clinical assessments during treatment, a treatment summary, and plan for subsequent care. Treatment related data shall be recorded in the patient's medical record at the time of each treatment.

(ii) A written and dated order or prescription for the medical use of radiation or radioactive material shall be made for each patient in accordance with subdivisions (b) and (c) of section 16.19 of this Part. The order or prescription shall be signed or approved electronically by a board-certified radiation oncologist or qualified physician who restricts their practice to radiation

oncology. Changes to the initial prescription or written directive shall be signed and dated clearly.

(iii) The accuracy of treatment plan data and any modifications to treatment plan data transferred to a radiation treatment delivery system shall be verified by qualified clinical staff prior to patient treatment.

(iv) The treatment plan shall be reviewed and approved prior to the start of treatment and after any change ordered by a board-certified radiation oncologist or qualified physician who restricts their practice to radiation oncology.

(v) Set up shall be verified and documented by a radiation therapy technologist prior to every treatment session and set up shall be verified and approved by the radiation oncologist prior to:

(*a*) the first treatment and;

(*b*) prior to treatment for any changes to the initial treatment plan and;

(*c*) during the course of the treatment at frequencies consistent with the written directive and treatment protocol.

(vi) A radiation therapy technologist or physician shall obtain clarification before beginning a patient's treatment if any element of the order or other record is confusing, ambiguous, erroneous, or suspected of being erroneous.

(vii) Each patient's identification shall be verified by at least two different means and matched to the treatment plan at the console, by a radiation therapy technologist or physician prior to each treatment.

(viii) Each patient's response to treatment shall be assessed by a board-certified radiation oncologist or other qualified physician in the active practice of external beam therapy and/or

brachytherapy at least weekly. Unusual responses shall be evaluated as possible indications of treatment errors and recorded in the patient's medical record, investigated, and resolved.

(ix) The medical records of patients undergoing fractionated treatment shall be checked for completeness and accuracy by the licensed medical physicist or their designee at intervals not to exceed six fractions, and the completion of the course of radiation therapy.

(x) Radiation treatment plans and related calculations shall be checked, consistent with the written policy and the conditions of the license, by a licensed medical physicist or their designee for accuracy before 25 percent of the prescribed dose for external beam therapy or 50 percent of the prescribed dose for brachytherapy is administered, except the check shall be performed prior to treatment for: any single fraction treatment; any fractional dose that exceeds 300 cGy or 700 monitor units; or when the output of a medical therapy accelerator or treatment machine exceeds 600 monitor units per minute or 600 cGy per minute during treatment.

(*a*) If a treatment plan and related calculations were originally prepared by a licensed medical physicist or authorized medical physicist, it may be rechecked by the same individual using a different calculation method. (*b*) Treatment plans and related calculations prepared by others must be checked by a licensed medical physicist or their designee using procedures specified in the registrant's or licensee's treatment planning procedures manual required pursuant to paragraph (2) of this subdivision, and who has received training in use of the manual pursuant to paragraph (2) of this subdivision.

(xi) A board-certified radiation oncologist or other qualified physician shall assess patient’s response to treatment during the course of treatment and at the completion of radiation therapy. Unusual responses shall be evaluated as possible indications of treatment errors and recorded in

the patient's medical record, investigated, and resolved. Plans and evidence of follow up care shall be documented in the medical record.

(xii) All equipment and other technology used in planning, guiding, and administering radiation therapy shall function properly and safely, and shall be calibrated properly and repaired and maintained in accordance with the written policy and the manufacturer's instructions. The equipment and technology that is subject to such quality control includes but is not limited to: computer software and hardware including upgrades and new releases; equipment used to perform simulation/treatment planning; dosimetry equipment; equipment used to guide treatment delivery, including but not limited to ultrasound units, kV and mV imaging equipment and monitors that are used to view patient imaging studies; and personnel radiation safety equipment. Data communication between various systems, including but not limited to treatment planning systems, treatment delivery systems, and data networks/storage media, shall be evaluated and tested to ensure accurate and complete data transfer.

(xiii) Quality control tests performed on equipment and technology used in planning and implementing radiation treatment shall be documented, including:

(*a*) detailed procedures for performing each test;

(*b*) the frequency of each test;

(*c*) acceptable results for each test;

(*d*) corrective actions taken;

(*e*) record keeping and reporting procedures for test results including the tester’s name, signature, and date of the test; and

(*f*) the qualifications are specified for the individual(s) conducting the test and for the person who reviews test data.

(xiv) Test results that exceed tolerances/limits shall be immediately reported to the licensed medical physicist or authorized medical physicist.

(xv) Records for all maintenance, repairs, and upgrades of equipment and technology shall be maintained for at least five years.

(xvi) Errors or defects in technology or equipment, including computer hardware and software, shall be reported to the technology or equipment manufacturer and to the United States Food and Drug Administration (MedWatch) as soon as possible and in no event more than 30 days of discovery, and records of equipment errors and reports required by this clause shall be maintained for review by the department for at least three years.

(xvii) External beam therapy equipment calibration/output required by section 16.60(c)(1) or 16.61(b)(1) of this Part shall be verified by an independent means and records of such measurements shall be retained for review by the department for at least three years.

(xviii) Patients with permanent brachytherapy implants shall be provided with instructions to take radiation safety precautions, as required by section 16.123(e)(4) of this Part (incorporating 10 CFR 35.75, as revised and implemented on August 13, 2007) and the licensee's radioactive materials license, after being released from the licensee’s facility.

(xix) All personnel involved in planning or administering radiation therapy shall be credentialed. Credentialing shall include verifying that all professional staff are appropriately licensed, including medical physicists and radiation therapy technologists. Records of credentialing shall be maintained during the period in which the credentialed person provides services to the licensee or registrant and for three years thereafter. In the cases of new or complex high fractional dose therapy, staff (in additional to radiation therapists) required at the therapy console should be clearly identified in a written policy and properly trained.

(xx) Any unintended deviation from the treatment plan that is identified shall be evaluated and corrective action to prevent recurrence shall be implemented. Records of unintended deviations and corrective action shall be maintained for audits required by paragraph (3) of this subdivision and for review by the department.

(xxi) There shall be a process to ensure quick and effective response to any radiation therapy related recalls, notices, safety alerts, and hazards.

(xxii) A registrant providing mobile therapeutic radiation machine services shall, at each location of service, comply with all requirements specified in section 16.24 of this Part, as applicable. The registrant shall have policies and procedures to assure proper operation of the device on each day of clinical use, consistent with the registrant's written policy, manufacturer's guidelines, and established professional body guidelines.

(2) Each licensee or registrant shall adopt and maintain a radiation treatment manual that includes the calculation methods and formulas to be used at the facility (including the methods for performing the checks of treatment plans and related calculations as required in paragraph (1) of this subdivision). The treatment planning manual may be part of the quality assurance manual required by paragraph (1) of this subdivision. The radiation treatment manual shall be included in training given pursuant to subdivision (c) of section 16.13 of this Part to facility staff who will participate in treatment planning. Each licensee or registrant shall ensure that a licensed medical physicist or authorized medical physicist prepares or reviews and approves a procedures manual describing how radiation therapy treatment planning is to be performed at the licensee's or registrant's facility and reviews the treatment planning manual at least annually. This review must include all parts of the system including both software and physical components and any new modality or protocols.

(3) Each licensee or registrant shall implement written procedures for auditing the effectiveness of the radiation therapy quality assurance program that include the following:

(i) Audits shall be conducted at intervals not to exceed 12 months by a licensed medical physicist or authorized medical physicist, and also by a physician, both of whom are in the active practice of the type of radiation therapy conducted by the licensee or registrant.

(ii) The licensee or registrant shall ensure that the individuals who conduct the audit prepare and deliver to the licensee or registrant a report which contains an assessment of the effectiveness of the quality assurance program and makes recommendations for any needed modifications or improvements.

(iii) The licensee or registrant shall promptly review the audit findings, address the need for modifications or improvements, and document actions taken. If recommendations are not acted on, the licensee or registrant shall document the reasons therefor and also alternative actions taken to address the audit findings.

(iv) Each licensee or registrant shall maintain for review and inspection by the department complete written records relating to quality assurance and audit activities. Audit records shall be maintained for at least six years.

(v) The findings of the audit shall be presented to the RSC or in facilities exempt from having an RSC, the RSO shall review and document.

(4) Accreditation in Radiation Oncology. Each registrant or licensee providing radiation therapy using radioactive material authorized under 10 CFR sections 35.400, 35.600 or 35.1000 (other than radiopharmaceuticals), as revised and implemented in full on November 14, 2022, or radiation equipment under sections 16.60 or 16.61 of this Part shall:

(i) maintain accreditation in radiation oncology by an accrediting organization that is approved by the department;

(ii) for a newly licensed or registered practice, submit an application for accreditation to an organization listed in subparagraph (i) of this paragraph no later than six months after patient treatments begins. Within 18 months after start of patient treatments, the licensed or registered practice shall earn and maintain accreditation in radiation oncology by such organization;

(iii) upon addition of a radiation oncology modality that did not fall under an existing accreditation, the registrant or licensee shall notify the department within 14 days and follow the requirements to obtain accreditation by the accrediting organization and as directed by the department;

(iv) notify the department within 14 days upon notice of the outcome of the accreditation survey;

(v) registrants, licensees, and practices where service is provided by physicians and surgeons who are not radiation oncologists, and whose practices do not qualify for an accreditation survey by an organization specified in subparagraph (i) of this paragraph, shall have an annual audit specified in paragraph (3) of this subdivision performed by a physician and a licensed medical physicist or authorized medical physicist, both in active practice of such modalities and who have not provided clinical services at the practice during the period for which they perform the audit.

(b) Radiopharmaceutical therapy. A quality assurance program for radiopharmaceutical therapy is a system of plans, actions, reviews, reports and records whose purpose is to ensure a consistent and safe fulfillment of the written directive or dose prescription by the authorized user.

(1) Each licensee who uses radiopharmaceuticals for therapy in humans shall implement a quality assurance program which includes at a minimum:

(i) the adoption of a manual containing written policies and procedures designed to assure effective supervision, safety, proper performance of equipment, effective communication, and quality control. These must include procedures to assure that:

(*a*) each patient's evaluation and intended treatment by an authorized user is documented in the patient's record;

(*b*) a written, signed and dated order for medical use of radioactive material is made in accordance with subdivision (c) of section 16.19 of this Part;

(*c*) all orders and other treatment records are clear and legible;

(*d*) staff will be instructed to obtain clarification before treating a patient if any element of the order or other record is confusing, ambiguous or suspected of being erroneous;

(*e*) each patient's response to treatment is assessed by a physician knowledgeable in radiopharmaceutical therapy and that unusual responses are evaluated as possible indications of treatment errors; and

(*f*) complete treatment records containing data recorded at the time of each treatment are maintained.

(2) Each licensee shall ensure that all equipment used in planning and administering radiopharmaceutical therapy is designed for the intended purpose and is properly functioning; is properly calibrated and is maintained in accordance with the manufacturer's instructions and the quality assurance program described in the licensee or registrant's quality assurance manual.

(3) Each licensee shall: audit the radiopharmaceutical quality assurance program at intervals not to exceed 12 months to assess the effectiveness of the program; document the audit and any modifications or improvements found to be needed; institute corrective actions and

improvements as indicated by the audit findings; and present the finding of audit to the RSC or in facilities exempt from having an RSC to the RSO for review and approval.

16.25 Misadministration or Medical Event.

(a) A medical event or a misadministration are equivalent terms for purposes of this Part. A medical event shall be the administration of:

(1) A radiopharmaceutical or radiation from a source other than the one ordered.

(2) A radiopharmaceutical or radiation to the wrong person.

(3) A radiopharmaceutical or radiation by a route of administration or to a part of the body other than that intended by the ordering physician.

(4) An activity of a radiopharmaceutical for diagnostic purposes that differs from the activity ordered by more than 50 percent.

(5) An activity of a radiopharmaceutical for therapeutic purposes that differs from the activity ordered by more than 10 percent.

(6) A therapeutic radiation dose from any source other than a radiopharmaceutical or brachytherapy source such that errors in computation, calibration, time of exposure, treatment geometry or equipment malfunction result in a calculated total treatment dose differing from the final total treatment dose ordered by more than 10 percent.

(7) A therapeutic radiation dose from a brachytherapy source such that errors in computation, calibration, treatment time, source activity, source placement or equipment malfunction result in a calculated total treatment dose differing from the final total treatment dose ordered by more than 10 percent.

(8) In a therapeutic radiation course consisting of more than 5 fractions, the administered dose in an individual treatment or fraction that differs from the dose ordered for that individual treatment or fraction by 50 percent or more, or a dose deviation of 20 percent or more in 5 consecutive fractions. In a treatment course of 5 or fewer fractions, dose deviations of 20 percent or more in any one fraction.

(i) Instances when the administered dose is less than the prescribed dose due to machine interruption or patient decision or inability to complete the treatment are not deemed medical events. However, machine performances resulting in incorrect dose administration shall be investigated and reported to the manufacturer if warranted and corrective actions documented pursuant to section 16.24(a)(1)(xvi) of this Part.

(9) A CT scan is performed on the wrong person.

(10) A CT scan is performed on the wrong body part.

(11) A CT scan that results in damage to an organ, organ system or results in hair loss or erythema as determined by a physician.

(b) Records and Reports of medical events or misadministrations.

(1) Diagnostic medical events or misadministrations.

(i) Records of medical events as defined in subdivision (a) of this section which involve diagnostic procedures, and the corrective actions taken pursuant to subparagraph (ix) of paragraph (1) of subdivision (a) of section 16.23 of this Part, shall be retained for three (3) years.

(ii) If such a medical event in a dose to the patient exceeding 5 rem (0.05 Sv) to the whole body or 50 rem (0.5 Sv) to any individual organ, or the administration of iodine-131 or iodine-125 in the form of iodide, and in a quantity greater than 30 microcuries, the licensee or registrant shall

notify the department in writing within 15 days and make and retain a record pursuant to paragraph (3) of this subdivision.

(iii) A medical event described in paragraphs (9), (10) or (11) of subdivision (a) of this section, shall be reported to the Bureau of Environmental Radiation Protection (Bureau) within 15 days of occurrence. All other diagnostic events may be entered into NYPORTS or otherwise documented for facilities not subject to article 28 requirements.

(2) Therapy medical events or misadministrations.

(i) When a medical event described in paragraphs (5), (6), or (7) of subdivision (a) of this section, in which the percentage of error is less than 20 per cent is discovered the licensee or registrant shall immediately investigate the cause and take corrective action.

(*a*) The licensee or registrant shall make and retain a record of all therapy medical events or misadministrations described in this subparagraph. The record shall contain all the information called for in paragraph (3) of this subdivision and shall be retained for six years.

(ii) When a therapy medical event described in paragraphs (a)(1), (2), (3) or (8) of this section is discovered; or when a medical event described in paragraphs (a)(5), (6) or (7) of this section in which the percentage of error is equal to or greater than 20 percent is discovered; the licensee or registrant shall notify the department by telephone. The licensee or registrant shall also notify the referring physician of the affected patient and the patient, of any therapy medical event described in this subparagraph, with the exception of medical events described in paragraphs (a)(1) and (8) of this section. When it is not medically advisable to give such information to the patient, the information shall be made available to the patient's responsible relative or guardian on the patient's behalf. These notifications must be made within 24 hours after the medical event is discovered. If the referring physician, patient, or the patient's responsible relative or guardian

cannot be reached within 24 hours, the licensee or registrant shall notify them as soon as practicable. It is not required that the patient be notified without first consulting the referring physician; however, medical care for the patient shall not be delayed.

(iii) Within 7 days after an initial therapy medical event report, the licensee or registrant shall send a written report to the bureau. The written report must contain the name of the licensee or registrant; the information called for in paragraph (3) of this subdivision; and whether the licensee or registrant notified the patient or the patient's responsible relative or guardian.

(3) Each licensee or registrant shall maintain a record of each reportable medical event for six years. The record must contain the names of all individuals involved in the event (including the treating physician, allied health personnel, the patient, and the patient's referring physician), the medical record number or identification number if one has been assigned, a brief description of the event, the effect on the patient, and actions taken to prevent recurrence.

(4) Within seven days after an initial therapy medical event report made pursuant to subparagraph (ii) of paragraph (2) of this subdivision, the licensee or registrant shall provide the patient a written report with a copy to the patient's referring physician. The report shall contain a brief description of the event, the effect on the patient including any change in the patient's health status which resulted or could result from the medical event, and recommendations for the appropriate course of treatment or follow-up. If it is not medically advisable to give such information to the patient, the report shall be made available to the patient's responsible relative or guardian on the patient's behalf and documented in the patient's treatment record.

16.26 Respiratory protection and controls to restrict internal exposure restricted areas.

(a) Any person using respiratory protection and controls to restrict internal in exposure restricted areas shall comply with the provisions of the following federal regulations, which are hereby incorporated by reference, with the same force and effect as if fully set forth at length herein: 10 CFR 20, subpart H, "Respiratory Protection and Controls to Restrict Internal Exposure in Restricted Areas," as revised and implemented in full on December 19, 2002, except as follows:

(1) Any reference to the "Commission" or "NRC" shall be deemed to be a reference to the New York State Department of Health.

16.40 Fees.

(a) General requirement. Unless exempt under subdivision (b) of this section, no person shall establish, maintain or operate a radiation installation with radiation equipment, that is subject to the registration requirements of section 16.50 of this Part, or hold a radioactive materials license as required pursuant to the licensing requirements of section 16.100 of this Part, except upon payment of the applicable fees prescribed in this section and section 16.41 of this Part.

(b) Exemptions.

(1) Agencies of the State of New York and its political subdivisions, except for hospitals and higher education academic institutions operated by such agencies, are exempt from the payment of any of the fees prescribed in this section and section 16.41 of this Part.

(2) Any operator of a radiation installation that is registered with the New York City Department of Health and Mental Hygiene or any person that holds a radioactive material license issued by the New York City Department of Health and Mental Hygiene, pursuant to sections 16.50(j) and 16.1(b)(2) of this Part, is exempt from paying the fees prescribed in this section and section 16.41 of this Part, unless they also hold a registration certificate or a radioactive material license

issued by the department for which fees are applicable. In the latter case, the applicable fees for the activities registered or licensed by the department shall be assessed.

(c) Payment of fees.

(1) Each application for a radiation installation registration or for a new radioactive material license, shall be accompanied by a remittance of the full amount of the applicable annual fees prescribed in section 16.41 of this Part. Annual fees for each subsequent year shall become due on each anniversary date thereafter, determined by the date of original registration or license issued.

(2) Any operator of a radiation installation who holds a current radiation installation registration certificate issued pursuant to this Part or any person who holds a current radioactive material license issued pursuant to this Part, shall pay the prescribed annual fee as billed by the department. Payment of fees shall be made within the 30-day period immediately following the billing date.

(3) The payment of all fees prescribed by this Part shall be by check or money order made payable to the New York State Department of Health.

(d) Prorating fees. For administrative purposes, the department may alter the fee due date and charge a fee for a period greater or less than one year. In such case the amount of the fee due will be prorated to correspond to the length of the period covered by the bill.

(e) No refund policy. Except in those cases where the department has determined that a payment of fees is not required, no fees, or portions thereof, paid to the department pursuant to this Part shall be refundable.

(f) Failure to pay prescribed fee. If an applicant for a license or registration fails to remit with such application the full amount of the fees as prescribed by this Part, the department will not

process the application and will notify the applicant that the application will not be processed unless fees are first paid. The department may revoke, suspend or amend a registration or radioactive material license in whole or in part for failure to pay all prescribed annual fees due.

(g) Registration fees charged by New York City Department of Health and Mental Hygiene. Provided that a written schedule of the registration fees to be charged by the New York City Department of Health and Mental Hygiene, has been submitted, in the manner prescribed, to, and approved by, the State Commissioner of Health, the New York City Department of Health and Mental Hygiene is authorized to charge within its jurisdiction registration fees as so approved. The State of New York or any political subdivision thereof or any agency or instrumentality of either are exempt from the payment of such fees.

(h) Fees charged by local health departments. Provided that a written schedule of the fees to be charged, together with a written analysis of the estimated costs of its radiation protection regulatory program, has been submitted to and approved by the State Commissioner of Health, the New York City Department of Health and Mental Hygiene or, as the department shall direct, the appropriate county or part-county health officer having jurisdiction that inspects installations with radiation equipment under a program of inspection certified by the State Department of Health, or any county, part-county or city health district that licenses and inspects radioactive materials in accordance with section 16.1(b)(2) of this Part, is authorized to charge adequate and reasonable fees for inspection, licensing and/or other radiation protection services rendered, as applicable, not exceeding the estimated costs of such services, except that, with the approval of the State Commissioner of Health, one or more of such services may be rendered without charge. The State of New York or any political subdivision thereof or any agency or instrumentality of either are exempt from the payment of such fees.

(i) Fees charged by certified radiation equipment safety officers. A certified radiation equipment safety officer shall not charge, or propose to charge, a fee for an inspection in excess of a fair and reasonable amount as determined by the department. Such officer shall furnish to the department, upon request, information as to fees charged or proposed to be charged by the officer. Such fees shall not exceed the estimated cost of services.

(j) Fees paid prior to the effective date of this section. Facilities that had paid fees which cover a period that extends beyond the effective date of this section, shall be responsible for the difference between the prorated amount of any fee previously paid for such period and that due under this section for such period.

16.41 Fee schedule.

Effective upon adoption, the annual fees assessable shall be as prescribed in this section.

(a) Registration fees. Except for entities exempt from fees under section 16.40(b)(1) of this Part, the annual registration fee for radiation installations required to be registered shall be as listed in this section.

(b) Fee categories for radiation installations required to be registered with the department. For the purpose of assessing annual fees, all radiation installations required to be registered with the department pursuant to section 16.50(a) of this Part are categorized in one of the following six categories:

Category I: Radiation installations with any five or more of the modalities listed below.

Category II: Radiation installations with three or four of the modalities listed below.

Category III: Radiation installations with two of the medical modalities listed below.

Category IV: Radiation installations with one of the medical modalities listed below and annual patient workload of 750 examinations or more.

Category V: Radiation installations with one of the medical modalities listed below and annual patient workload of less than 750 examinations, and all other radiation installations with one or two of the non-medical modalities listed below except as listed under Category VI.

Category VI: Dental, podiatric, bone densitometry or veterinary installations.

The modalities to be used in determining the fee category for radiation installations required to be registered with the department pursuant to section 16.50(a) of this Part are:

Medical Modalities: radiography, fluoroscopy, computed tomography, angiography, stereotactic breast biopsy systems, and Grenz/orthovoltage therapy, utilized in humans.

Non-medical Modalities: radiography, fluoroscopy, analytical equipment (including electron microscopes, fluorescence analysis and x-ray diffraction equipment), gauges and other commercial device not otherwise listed here, and computed tomography and particle accelerators that are not utilized on humans.

(c) Fee schedule for radiation installations routinely inspected by the department. All radiation installations required to be registered with the department pursuant to section 16.50(a) of this Part that are not exempt from fees under section 16.40(b) of this Part and that are routinely inspected by the department shall, in addition to the registration fee prescribed in subdivision (a) of this section, be assessed annual fees according to the following schedule:

Category I radiation installations:	$ 2600
Category II radiation installations:	$ 1800

Category III radiation installations: $ 1250

Category IV radiation installations: $ 550

Category V radiation installations: $ 325

Category VI radiation installations: $ 100

(d) Fee schedule for radiation installations routinely inspected by a county or part-county health officer or by a certified radiation equipment safety officer. All radiation installations required to be registered with the department pursuant to section 16.50(a) of this Part that are not exempt from fees under section 16.40(b) of this Part and that are routinely inspected by a county or part-county health officer having jurisdiction, as the department shall direct, under a program certified by the department, or by a certified radiation equipment safety officer as directed by the department shall, in addition to the registration fee prescribed in subdivision (a) of this section, be assessed an annual fee according to the following schedule:

Category I radiation installations: $ 600

Category II radiation installations: $ 450

Category III radiation installations: $ 300

Category IV radiation installations: $ 125

Category V radiation installations: $ 65

Category VI radiation installations: $ 25

(e) Fee categories for non-commercial, radioactive material licensees and radiation installations that use accelerators in medical therapy. For the purpose of assessing annual fees, all persons holding radioactive material licenses issued by the department and all radiation installations that are required to be registered with the department, pursuant to section 16.50(a) of this Part and

that use accelerators in medical therapy are categorized in one or more of the following six categories:

Category I: Persons issued a broad scope medical license.

Category II: Persons issued a broad scope academic or broad scope research and development license.

Category III: Persons issued a specific license which allows the use of radioactive materials for both nuclear medicine and brachytherapy, or a license which authorizes the operation of a nuclear pharmacy at an institution or a pharmaceutical production cyclotron.

Category IV: Radiation installations operating a medical therapy accelerator and/or persons issued a specific license which authorizes the use of radioactive materials in nuclear medicine, brachytherapy, mobile nuclear medicine service, teletherapy (including Co-60 teletherapy and gamma knife), research and development, academic uses, veterinary medicine or large irradiators.

Category V: Persons issued a specific license which authorizes the use of radioactive materials in a clinical laboratory, lead paint analyzers, mobile nuclear medicine sites, leak tests, equipment calibration, self-shielded irradiators, diagnostic sealed sources, and any other use not included in categories I through VI as listed in this subdivision.

Category VI: Persons issued a specific license for use of radioactive materials in gas chromatographs.

(f) Radioactive materials/medical therapy accelerator fee schedule.

(1) Except for entities exempt from fees under section 16.40(b) of this Part, all persons that hold radioactive material licenses issued by the department and all radiation installations that are required to be registered with the department and that use accelerators in medical therapy shall be assessed annual fees according to the following schedule:

Category I: $ 9600

Category II: $ 6200

Category III: $ 2400

Category IV: $ 1500

Category V: $ 600

Category VI: $ 120

(2) When more than one fee category as described in section 16.41(e) of this Part applies, the fee which corresponds to the highest applicable category will be assessed, provided, however, that separate Category III fees will be assessed to any person that holds a license to operate a nuclear pharmacy or a pharmaceutical production cyclotron for each type of these uses that applies, in addition to any other categories of fees that apply; and radiation installations or licensees that provide teletherapy (Co-60, gamma knife or a medical therapy accelerator) services or veterinary medicine services, or use radioactive materials in large irradiators, or, except for Category I or II licensees, use radioactive materials in research and development, will be assessed Category IV fees for each type of these uses that applies, in addition to any other categories of fees that apply. If a person that holds a radioactive material license is also the operator of a radiation installation that uses an accelerator in medical therapy and the licensed activities are conducted at such installation, the licensed radiation installation shall be considered as one and the same entity for purposes of assessing fees described under section 16.41(e) of this Part.

(g) Fee categories for commercial radioactive material licensees. For the purpose of assessing annual fees, all persons holding radioactive material licenses issued by the department shall be categorized in one or more of the following six categories:

Category I: Persons issued a specific license which authorizes the use of radioactive material for cyclotron operations, industrial radiography - fixed facility only, industrial radiography - temporary job sites (may include fixed), licenses of broad scope not otherwise specified (NOS), manufacturing NOS, manufacturing of radioactive products - broad scope, nuclear laundry, nuclear pharmacy operations, open irradiator (> 1MCi), research and development - broad scope, waste broker, waste disposal facility (active), or waste services NOS.

Category II Persons issued a specific license which authorizes the use of radioactive material for commercial distribution of radioactive products, decontamination and decommissioning service, distribution of radioactive medical products, distribution of radioactive products NOS, manufacturing of radioactive medical products – limited scope, manufacturing of radioactive products – limited scope, open irradiator (>10,000 Ci <1MCi), research and development – limited scope (>1 Ci), waste disposal facility (inactive), waste processing or repackaging, or well logging and tracer studies

Category III Persons issued a specific license which authorizes the use of radioactive material for device installation, maintenance and repair service, full health physics consulting service, leak test and calibration service, medical system service, moisture/density gauge, open irradiator (<= 10,000 Ci), redistribution of

radioactive products, research and development – limited scope (<1 Ci), sealed or unsealed sources NOS, services NOS, and well logging (sealed sources only).

Category IV Persons issued a specific license which authorizes the use of radioactive material for analytical laboratory (radioactive sample analysis), calibration service, fixed gauges, gauges NOS, leak test service, portable X-ray fluorescence analyzer, possession incident to exempt distribution (NRC E-license), and self-shielded irradiators.

Category V Persons issued a specific license which authorizes the use of radioactive material for Analytical instruments NOS, demonstration and sales of radioactive products, gas chromatograph, or storage only pending disposal.

(h) Annual fee schedule for commercial radioactive materials licenses.

Category I $3600

Category II $3000

Category III $2400

Category IV $1800

Category V $ 600

(i) Generally licensed devices. A non-refundable fee in the amount of $120, payable to the department, shall be submitted with each registration of a generally licensed device.

(j) Additional fees.

A non-refundable fee for commercial licenses shall be submitted to the department according to the following schedule:

(1) Fee for the review of decommissioning plan submitted in accordance with section 16.113 of this Part shall be $2,500.

(2) Fee for sealed source and device certificate application review shall be $1,500.

(3) Fee for reciprocity shall be 50% of the commercial license fee by category (i.e., category 1 reciprocity will be $1800 for 6 months).

RADIATION EQUIPMENT

Introductory note: Sections under this heading contain the registration and transfer notification provisions for radiation equipment and general and additional radiation protection requirements applicable only to specific radiation equipment.

16.50 Registration of installations with radiation equipment; notification of transfer of radiation equipment.

(a) No person shall establish, maintain or operate any radiation installation at which is located or used any radiation equipment in operable condition or intended to be used, unless such installation has been registered as evidenced by a current certificate of registration issued to the operator thereof by the department or has been registered in an alternate manner accepted by the department in accordance with subdivision (j) of this section. Radiation equipment exempted from the requirements of this Part under section 16.4 is exempt from the registration requirement.

(b) Radiation installation application for registration, as described in subdivision (a) of this section shall be made by the operator thereof, to the department on a written form and in a manner prescribed by the department. This must be done 30 to 60 days prior to: a new installation of equipment, an existing installation certificate expiration date (renewal), and any changes in ownership, operation status, or location.

(c) The department may withhold, suspend, or revoke a certificate of registration if it finds that:

(1) the information submitted in the application is incorrect or incomplete; or

(2) the fees for registration and/or the certificate have not been paid as required; or

(3) the installation is, has been or will be established, maintained or operated in violation of the State Public Health Law, the State Sanitary Code (Chapter I of this Title) or any other applicable law, rule, regulation or order; or

(4) the certificate has not been issued correctly.

(d) A certificate of registration shall be issued for a limited period of time extending from the date of issuance to the date of expiration as specified on the certificate.

(e) The certificate of registration issued for a radiation installation to the operator thereof shall expire upon:

(1) the expiration date specified on the certificate; or

(2) revocation by the department; or

(3) a change of the operator; or

(4) a change in location of the radiation installation if it is not a mobile unit; or

(5) a change in the name of the installation; or

(6) the discontinuance of the installation.

(7) failure to pay the required fee by the specified date.

(f) A certificate of registration shall not be transferable or assignable except as approved by the department.

(g) An unexpired certificate of registration issued for a radiation installation shall be conspicuously posted at the installation and made available by the operator, upon request, to the department, the health officer having jurisdiction, or other person or agency making a survey of the installation pursuant to paragraph (1) of subdivision (a) of section 16.10 of this Part.

(h) The certificate of registration shall not imply endorsement or approval by the department and shall not be used to advertise or promote business.

(i) The operator of a radiation installation shall keep correct and complete the information submitted in his application for registration by reporting to the department in writing within 10 days any change affecting such information.

(j) The department may accept, in lieu of registration with the department, registration with the New York City Department of Health and Mental Hygiene. Acceptance of registration may be done only for radiation installations surveyed under an inspection program conducted by the New York City Department of Health and Mental Hygiene as described in paragraph (1) of subdivision (a) of section 16.10 of this Part. As a condition of the department's acceptance of registration pursuant to this section, the registering agency shall furnish to the department in writing, at such times and in such form as the commissioner may prescribe, pertinent information concerning the registration of each and every radiation installation registered by the agency. The information furnished to the department shall cover at least those items contained in the department's application form for registration of a radiation installation.

(k) The distributor, retailer or other agent who sells, leases, transfers, loans or installs X-ray or fluoroscopic equipment or other radiation equipment subject to the registration requirements of this section shall notify the department in writing within 10 days after making such sale, lease, transfer, loan, or installation on, and in accordance with the instructions of, a form prescribed by the department.

(l) No person shall make, sell, lease, transfer, loan, or install radiation equipment subject to the registration requirement of this section or the supplies used in connection with such equipment unless such supplies and equipment, when placed in operation and used, will meet the requirements of this Part.

(m) Every distributor or retailer of radiation equipment, or agent thereof, or radiation consultant, who installs, tests, or otherwise services radiation equipment shall be registered with the commissioner on a form prescribed by them. Registration shall be made prior to undertaking such installation, testing, or servicing. Such distributors, retailers, agents, or consultants shall, while engaged in installation, testing, or other servicing of radiation equipment, comply with the requirements of this Part.

16.51 General requirements for and prohibited uses of radiation equipment.

(a) General requirements. All radiation equipment shall meet any applicable specific provision of the sections of this Part set forth under the heading "Radiation Equipment" (section 16.50 to 16.70), and all possession or use thereof shall comply with the requirements of sections of this Part set forth under the heading "General Provisions" (section 16.1 through 16.20), and any other requirement imposed by the department. Radiation equipment which is not intended to be used must be made inoperable to the satisfaction of the department by dismantling or sealing with an official New York State Department of Health seal or other suitable method; and shall not be unsealed or restored to operable condition without prior authorization by the department.

(b) Prohibited uses and activities include the following:

(1) non-image intensified fluoroscopic equipment which has not been certified in accordance with 21 CFR 1020 as revised and implemented in full on January 20, 2023. (*See* section 16.200 of this Part);

(2) shoe-fitting fluoroscopic devices;

(3) intra-oral fluoroscopy used in dental examinations;

(4) photofluorographic equipment;

(5) the sale of gold jewelry which is known by the owner to be contaminated with radioactive materials, except for sale to the department;

(6) body composition assessment or analysis not under the direction and order of an authorized individual pursuant to section 16.19 of this Part;

(7) exposure of human beings for demonstration purposes;

(8) hand-held fluoroscopic devices.

(c) Beam Quality *Half-value layer (HVL)*. The HVL of the useful beam for a given x-ray tube potential shall not be less than the appropriate value shown in Table 1 in paragraph (c)(1) of this section under the heading "Specified Dental Systems," for any dental x-ray system designed for use with intraoral image receptors and manufactured after December 1, 1980; under the heading "I--Other X-Ray Systems," for any dental x-ray system designed for use with intraoral image receptors and manufactured before December 1, 1980, and all other x-ray systems subject to this section and manufactured before June 10, 2006; and under the heading "II--Other X-Ray Systems," for all x-ray systems, except dental x-ray systems designed for use with intraoral image receptors, subject to this section and manufactured on or after June 10, 2006. If it is necessary to determine such HVL at an x-ray tube potential which is not listed in Table 1 in paragraph (c)(1) of this section, linear interpolation or extrapolation may be made. Positive means[2] shall be provided to ensure that at least the minimum filtration needed to achieve the above beam quality requirements is in the useful beam during each exposure. Table 1 follows:

Table 1

X-Ray Tube Voltage (kilovolt peak)	Measured Operating	Minimum HVL (mm of aluminum)		
Designed Operating Range	Potential	Specified Dental Systems[1]	I--Other X-Ray Systems[2]	II--Other X-Ray Systems[3]
Below 51	30	1.5	0.3	0.3
	40	1.5	0.4	0.4
	50	1.5	0.5	0.5
51 to 70	51	1.5	1.2	1.3
	60	1.5	1.3	1.5
	70	1.5	1.5	1.8
Above 70	71	2.1	2.1	2.5
	80	2.3	2.3	2.9
	90	2.5	2.5	3.2
	100	2.7	2.7	3.6
	110	3.0	3.0	3.9
	120	3.2	3.2	4.3
	130	3.5	3.5	4.7
	140	3.8	3.8	5.0
	150	4.1	4.1	5.4

[1]Dental x-ray systems designed for use with intraoral image receptors and manufactured after December 1, 1980.

[2]Dental x-ray systems designed for use with intraoral image receptors and manufactured before or on December 1, 1980, and all other x-ray systems subject to this section and manufactured before June 10, 2006.

[3]All x-ray systems, except dental x-ray systems designed for use with intraoral image receptors, subject to this section and manufactured on or after June 10, 2006.

16.52 Electrical hazards.

(a) All radiation equipment, except equipment used solely in research and development, installed in a radiation installation shall, where applicable, be listed by the Underwriters Laboratories Inc., or shall comply with The National Electrical Code of the National Fire Protection Association (NFPA), as implemented by NFPA70: National Electric Code 2023, which is hereby incorporated by reference, or an equivalent safety standard.

(b) Existing equipment employing uninsulated or bare overhead conductors moved to a new location or registered as a new installation under section 16.50 of this Part shall be certified as being free of electrical hazards.

(c) Certification by a duly constituted local authority that the installation is free of electrical hazards shall be acceptable.

16.53 Dental radiographic installations.

(a) Intraoral Equipment.

(1) The protective tube housing shall be of diagnostic type.

(2) Diaphragms or cones shall be used for restricting the useful beam to the area of clinical interest and shall provide at least the same degree of protection as is required of the tube housing.

(3) The diameter of the useful beam at the face of the patient shall not exceed three inches.

(4) A cone or spacer frame shall provide a source-skin distance of not less than seven inches with equipment operating above 50 kVp or four inches with equipment operating at 50 kVp or below for intra-oral radiography.

(5) The aluminum equivalent of the total filtration in the useful beam shall not be less than that shown in Table 1 of section 16.51(c) of this Part.

(6) A device shall be provided to terminate the exposure after a preset time interval or exposure. The exposure switch shall be of the dead-man type, and where protective barriers are required shall be so arranged that it cannot be operated outside the shielded area.

(7) Each installation shall be so arranged that the operator can stand at least six feet from the patient, the X-ray tube, and the useful beam during exposure. A protective barrier shall be provided where the operator cannot stand at least six feet away from the patient, the X-ray tube and the useful beam during exposures.

(8) The tube head shall remain stationary when placed in the exposure position.

(b) Conditions for operation of equipment.

(1) The film or image receptor shall not be held by the dentist or technician during the exposure.

(2) Only the patient shall be in the useful beam.

(3) Neither the tube housing, pointer nor cone shall be handheld during the exposure.

(4) Only persons required for the radiographic procedure shall be the radiographic room during the exposure.

(5) For extra-oral radiography, the x-ray film used as the recording medium during the x-ray examination shall show substantial evidence of cut-off (beam delineation).

(c) Special installations.

(1) Panoramic installations are dental installations which consist of a tube head with a collimator providing a narrow (12mm) useful beam and an extra-oral film carrier which are interlocked in their motion about the patient.

(i) Equipment.

(*a*) The protective tube housing shall be of diagnostic-type.

(*b*) Diaphragms or cones shall be used for restricting the useful beam to the area of clinical interest and shall provide the same degree of protection as is required of the tube housing.

(*c*) The aluminum equivalent of the total filtration in the useful beam shall not be less than that shown in Table 1 of section 16.51(c) of this Part.

(*d*) A device shall be provided to terminate the exposure after a preset time interval or exposure. The exposure switch shall be of the dead-man type.

(*e*) Each installation shall be provided with a protective barrier for the operator or shall be so arranged that the operator can stand at least six feet from the patient, the X-ray tube, and the useful beam.

(ii) Conditions for operation of equipment. Only the patient shall be in the useful beam.

(2) Handheld X-ray devices - portable dental X-ray devices which are used in dentistry for taking intraoral radiographs. The devices are battery-powered, portable and designed to be used when held in the hands of the operator during exposure. Only units that are FDA approved and have been reviewed and approved by the department may be used in New York State.

(i) Equipment.

(*a*) The protective tube housing shall be of diagnostic type.

(*b*) Diaphragms or cones shall be used for restricting the useful beam to the area of clinical interest and shall provide at least the same degree of protection as is required of the tube housing.

(*c*) For intra-oral radiography the diameter of the useful beam at the face of the patient shall not exceed three inches.

(*d*) A cone or spacer frame shall provide a source-skin distance of not less than seven inches with equipment operating above 50 kVp or four inches with equipment operating at 50 kVp or below for intra-oral radiography.

(*e*) The aluminum equivalent of the total filtration in the useful beam shall not be less than that shown in Table 1 of section 16.51(c) of this Part.

(*f*) A device shall be provided to terminate the exposure after a preset time interval or exposure. The exposure switch shall be of the dead-man type, the handheld unit shall be operated with the scatter shield in place.

(*g*) Each installation shall be so arranged that the operator can stand behind the X-ray tube, and the useful beam during exposure.

(*h*) The unit shall only be operated by authorized personnel who have been trained in the operation of the device.

(*i*) When not in use the handheld unit must be secured to prevent inadvertent exposures or use by unauthorized personnel.

(*j*) The backscatter shield shall be in place.

(3) Cone Beam CT (CBCT) – the requirements of section 16.65 of this Part shall apply.

16.54 Veterinary radiographic and fluoroscopic installations.

(a) Fixed radiographic, CT, CBCT installations.

(1) Equipment.

(i) The protective tube housing shall be of diagnostic type.

(ii) Collimating devices capable of restricting the useful beam to the area of clinical interest shall be used and shall provide the same degree of protection as is required of the tube housing.

(iii) The images shall show substantial evidence of cut-off (beam delineation).

(iv) The aluminum equivalent of the total filtration in the useful beam shall not be less than that shown below:

Operating kVp	Minimum total filter (Inherent plus added)
Below 50 kVp	0.5 mm aluminum
50-70 kVp	1.5 mm aluminum
Above 70 kVp	2.5 mm aluminum

(v) A device shall be provided which terminates the exposure after a preset time interval or exposure. The exposure switch shall be of the dead-man type and shall be so arranged that it cannot be operated outside a shielded area.

(2) Structural shielding.

(i) Control apparatus for the radiographic equipment shall be located in an adjacent room or in a fixed booth within the same room provided such booth is composed of radiation shielding to a minimum height of seven feet. The control booth either shall be so arranged that the radiation has to be scattered at least twice before entering the booth, or shall be provided with a protective door that is interlocked in such a way that the X-ray tube(s) cannot be energized unless the door is in the closed position.

(ii) The operator shall be able to see the animal patient by means of a mirror or through a window of lead equivalent sufficient for the required protection and so placed that the operator is always in a shielded position.

(3) Conditions for operation of equipment.

(i) Only persons required for the X-ray procedure shall be in the X-ray room during the exposures.

(ii) When an animal patient must be held in position during exposures, mechanical supporting or restraining devices shall be used. Animal patients or image receptors shall be held only under extreme conditions when clinically necessary. Individuals holding animal patients or image receptors shall wear protective gloves having at least 0.5 mm lead equivalent, a protective apron of at least 0.25 mm lead equivalent, and shall keep all parts of their body out of the useful beam. The exposure of any individual used for holding animals shall be monitored. Pregnant women and persons under 18 years of age shall not hold animal patients or films under any conditions.

(b) Portable or mobile radiographic installations.

(1) Equipment.

(i) The protective tube housing shall be of diagnostic type.

(ii) Collimating devices capable of restricting the useful beam to the area of clinical interest shall be used and shall provide the same degree of protection as is required of the tube housing.

(iii) The X-ray images shall show evidence of cut-off (beam delineation).

(iv) The aluminum equivalent of the total filtration in the useful beam shall not be less than that shown below:

Operating kVp	Minimum total filter (Inherent plus added)
Below 50 kVp	0.5 mm aluminum
50-70 kVp	1.5 mm aluminum
Above 70 kVp	2.5 mm aluminum

(v) A device shall be provided which terminates the exposure after a preset time interval or exposure.

(vi) A dead-man type of exposure switch shall be provided with a cord sufficiently long so that the operator can stand at least six feet from the animal patient, the X-ray tube, and the useful beam.

(2) Conditions for operation of equipment.

(i) No person shall be regularly employed to support or hold animals or film during X-ray exposures.

(ii) When an animal must be held in position during exposures, mechanical supporting or restraining devices shall be used. Individuals should hold animals only when clinically necessary under extreme conditions. Such individuals shall wear protective gloves having at least 0.5 mm lead equivalent, a protective apron of at least 0.25 mm lead equivalent, and shall keep all parts of his body out of the useful beam. The exposure of any individual used for holding animals shall be monitored. Pregnant women and individuals under 18 years of age shall not hold animals under any conditions,

(c) Fluoroscopic installations.

(1) Equipment.

(i) The protective tube housing shall be of diagnostic type.

(ii) Equipment shall be so constructed that the entire cross section of the useful beam is always intercepted by a primary protective barrier (usually a lead glass screen or image intensifier assembly) irrespective of the panel screen distance. For conventional fluoroscopes, this requirement may be assumed to have been met if, when the collimating system is opened to its fullest extent, an unilluminated margin is left on all edges of the fluorescent screen regardless of the position of the screen during use.

(*a*) Collimators, and adjustable diaphragms, or shutters used to restrict the size of the useful beam shall provide the same degree of protection as is required of the tube housing.

(*b*) The exposure shall automatically terminate when the barrier is removed from the useful beam.

(*c*) With the fluorescent screen 14 inches from the panel of the tabletop, the exposure rate two inches beyond the viewing surface of the screen shall not exceed 30 mR/hr for each roentgen per minute at the tabletop with the screen in the useful beam without a patient and with the fluoroscope operating at the highest potential employed.

(iii) The aluminum equivalent of the total filtration in the useful beam shall not be less than that shown below:

Operating kVp	Minimum total filter (Inherent plus added)
Below 50 kVp	0.5 mm aluminum
50-70 kVp	1.5 mm aluminum
Above 70 kVp	2.5 mm aluminum

(iv) The fluoroscopic exposure switch shall be of the dead-man type.

(v) Mobile fluoroscopic equipment is subject to the following additional requirements:

(*a*) in the absence of a tabletop, a cone or spacer frame shall limit the source-to-skin distance to not less than 12 inches;

(*b*) image intensification shall always be provided;

(*c*) it shall be impossible to operate a machine unless the useful beam is intercepted by the image intensifier.

(2) Conditions for operation of equipment.

(i) Protective gloves and aprons of at least 0.25 mm lead equivalent each shall be made available and shall be worn by the fluoroscopist during every examination.

(ii) Unless measurements indicate that they are not needed protective gloves and protective aprons of at least 0.25 mm lead equivalent each shall be worn by the physician, nurse, technician and all other persons within the fluoroscopic room.

(iii) Only persons needed in the fluoroscopic room shall be present during the exposure.

(iv) The fluoroscopic room shall be free of extraneous light that interferes with the examination.

(d) Special installations.

(1) Handheld X-ray devices.

(i) The requirements of paragraph 16.53(c)(2) of this Part shall apply.

(ii) “Animal” shall replace “human being” or “patient”

16.55 Podiatric radiographic installations.

(a) Equipment.

(1) The protective tube housing shall be of diagnostic type.

(2) Collimating devices capable of restricting the useful beam to the area of clinical interest shall be used and shall provide the same degree of protection as is required of the tube housing.

(3) The X-ray images shall show substantial evidence of cut-off (beam delineation).

(4) The aluminum equivalent of the total filtration in the useful beam shall not be less than that shown in Table 1 of section 16.51(c) of this Part.

(5) A device shall be provided which terminates the exposure after a preset time interval or exposure. The exposure switch shall be of the dead-man type and where protective barriers are required shall be so arranged that it cannot be operated outside the shielded area.

(6) Each installation shall be arranged so that the operator can stand at least six feet from the patients, the X-ray tube and the useful beam during exposure. A protective barrier shall be provided when the operator cannot stand at least six feet away from the patient, the X-ray tube and useful beam during exposures.

(b) Conditions for operation of equipment.

(1) No person shall hold film during the exposure.

(2) Only persons required for the radiographic procedure shall be in the radiographic room during exposure.

(c) Special Installations.

(1) Handheld X-ray devices,

(i) The requirements of paragraph 16.53(c)(2) of this Part shall apply for patient anatomy limited to the foot.

(ii) The handheld unit is operated with the manufacturer's stand.

(2) Cone Beam CT – the requirements of section 16.65 of this Part shall apply.

16.56 Radiographic installations excluding dental, veterinary, and podiatric installations.

(a) Equipment.

(1) The protective tube housing shall be of diagnostic type.

(2) Collimating devices capable of restricting the useful beam to the area of clinical interest shall be used and shall provide the same degree of protection as is required of the tube housing.

(3) The X-ray images shall show substantial evidence of cut-off (beam delineation).

(4) The aluminum equivalent of the total filtration in the useful beam shall not be less than that shown in Table 1 of section 16.51(c) of this Part.

(5) A device shall be provided which terminates the exposure after a preset time interval or exposure.

(6) A dead-man type of exposure switch shall be used and so arranged that it cannot be operated outside a shielded area. Exposure switches for "spot-film" devices used in conjunction with fluoroscopic equipment are excepted from this shielding requirement.

(7) The tube head shall remain stationary when placed in the exposure position.

(b) Structural shielding.

(1) Except for mammography systems, control apparatus for the radiographic equipment shall be located in an adjacent room or in a fixed booth within the same room provided such booth is composed of radiation shielding to a minimum height of seven feet. The control booth either shall be so arranged that the radiation has to be scattered at least twice before entering the booth, or shall be provided with a protective door that is interlocked in such a way that the X-ray tube(s) cannot be energized unless the door is in the closed position.

(2) The operator shall be able to see the patient by means of a mirror or through a window of lead equivalent sufficient for the required protection and so placed that the operator is always in a shielded position.

(3) Provision shall be made for the operator to communicate with the patient from a shielded position.

(c) Conditions for operation of equipment.

(1) No person shall be regularly employed to hold patients or image receptors during exposures, nor shall such duty be performed by any individual occupationally exposed to radiation during the course of their other duties. When it is necessary to restrain the patient, mechanical supporting or restraining devices shall be used whenever possible. If patients or image receptors must be held by an individual, that individual shall be provided with appropriate shielding devices such as protective gloves and a protective apron of at least 0.25 mm lead equivalent. No part of the attendant's body shall be in the useful beam. The exposure of any individual used for holding patients shall be determined. Pregnant women and persons under 18 years of age shall not hold patients under any conditions.

(2) Only persons required for the radiographic procedure shall be in the radiographic room during exposure; and, except for the patient, all such persons shall be equipped with appropriate shielding devices such as protective gloves and a protective apron of at least 0.25 mm lead equivalent.

16.57 Portable, bedside or mobile X-ray equipment excluding dental, veterinary and podiatric equipment.

(a) Equipment.

(1) The protective tube housing shall be of diagnostic type.

(2) Collimating devices capable of restricting the useful beam to the area of clinical interest shall be used and shall provide the same degree of protection as is required of the tube housing.

(3) The X-ray images shall show substantial evidence of cut-off (beam delineation).

(4) The aluminum equivalent of the total filtration in the useful beam shall not be less than that shown in Table 1 of section 16.51(c) of this Part.

(5) A device shall be provided which terminates the exposure after a preset time interval or exposure.

(6) All mobile, portable or beside equipment shall be provided with cones or metal frames so that the minimum source to skin distance is at least 12 inches.

(7) The exposure switch shall be of the dead-man type and shall be provided with a cord sufficiently long that the operator can stand at least six feet from the patient, the X-ray tube and the useful beam.

(b) Use. If a mobile unit is used routinely in any location, it shall be considered a fixed installation, and shall meet the requirements of section 16.56 of this Part.

(c) Conditions for operation of equipment.

(1) No person shall be regularly employed to hold patients or image receptors during exposures, nor shall such duty be performed by any individual occupationally exposed to radiation during the course of their other duties. When it is necessary to restrain the patient, mechanical supporting or restraining devices shall be used. If patient or image receptors must be held by an individual, that individual shall be protected with appropriate shielding devices such as protective gloves and a protective apron of at least 0.25 mm lead equivalent. No part of the attendant's body shall be in the useful beam. The exposure of any individual used for holding patients shall be monitored. Pregnant women and persons under 18 years of age shall not hold patients under any conditions.

16.58 Fluoroscopic installations excluding veterinary installations.

(a) Equipment.

(1) The protective tube housing shall be of diagnostic type.

(2) Equipment shall be so constructed that the entire cross section of the useful beam is always intercepted by the primary protective barrier irrespective of the position.

(i) Collimators and adjustable diaphragms or shutters used to restrict the size of the useful beam shall provide the same degree of protection as is required of the tube housing.

(ii) The exposure shall automatically terminate when the barrier is removed from the useful beam.

(3) The aluminum equivalent of the total filtration in the useful beam shall not be less than that shown in Table 1 of section 16.51(c) of this Part.

(4) Fluoroscopic exposure switch shall be of the dead-man type.

(5) Source-skin distance.

(i) Means shall be provided to limit the source-skin distance to not less than 38 cm on stationary fluoroscopes and to not less than 30 cm on mobile and portable fluoroscopes. In addition, for fluoroscopes intended for specific surgical application that would be prohibited at the source-skin distances specified in this paragraph, provisions may be made for operation at shorter source-skin distances but in no case less than 20 cm. When provided, the manufacturer must set forth precautions with respect to the optional means of spacing.

(ii) For stationary, mobile, or portable C-arm fluoroscopic systems manufactured on or after June 10, 2006, having a maximum source-image receptor distance of less than 45 cm, means shall be provided to limit the source-skin distance to not less than 19 cm. Such systems shall be labeled for extremity use only. In addition, for those systems intended for specific surgical application

that would be prohibited at the source-skin distances specified in this paragraph, provisions may be made for operation at shorter source-skin distances but in no case less than 10 cm. When provided, the manufacturer must set forth precautions with respect to the optional means of spacing.

(6) Fluoroscopy equipment shall not be operated for human use unless a cumulative timing device, activated by the fluoroscope exposure switch, is functioning. It shall indicate the passage of a period of irradiation, not exceeding five minutes, either by an audible signal or by temporary interruption of the irradiation.

(7) The exposure rate as measured, at no less than 70 kVp in the mode of least magnification with the image intensifier at 40 cm above the tabletop or over table fluoroscopy tube at a source to image distance normally used for an average patient, with a patient phantom composed of 1 and 1/2 inches of Type 1100 aluminum in a 7 inch square or an equivalent device in the fluoroscopic beam shall not exceed 5 roentgens per minute except during recording of fluoroscopic images or during activation of optional high level control. The maximum exposure rate measured in air at a point where the center of the useful beam enters the patient shall not exceed 88 mGy per minute (10 roentgens per minute) except as follows:

(i) Equipment manufactured before May 19, 1995 and certified in accordance with 21 CFR 1020 as revised and implemented in full on January 20, 2023, (see section 16.200 of this Part) and having an optional high level control is limited to a maximum output of 44 mGy per minute (5 roentgens per minute) unless the high level control is activated and an audible signal to that effect is provided. When the high level control is activated, the maximum exposure rate measured in air at a point where the center of the useful beam enters the patient shall not exceed 176 mGy per minute (20 roentgens per minute).

(ii) Certified equipment manufactured after May 19, 1995 with automatic exposure rate and having an optional high level control is limited to a maximum output of 88 mGy per minute (10 roentgens per minute) unless the high level control is activated and an audible signal to that effect is provided. When the high level control is activated, the maximum exposure rate measured in air at a point where the center of the useful beam enters the patient shall not exceed 20 roentgens per minute.

(iii) Certified equipment manufactured after May 19, 1995 without automatic exposure rate is limited to 44 mGy per minute (5 roentgens per minute) unless the high level control is activated and an audible signal to that effect is provided. When the high level control is activated, the maximum exposure rate measured in air at a point where the center of the useful beam enters the patient shall not exceed 176 mGy per minute (20 roentgens per minute).

(8) Primary protective barriers shall provide the following protection:

(i) For uncertified equipment, with the image intensifier 36 cm (14 inches) from the tabletop, the exposure rate two inches beyond the image intensifier shall not exceed 5uGy/hr (30 mR/hr) for each roentgen per minute at the tabletop with the intensifier in the useful beam without a patient and with the fluoroscope operating at the highest potential available for use.

(ii) For certified equipment, the exposure rate due to transmission through the barrier with the attenuation block in the useful beam combined with radiation from the image intensifier, if provided, shall not exceed 0.33 uGy per hour (two milliroentgens per hour) at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each 0.01 Gy per hour (roentgen per minute) or entrance exposure rate.

(9) The high contrast resolution of the fluoroscopic system shall be capable of resolving a minimum mesh number of 24 for the center of the beam and 20 for the edges using a test tool

composed of 8 groups of copper or brass mesh screening ranging from 16 to 60 lines/inch set in plastic or an equivalent device.

(10) The low contrast performance of the fluoroscopic system shall be capable of resolving a minimum hole size of 3 mm using a test tool composed of a 1.0 mm aluminum sheet with two sets of four holes of dimension 1.0, 3.0, 5.0 and 7.0 mm and a patient equivalency phantom or an equivalent device.

(11) Radiation therapy simulation systems shall be exempt from the requirements of paragraphs (2), (6), (7) and (8) of this subdivision provided that:

(i) the systems are designed and used in a manner such 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

(ii) systems which do not meet the requirements of paragraph (6) of this subdivision 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.

(b) Conditions for operation of equipment.

(1) The operator of the installation shall make and record the outputs made pursuant to paragraph (7) of subdivision (a) of this section, where the center of the useful beam enters the patient during routine fluoroscopy and cinefluoroscopy, at annual intervals or more frequently if outputs are found to exceed the limits defined in this section.

(2) Other than tabletop mini C-arms, protective garments of at least 0.25 mm lead equivalent each shall be worn by the physician, nurse, radiologic technologist and all other persons within the fluoroscopic room.

(3) Only persons needed in the fluoroscopic room shall be present during the exposure.

(4) The cumulative fluoroscopic time must be reset for each new patient.

(5) Displays of values of AKR and cumulative air kerma. Fluoroscopic equipment manufactured on or after June 10, 2006, shall display at the fluoroscopist's working position the AKR and cumulative air kerma. The following requirements apply for each x-ray tube used during an examination or procedure:

(i) When the x-ray tube is activated and the number of images produced per unit time is greater than six images per second, the AKR in mGy/min shall be continuously displayed and updated at least once every second.

(ii) The cumulative air kerma in units of mGy shall be displayed either within 5 seconds of termination of an exposure or displayed continuously and updated at least once every 5 seconds.

(iii) The display of the AKR shall be clearly distinguishable from the display of the cumulative air kerma.

(iv) The AKR and cumulative air kerma shall represent the value for conditions of free-in-air irradiation at one of the following reference locations specified according to the type of fluoroscope. The reference location shall be identified and described specifically in the information provided to users according to 21 CFR 1020.30(h)(6)(iii) as revised and implemented on January 20, 2023.

16. 59 Computed Tomography (CT) equipment.

(a) Definitions

(1) “Computed tomography (CT)” scan and “computerized axial tomography (CAT)” scan refer to an imaging procedure that uses x-rays to create cross-sectional images of the human body.

(2) “Computed tomography dose index” (CTDI) means the integral of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan where the dose profile is centered around z = 0 and for a multiple tomogram system, the scan increment between adjacent scans is nT;

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

D (z) = Dose at position z;

T = Nominal tomographic section thickness;

n = Number of tomograms produced in a single scan

(3) “CT x-ray system” is technology that is used to perform CT scans and includes but is not limited to, a control panel, image display device, gantry, x-ray tube, collimating device with filters, high voltage transformer and a data acquisition system.

(4) “CT scanner” refers to technology used to perform and interpret CT scans and includes, but is not limited to, a control panel, gantry, high voltage generator, x-ray tube, table and display devices that are used for image interpretation.

(5) “CTDI100” is the dose measurement made with a 16 cm diameter (head/pediatric body) or a 32 cm diameter (body) acrylic phantom. The measurements are made utilizing a 100 mm long pencil ionization chamber. Readings are made with the ion chamber in both the center (axial or central dose) position and near surface slots of the phantom (the peripheral dose).

(6) “CTDIW”, the weighted or blended dose, is calculated by adding together two-thirds of the CTDI100 peripheral dose with one-third of the CTDI100 axial or center dose. (CTDIW = 2/3 CTDI100 peripheral + 1/3 CTDI100 axial or center). CTDIW represents an average dose in the x and y planes.

(7) “CTDIVOL” represents the integrated dose over the total volume that is irradiated, CTDIVOL = (1/PITCH) x (CTDIW), where “Pitch” is defined as the table travel per rotation divided by the collimation of the x-ray beam. CTDIVOL represents the average dose in the x, y and z planes.

(8) "CT conditions of operation" means all selectable parameters governing the operation of a CT x-ray system including nominal tomographic section thickness, filtration, and the technique factors.

(9) "CT dosimetry phantom" means the phantom used for determination of the dose delivered by a CT x-ray system. The phantom shall be a right circular cylinder of polymethyl-methacrylate of density 1.19±0.01 grams per cubic centimeter. The phantom shall be at least 14 centimeters in length and shall have diameters of 32.0 centimeters for testing any CT system designed to image any section of the body (whole body scanners) and 16.0 centimeters for any system designed to image the head (head scanners) or for any whole-body scanner operated in the head scanning mode. The phantom shall provide means for the placement of a dosimeter(s) along its axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom.

(10) “Dose length product” (DLP) is defined as the CTDIvol times the irradiated length of the body for the whole series of images that are taken during a CT scan.

(11) “Picture Archiving and Communication System (PACS)” is a medical imaging technology that provides access to and storage for medical images from multiple modalities. It is comprised of an image acquisition system, display, network and data storage or archiving system.

(12) "Reference plane" means a plane which is displaced from and parallel to the tomographic plane.

(13) "Scan" means the complete process of collecting x-ray transmission data for the production of a tomogram or a series of tomograms.

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

(15) “Technique” means the settings selected on the control panel of the equipment and may include the position of the x-ray tube, image intensifier and patient.

(16) “Technique chart” means a chart that lists the standard settings and positions for a given technique.

(17) “Tomogram” is an image of a tissue plane or section of tissue.

(18) "Tomographic plane" means that geometric plane which the manufacturer identified as corresponding to the output tomogram.

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

(b) CT X-Ray System Equipment Requirements.

(1) Each control panel and gantry of a CT x-ray system shall include visual signals that indicate to the operator of the CT x-ray system whenever x-rays are being produced and when x-ray production is terminated, and, if applicable, whether the shutter is open or closed.

(2) Each CT x-ray system shall be equipped with a control that allows the operator of the CT x-ray system to terminate the x-ray exposure at any time during a scan, or series of scans, when the exposure time is greater than one-half second duration.

(3) 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 are indicated prior to the initiation of a scan or a scan sequence.

(4) Each CT x-ray system shall include a clearly and conspicuously labeled emergency shutoff button or switch.

(5) Premature termination of the x-ray exposure by the operator shall necessitate resetting of the CT conditions of operation by the operator prior to the initiation of another scan.

(c) Patient communication and viewing requirements.

(1) Each CT x-ray system shall be equipped to allow two-way aural communication between the patient and the operator at the control panel.

(2) Each CT x-ray system shall be equipped with windows, mirrors, closed-circuit television, or an equivalent to permit continuous visual observation of the patient during CT scanning by the CT operator from the control panel.

(3) When the primary viewing system is by electronic means, an alternate viewing system (which may be electronic) shall be available for use in the event of failure of the primary viewing system.

(d) Calibration.

(1) Each registrant shall ensure that the calibration of the radiation output of each CT x-ray system that it operates is performed by, or under the direction of, a licensed medical physicist.

(2) Each registrant shall maintain and make available for review by the department, on the premises of its radiation installation where a CT x-ray system is located written procedures for the appropriate calibration of the CT x-ray system.

(3) After initial installation, the CT x-ray system shall be calibrated prior to its use on human beings and recalibrated at least within every 14 months thereafter. Any change or replacement of components of a CT x-ray system which could cause a change in the radiation output will require

a recalibration within 30 days of component installation by a licensed medical physicist operating within their scope of practice.

(4) The calibration of the radiation output of a CT x-ray system shall be performed with a calibrated dosimetry system. This system shall have been calibrated either by the National Institute of Standards and Technology (NIST) or by an American Association of Physicists in Medicine (AAPM) Accredited Dosimetry Calibration Laboratory (ADCL) and traceable to NIST. The calibration shall have been performed within the previous 24 months and after any servicing that might have affected system calibration.

(5) CT dosimetry phantom(s) shall be used in determining the radiation output of each CT x-ray system. Such phantom(s) shall meet the following specifications and conditions of use:

(i) Any effects on the doses measured because of 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.

(ii) All dose measurements shall be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuation materials present.

(iii) The requirements of subparagraphs (i) and (ii) of this paragraph can also be met by using an alternative method of radiation measurement and calculation published in the peer-reviewed scientific literature and acceptable to the department.

(6) Records of calibrations performed shall be maintained for a period of three (3) years at the radiation installation where the CT is located.

(e) Quality Assurance Testing

(1) Each registrant shall maintain a Quality Assurance (QA) manual that shall contain written procedures for all testing and shall meet the requirements specified in this section and section 16.23(a)(1) of this Part. The CT Quality Assurance procedures shall have been developed under the direction of a licensed medical physicist or radiologist.

(2) The QA procedures shall incorporate the use of one or more image quality dosimetry phantoms, or the phantom supplied by the original equipment manufacturer which have the capability of providing an indication of contrast scale, noise, nominal tomographic section thickness, the resolution capability of the system for low and high contrast objects, and measuring the mean CT Number for water or other reference material. All these image quality parameters shall be evaluated at least annually by a licensed medical physicist.

(3) Written records of the QA checks performed by the registrant shall be maintained for review by the department for a period of at least three (3) years.

(4) QA checks shall include the following:

(i) Images obtained with the CT dosimetry phantom(s) using the same processing mode and CT conditions of operation as are used to perform calibrations. The images shall be retained as photographic copies or as electronic copies stored within the CT x-ray system or stored on the PACS.

(ii) Dose assessment for the most common CT examinations that are performed on the system for which reference levels have been published by the American College of Radiology (ACR), the American Association of Physicists in Medicine (AAPM) or the National Council on Radiation Protection and Measurements (NCRP) for pediatric heads, pediatric abdomens, adult heads and adult abdomens.

(iii) An evaluation of image quality.

(f) Operating Procedures and Policies

(1) The CT x-ray system shall not be operated on a human being except by a physician or by a radiologic technologist licensed pursuant to article 35 of the Public Health Law who has been specifically trained in its operation.

(2) The registrant shall ensure that each CT x-ray system has a radiation protection survey or other measurement and assessment of exposure to persons in controlled and non-controlled areas made at the time of installation. Additional radiation protection surveys shall be done after any change in the radiation installation or equipment which might cause a significant increase in radiation hazard.

(3) Each CT x-ray system shall have available at the control panel written information regarding the operation and calibration of the CT x-ray system. Such information shall include:

(i) dates of the latest calibration and QC 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 phantom(s) including a schedule of QC tests that are appropriate for the system as determined by the manufacturer, allowable variations for the indicated parameters, and the results of at least the most recent spot checks conducted on the system;

(iii) a current set of default protocols are available at the control panel (either electronically or as a document) which specifies for each routine examination the CT conditions of operation and the slice thickness, spacing between slices and/or pitch;

(iv) a list of techniques optimized for the body part being imaged to obtain a quality image and to ensure that the lowest amount of radiation is used as consistent with good medical practice.

(4) If the QC testing on the CT x-ray system identifies that a system operating parameter has exceeded a tolerance as specified in the Quality Assurance manual, use of the CT x-ray system on patients shall be limited to those exceptions permitted by established written instructions of the licensed medical physicist or radiologist. Upon completion of corrective action, the QC testing shall be repeated to verify that the system is back within tolerance.

(5) Each registrant performing CT scans on human beings shall ensure that for each scan, the radiation dose delivered by the scanner to a reference phantom or the dose received by the patient is saved and recorded. The dose delivered shall be recorded as Computed Tomography Dose Index volume (CTDIvol), dose length product (DLP) or other dosimetry metric published in the peer reviewed scientific literature and acceptable to the department. The dose received by a patient shall be recorded as organ dose or other dosimetry metric published in the peer reviewed scientific literature and acceptable to the department.

(6) The displayed dose shall be verified on an annual basis by or under the supervision of a licensed medical physicist to ensure that the equipment manufacturer's displayed dose is within 20% of the measured dose.

(7) Each current registrant that performs diagnostic CT scans on human beings shall be accredited by a nationally recognized accreditation program that is acceptable to the department. A facility performing CT that loses their existing accreditation or a registrant or licensee that fails to obtain accreditation must report this fact within 30 days to the department. New licensees or registrants will have 18 months to become accredited, but must demonstrate that they have initiated the accreditation process within 90 days of the start of operations. New units at existing registrations and replacement units will begin accreditation as soon as possible but no later than 90 days following installation.

(8) Each registrant that performs CT scans on human beings shall establish and implement a policy and a procedure to ensure that:

(i) a request for a CT scan originates from a physician or other authorized health care practitioner familiar with the patient's clinical condition; and

(ii) the request includes sufficient information to demonstrate the medical indication for the CT examination and allow for the proper performance and interpretation of the CT scan.

(g) Exemptions – CT equipment used exclusively for attenuation correction, biopsy, guiding or delivering treatment planning does need to meet the accreditation requirements of this section.

16.60 Therapy equipment operated at potentials over 60 kVp.

(a) Equipment.

(1) The protective tube housing shall be of therapeutic type.

(2) Fixed diaphragms or cones used to restrict the useful beam shall be so constructed as to provide the same degree of protection as is required of the tube housing.

(3) Adjustable or removable beam limiting diaphragms or cones shall not transmit more than five percent of the useful beam at the maximum kilovoltage and with the maximum treatment filter.

(4) The filter system shall be so arranged as to minimize the possibility of error in filter selection and alignment. The filter slot shall be so constructed that the radiation escaping through it does not produce an exposure exceeding one roentgen per hour at one meter, or if the patient is likely to be exposed to radiation escaping from the slot, 30 roentgens per hour at two inches (five centimeters) from the external opening. Each removable filter shall be marked with its thickness and material.

(5) It shall be possible for the person operating the controls of the therapeutic equipment to determine from the operating position what filters are in place in the equipment. Filters shall be so mounted as to prevent their movement during the treatment.

(6) The X-ray tube shall be secured so that it cannot move in respect to the housing aperture. A mark on the exterior of the tube housing is recommended to indicate the focal spot.

(7) Adequate devices shall be provided to secure the tube housing during stationary portal treatment.

(8) An easily discernible indicator which shows whether or not X-rays are being produced shall be on the control panel.

(9) A suitable exposure control device (e.g. an automatic timer, exposure meter or dose meter) shall be provided to terminate the exposure automatically after a preset time interval or preset exposure or dose limit. Means shall be provided for the operator to terminate the exposure at any time.

(10) Equipment utilizing shutters to control the useful beam shall have a shutter position indicator on the control panel.

(b) Structural shielding.

(1) The protective barriers for all therapy equipment operating at voltages above 60 kVp shall not be removable.

(2) The control panel for all therapy equipment operating at voltages above 150 kVp shall be located outside the treatment room.

(c) Conditions for operation of equipment.

(1) The beam output shall be calibrated prior to the use of the apparatus for treating humans. Calibration shall be performed by an individual who is currently licensed by the New York State

Department of Education as a Medical Physicist – Therapeutic Radiology. The method of calibration used shall be in accordance with procedures recommended by the American Association of Physicists in Medicine for the energy and type of radiation employed. Calibration shall be made at least annually. Recalibration, however, shall be made after each tube replacement and after any changes or replacements in the generating apparatus, or changes or updates in computer programs which govern or interact with the functions of the machine, and which could change the X-ray output.

(2) No person other than the patient, shall be permitted to remain within the therapy room while the generator is in operation.

(3) Every entrance to a therapy room in which equipment is capable of operating above 150 kV shall be protected by interlocks to insure that during the production of X rays no person can enter the therapy room without turning off the radiation equipment. Interlocks shall be so arranged that irradiation equipment cannot be started again without manually resetting the controls.

(4) Windows, mirror systems, or closed-circuit television viewing screens shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator may see the patient and the control panel from the same position.

(5) Provision shall be made for oral communication with the patient.

(6) In addition to the interlocking controls, there shall be installed signals which are readily observable or discernible near the outside of all access doors to indicate the production of X rays.

(7) No therapy vault shall be able to be closed from inside the therapy vault.

(8) Instructions for emergency response, contact information for manufacturer's technical assistance, radiation oncologist, medical physicist and the RSO should be posted at the control console.

16.61 Therapy equipment operating at potentials of 60 kVp and below.

(a) Equipment. All provisions of subdivision (a) of section 16.60 shall apply except that the leakage five centimeters from the surface of the tube housing shall not exceed 0.1 roentgen per hour.

(b) Conditions for operation of equipment.

(1) The output of the X-ray generator shall be calibrated prior to the use of the apparatus for treating humans. Calibration shall be performed by an individual who is currently licensed by the New York State Department of Education as a Medical Physicist – Therapeutic Radiology. The method of calibration used shall ensure accurate delivery of the prescribed dose under all conditions of use. Calibrations shall be made at least annually. Recalibration, however, shall be made after each tube replacement and after any changes or replacements in the generating apparatus which could change the x-ray output.

(2) If the tube must be hand-held during irradiation, the operator shall wear protective gloves and a protective apron of no less than 0.5 mm lead equivalent.

(3) The operator shall be able to observe and communicate with the patient during irradiation.

(4) Equipment having an output of more than 1,000 roentgens per minute at any accessible place shall not be left unattended without the power being shut off at the main disconnect switch in addition to the control panel switch.

(5) When operating equipment constructed with beryllium or other low filtration windows, the operator shall insure that the useful beam is blocked at all times except when actually being used.

(6) Instructions for emergency response, contact information for manufacturer's technical assistance, radiation oncologist, medical physicist and the RSO should be readily available. at the location of use of the device

16.62 Industrial Radiography.

Use of x-ray based Industrial Radiography equipment shall follow the requirements of section 16.119 of this Part, as applicable.

16.63 Miscellaneous and special types of radiation producing equipment. Types or uses of radiation producing equipment not specifically covered by this Part and not exempted in section 16.4 of this Part, and such other types or uses of radiation producing equipment as may be designated by the department shall be governed by special inspection or surveys by the department. Such special inspections or surveys by the department shall, with respect to the radiation producing equipment so inspected or surveyed, substitute for the inspections required by paragraph (1) of subdivision (a) of section 16.10 of this Part.

16.64 RESERVED.

16.65 Cone Beam Computed Tomography (CBCT).

Cone Beam Computed Tomography – Cone beam computed tomography (or CBCT, also referred to as C-arm CT, Cone beam volume CT, or flat panel CT) is a medical imaging technique consisting of x-ray computed tomography where the x-rays are divergent, forming a cone.

(a) Equipment

(1) The protective housing shall be of diagnostic type.

(2) X-ray activation controls shall be mounted in a protected area and situated so that the operator is required to remain in the protected area during the entire exposure.

(3) Each control panel and CBCT system shall include visual signals that indicate to the operator of a system whenever x-rays are being produced and when x-ray production is terminated.

(4) Each CBCT x-ray system shall be equipped with a control that allows the operator of the CBCT system to terminate the x-ray exposure at any time during a scan, or series of scans.

(5) Each CBCT system shall include a clearly and conspicuously labeled emergency shutoff button or switch.

(6) Premature termination of the x-ray exposure by the operator shall necessitate resetting of the CBCT conditions of operation by the operator prior to the initiation of another scan or series of scans.

(7) Each CBCT system shall be equipped to allow the operator at the control panel to maintain view of the patient by means of a window or mirror and two-way aural communication.

(b) Quality Assurance Program shall include:

(1) Identification of the facility New York State registration identification number.

(2) Identification of the make and model of the unit.

(3) Identification of the staff trained to perform QC testing and patient care.

(4) Identification of the licensed medical physicist.

(5) The most recent licensed medical physicist survey.

(i) Copies of the licensed medical physicist surveys shall be kept on file electronically or on paper for a period of three years.

(6) Documentation of preventive maintenance and service records, including any corrective actions.

(7) The provision of a formalized in-service training program for employees, provided prior to use on patients and thereafter annually, including:

(i) Basic radiation principles and safety.

(ii) Machine model specific training.

(iii) Displays and systems used for viewing.

(iv) Documentation of initial and annual training completion shall be maintained for a period of three years and available upon request.

(v) The practitioner shall attest in writing to employee completion of initial and annual training for each qualified employee allowed to operate the CBCT.

(vi) Examinations shall be performed only when clinically indicated and by written order of the practitioner.

(vii) No person shall be regularly employed for the purpose of imaging training demonstrations. This means that no person shall be imaged for the express purpose of testing or demonstrating the equipment.

(8) Eighteen months after the effective date of this Part, each current registrant that performs diagnostic CBCT scans on human beings shall be accredited by a nationally recognized accreditation program that is acceptable to the department. A facility performing CBCT scans that loses their existing accreditation or a registrant or licensee that fails to obtain accreditation must report this fact within 30 days to the department. After the effective date of this Part new licensees or registrants will have 18 months to become accredited and must demonstrate that they have initiated the accreditation process within 90 days of the start of operations.

(c) Cone Beam CT Quality Control program.

(1) Test requirements may vary from manufacturer to manufacturer. Each cone beam CT unit shall be tested to the manufacturer's requirements, or a QC test program shall be developed in consultation with the New York State licensed medical physicist if not provided by the manufacturer. Requirements include:

(i) Phantom test device from the manufacturer (FDA 21 CFR subchapter J section 1020.33 as revised and implemented in full on January 20, 2023) capable of QA/QC test completion as directed by the manufacturer or licensed medical physicist.

(ii) Documentation of QC test results and completion, including any system used for image viewing.

(2) Quality Control testing performed by a New York State licensed medical physicist:

(i) Initial acceptance testing, testing after a major repair, software upgrade, or change to any part of the system affecting unit output and patient dose, and annual testing thereafter shall be performed by a New York State licensed medical physicist, consistent with currently accepted professional standards. Physicist testing shall include but not be limited to:

(*a*) Calibration of the CBCT unit. The radiation output calibration of a CBCT x-ray system shall be performed with a calibrated dosimetry system. This system shall have been calibrated either by the National Institute of Standards and Technology (NIST) or by an American Association of Physicists in

Medicine (AAPM) Accredited Dosimetry Calibration Laboratory (ADCL) traceable to NIST. The calibration shall have been performed within the previous 24 months and after any servicing that may affect system calibration.

(*b*) Dose area product (DAP) or (KAP).

(*c*) Dose to pediatric and adult patients for the most common exam techniques.

(*d*) CT number for water or other reference material.

(*e*) Low and high contrast resolution.

(*f*) Noise.

(*g*) Scan localization accuracy.

(*i*) Artifacts.

(*j*) Field of View.

(*k*) Scatter measurements performed within 30 days of installation.

(*l*) Documentation of the area exposure results from an NVLAP approved laboratory at the console or operator location for a duration of one year.

(3) Registrant QC testing responsibilities shall include:

(i) Daily or days of CBCT patient imaging:

(*a*) Equipment function indicators, mechanical, and other safety checks.

(*b*) Film processing or digital system QC, if applicable.

(*c*) CT number for water and bone.

(*d*) Field uniformity.

(*e*) Artifacts.

(*f*) Repeat or rejected patient images shall be monitored and include the reason for patient image repeat or reject.

(ii) Weekly:

(*a*) Image viewing system software and hardware – as applicable.

(iii) Ongoing:

(*a*) Repeat reject analysis as determined by section 16.23(a)(1)(xi) of this Part.

(4) Each registrant shall maintain and make available for review by the department, on the premises of its radiation installation where the CBCT system is located, written procedures for appropriate calibration of the CBCT x-ray system.

(d) Additional Requirements.

(1) Each patient record shall document exposure or dose area product (DAP) or air kerma (AK) (DAP or AK where indicated, system may display DAP or AK for each examination).

(2) Pediatric and adult patients' most common exam technique and the resulting dose, as determined annually by the licensed medical physicist, shall be displayed at the operator console.

(3) The CBCT system shall not be operated except by an individual who has been specifically trained in its operation.

16.66 RESERVED.

16.67 RESERVED.

16.68 RESERVED.

16.69 RESERVED.

16.70 Use of Body Scanning.

(a) This section shall not apply in cities having a population of two million or more.

(b) Practitioners licensed under article 35 of the Public Health Law and unlicensed personnel employed at a local correctional facility may utilize body imaging scanning equipment that applies ionizing radiation to humans for purposes of screening inmates committed to such facility, solely in connection with the implementation of such facility's security program and in accordance with the provisions of this Part.

(c) Definitions.

(1) “Body imaging scanning equipment" or "equipment" means equipment that is specifically manufactured for security screening purposes and utilizes a low dose of ionizing radiation, with a maximum exposure per scan equal to or less than 10 uSv (1 mrem), to produce an anatomical image capable of detecting objects placed on, attached to or secreted within a person's body. The utilization of body imaging scanning equipment is for purposes of screening inmates committed to such facility, in connection with the implementation of such facility's security program.

(2) "Local correctional facility” shall mean a local correctional facility as defined in Correction Law section 2(16).

(3) “Equipment operator” or “operator” means personnel employed at the local correctional facilities that have successfully completed a training course approved by the department.

(4)"Screening" means the sum of radiation exposures or scans necessary to image objects concealed on all sides of the body as intended by the system design under normal conditions.

(d) Equipment use and installation requirements.

(1) Prior to the equipment’s first use on humans at a specific physical location or upon any major repairs that could influence image quality or exposure:

(i) body imaging scanning equipment purchased or installed at a local correctional facility must be registered with the department, in accordance with section 16.50 of this Part; and

(ii) a radiation protection survey, shielding evaluation and verification of image usefulness for detecting foreign objects must be completed by a licensed medical physicist.

(2) Equipment must have a clearly marked restricted area and one or more indicators when a scan is in process that is clearly visible to all security screening system operators and anyone approaching the restricted area.

(3) Equipment must be periodically inspected by the department as described in section 16.10 of this Part.

(4) Equipment must be tested by a licensed medical physicist annually to verify the equipment is operating as designed.

(5) The facility must maintain a policy and procedure manual describing equipment operations and body scanning procedures. Records and associated facility policies shall be maintained and available upon request by the department. The policy and procedure manual must include the following items:

(i) operating procedures appropriate for the specific equipment and intended scan types;

(ii) policy prohibiting the use of the equipment on individuals who are not inmates;

(iii) policy regarding the determination of pregnancy that has been approved by the jail physician;

(iv) emergency contact information in the event the equipment overexposes any individual or there is equipment related failure that potentially requires service prior to scanning other inmates;

(v) requirements for exposure records to be provided to an inmate upon release or transfer to another facility; and

(vi) exposure per scan for each scan protocol used.

(6) Records and documentation of the program operation shall be maintained in accordance with section 16.14 of this Part and shall include, at a minimum, the following:

(i) the number of times the equipment was used on inmates upon intake, after visits, and upon the suspicion of contraband, as well as any other event that triggers the use of such equipment;

(ii) the average, median, and highest number of times the equipment was used on any inmate, with corresponding exposure levels;

(iii) the number of times the use of the equipment detected the presence of drug contraband, weapon contraband, and any other illegal or impermissible object or substance; and

(iv) the number of times an inmate has been scanned.

(e) Exposure limits and reporting requirements

(1) No person other than an inmate of a local correctional facility shall be exposed to the useful beam and then only by an individual that has met the provisions of subdivision (f) of this section.

(2) Limits on the use of equipment exposure to inmates are:

(i) no more than fifty percent of the annual exposure limits for non-radiation workers as specified by applicable regulations, not to exceed 0.5 mSv (50 mrem);

(ii) inmates under the age of eighteen shall not be subject to more than five percent of such annual exposure limits, not to exceed 0.05 mSv (5 mrem); and

(iii) pregnant women shall not be subject to scanning at any time.

(3) The following events shall be reported to the department in writing within 30 days:

(i) incidents or any injuries or illness resulting from the use of such equipment or reported by persons scanned by such equipment; and

(ii) exposure that exceeds the limits set forth in this Part.

(f) Training Requirements.

(1) Every equipment operator shall receive initial operator training, to be provided by the equipment manufacturer or their approved representative, or another source approved by the department.

(2) The contents of the initial operator training must include radiation safety, equipment operations, exposure and exposure limits for occupational exposed staff and inmates; applicable regulations; and facility policies and procedures.

(3) Initial operator training must be documented and available for review by the department upon request. Such documentation must include the names of the presenter or sources, attendees, dates and contents of the training.

(4) Every equipment operator shall receive annual refresher training, to be provided by the equipment manufacturer or their approved representative, or another source approved by the department. Such training shall meet the requirements listed in paragraphs (1), (2) and (3) of this subdivision and include any changes to the policies and procedures manual or updates to the regulations.

LICENSING OF RADIOACTIVE MATERIALS

Introductory note: The sections under this heading contain the licensing provisions for radioactive material, i.e., byproduct material, source material, special nuclear material in quantities not sufficient to form a critical mass naturally occurring radioactive material, and accelerator produced radioactive material.

16.100 Overall licensing requirements for radioactive material.

(a) A person may manufacture, produce, acquire, receive, possess, prepare, use or transfer any radioactive materials only in accordance with a specific license issued by the department or as allowed in subdivisions (b) or (c) of this section.

(b) A specific license is not required for persons who comply with all applicable requirements for a general license as set forth in section 16.101 of this Part.

(c) A specific license is not required for persons who comply with all applicable requirements to qualify for an exemption as set forth in section 16.4 of this Part or other exemptions provided for in this Part or for the removal of source material from its place of deposit in nature.

16.101 General licenses

(a) This section establishes:

(1) general licenses for the possession and use of radioactive material;

(2) a general license for ownership of radioactive material;

(3) registration requirements for certain devices;

(4) a limit of no more than one millicurie of gamma-emitting radioactive material in a sealed source, where gamma radiation is the emission of interest, and no more than one millicurie of strontium 90 or any transuranic radionuclide per device that may be possessed or used under a general license, and;

(5) terms, conditions and limitations.

(b) Any person who possesses or uses radioactive material under a general license shall comply with the provisions of the following federal regulations, which are hereby incorporated by reference, with the same force and effect as if fully set forth at length herein: 10 CFR 31, General Domestic Licenses for Byproduct Material, as revised and implemented in full on July 23, 2008, except as follows:

(1) Sections 31.1-31.4, 31.11, 31.5(c)(13)(i), (ii) and (iv), and 31.21-31.23 are excluded.

(2) Any reference to the “Commission”, “NRC”, “Director”, “Office of Nuclear Material Safety and Safeguards”, “NRC Regional Office” or any other office thereof shall be deemed to be a reference to the New York State Department of Health, except for when used in sections 31.8(c)(2) and 31.11(d)(2).

(3) Reporting required in 10 CFR 31.5, as revised and implemented in full on July 23, 2008, other than reports of import or export, shall be submitted to the department by means specified in section 16.1(c) of this Part, instead of to the NRC by method listed in 10 CFR30.6(a) as revised and implemented in full on October 16, 2020.

(4) Upon receipt of any fixed measuring, gauging or controlling devices that contain radioactive material not exceeding the limits specified in subdivision (a) of this section, each person shall register the device with the department on a form prescribed by the department and accompanied by the required fee. Each address for a location of use represents a separate general licensee and requires a separate registration and fee. Portable or mobile measuring, gauging or controlling devices containing radioactive material are not applicable under this paragraph and thereby require a specific license under 16.100 of this Part.

(5) Any reference in 10 CFR 31 as revised and implemented in full on July 23, 2008, to the import or export of radioactive material is under the direct and exclusive jurisdiction of the NRC.

(c) Any person who is licensed pursuant to section 16.123 of this Part for medical use is also authorized to use radioactive material described in 10 CFR31.11(a) as revised and implemented in full on November 14, 1968, under the conditions of such specific license without filing for a general license registration.

16.102 Applications for specific licenses.

(a) An application for a specific license for any radioactive material shall be filed in duplicate on, and shall contain completely and accurately all information called for by, a form prescribed by the department. The application may incorporate by clear and specific reference information contained in any previous application, supplementary statement, notification or report filed with the department.

(b) At any time subsequent to the filing of an application for a license and before the termination of a license issued in response thereto, the department may require the applicant to submit one or more supplementary statements containing additional information to enable the department to determine whether such application should be approved or denied, or whether a previously issued license should be amended, suspended or revoked.

(c) Each application or supplementary statement shall be signed by either the applicant personally or a person duly authorized by the applicant to sign for and on the applicant's behalf.

(d) A single application may apply for more than one license or for a license covering more than one radioactive material.

(e) The applicant shall permit the department to perform an onsite inspection or inspections prior to issuance of a license in order to verify information provided in the license application and any supplemental application information.

(f) Applications submitted without the fee specified in section 16.41 of this Part will not be processed until the department receives payment in full.

(g) As provided by section 16.114 of this Part, certain applications for specific licenses filed under this Part must contain a proposed decommissioning funding plan or a certification that financial assurance for decommissioning has been provided.

(h) Emergency plans for responding to a release of radioactive material.

(1) Each application to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in 10 CFR30.72, schedule C, "Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release," as revised and implemented in full on October 1, 2007, must contain either:

(i) an evaluation showing that the maximum dose to a person offsite due to a release of radioactive materials would not exceed 1 rem (10 mSv) effective dose equivalent or 5 rems (50 mSv) to the thyroid; or

(ii) an emergency plan for responding to a release of radioactive material.

(2) One or more of the following factors may be used to support an evaluation submitted under subparagraph (1)(i) of this subdivision:

(i) the radioactive material is physically separated so that only a portion could be involved in an accident;

(ii) all or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged;

(iii) the release fraction in the respirable size range would be lower than the release fraction shown 10 CFR30.72 as revised and implemented in full on October 1, 2007, due to the chemical or physical form of the material;

(iv) the solubility of the radioactive material would reduce the dose received;

(v) facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in 10 CFR30.72 as revised and implemented in full on October 1, 2007;

(vi) operating restrictions or procedures would prevent a release fraction as large as that shown in 10 CFR30.72 as revised and implemented in full on October 1, 2007; or

(vii) other factors appropriate for the specific facility.

(3) An emergency plan for responding to a release of radioactive material submitted under subparagraph (1)(ii) of this subdivision must include the following information:

(i) Facility description. A brief description of the licensee's facility and area near the site.

(ii) Types of accidents. An identification of each type of radioactive materials accident for which protective actions may be needed.

(iii) Classification of accidents. A classification system for classifying accidents as alerts or site area emergencies.

(iv) Detection of accidents. Identification of the means of detecting each type of accident in a timely manner.

(v) Mitigation of consequences. A brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers onsite, and a description of the program for maintaining the equipment.

(vi) Assessment of releases. A brief description of the methods and equipment to assess releases of radioactive materials.

(vii) Responsibilities. A brief description of the responsibilities of licensee personnel should an accident occur, including identification of personnel responsible for promptly notifying offsite response organizations and the commissioner; also responsibilities for developing, maintaining, and updating the plan.

(viii) Notification and coordination. A commitment, and a brief description of the means, to promptly notify offsite response organizations and request offsite assistance, including medical assistance for the treatment of contaminated injured onsite workers when appropriate. A control point must be established and the notification and coordination must be planned so that

unavailability of some personnel, parts of the facility, and some equipment will not prevent the notification and coordination. The licensee shall also commit to notify the commissioner immediately after notification of the appropriate offsite response organizations and not later than one hour after the licensee declares an emergency.

(ix) Information to be communicated. A brief description of the types of information on facility status, radioactive releases, and recommended protective actions, if necessary, to be given to offsite response organizations and to the commissioner.

(x) Training. A brief description of the frequency, performance objectives and plans for the training that the licensee will provide to workers on how to respond to an emergency; including any special instructions and orientation tours the licensee would offer to fire, police, medical and other emergency personnel. The training shall familiarize personnel with site-specific emergency procedures. Also, the training shall thoroughly prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site, including the use of team training for such scenarios.

(xi) Safe shutdown. A brief description of the means of restoring the facility to a safe condition after an accident.

(xii) Exercises. Provisions for conducting quarterly communications checks with offsite response organizations and biennial onsite exercises to test response to simulated emergencies. Quarterly communications checks with offsite response organizations must include the check and update of all necessary telephone numbers. The licensee shall invite offsite response organizations to participate in the biennial exercises. Participation of offsite response organizations in biennial exercises, although recommended, is not required. Exercises must use accident scenarios postulated as most probable for the specific site and the scenarios shall not be known to most

exercise participants. The licensee shall critique each exercise using individuals not having direct implementation responsibility for the plan. Critiques of exercises must evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response. Deficiencies found by the critiques must be corrected

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

(4) The licensee shall allow the offsite response organizations expected to respond in case of an accident 60 days to comment on the licensee's emergency plan before submitting it to the commissioner. The licensee shall provide any comments received within 60 days to the commissioner with the emergency plan.

(5) Prior to the commencement of the on-site biannual emergency exercises required by paragraph (3) of this subdivision, at least 72 hours' notice must be provided to the New York State Department of Health, Bureau of Environmental Radiation Protection.

(i) An application from a medical facility, education institution, or federal facility to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to licenses in its consortium authorized for medical use under section 16.123 of this Part shall include:

(*a*) A request for authorization for the production of PET radionuclides or evidence of existing license issued under this part for a PET radionuclide production facility within its consortium from which it receives PET radionuclides.

(*b*) Evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in 10 CFR32.72(a)(2) as revised and implemented on August 24, 2023.

(*c*) Identification of individual(s) authorized to prepare the PET radioactive drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an authorized medical physicist as specified in 10 CFR32.72(b)(2) as revised and implemented in full on August 24, 2023.

(*d*) Information identified in 10 CFR 32.72(a)(3) as revised and implemented in full on August 24, 2023, on the PET drugs to be noncommercially transferred to members of its consortium.

16.103 Licensing requirements for radioactive materials.

(a) The department may approve an application for, and issue in response thereto, a specific license to transfer, receive, possess and use any radioactive material, if the department determines that the following requirements have been met:

(1) the applicant's proposed use, equipment, facilities and procedures will protect public health and safety, and will minimize danger to life and property, from radiation hazards;

(2) the applicant's radiation detection and measuring instrumentation is appropriate for the uses of radioactive materials requested in the application;

(3) the applicant, (or the applicant's personnel if the applicant is not an individual), is qualified by training and experience to use such radioactive material for each purpose covered by the application so as to protect public health and safety and to minimize danger to life and property from radiation hazards; and

(4) the applicant submits sufficient information to support a determination that the requirements of this section are satisfied.

(b) Any person issued a specific license to manufacture, transfer, receive, possess or use any radioactive material shall comply with the provisions of the following federal regulations, which

are hereby incorporated by reference, with the same force and effect as if fully set forth at length herein: 10 CFR 30, Rules of General Applicability to Domestic Licensing of Byproduct Material as revised and implemented in full on October 16, 2020; Part 40, Domestic Licensing of Source Material as revised and implemented in full on August 24, 2023: and Part 70, Domestic licensing of Special Nuclear Material, as revised and implemented in full on August 24, 2023, except as follows:

(1) Sections 30.2, 30.3, 30.4 definitions of "Utilization facility", "Commencement of construction" and "construction", 30.5, 30.7, 30.8, 30.9, 30.21(c), 30.31, 30.32(a)-(f), 30.32(h), 30.33, 30.34(d), 30.34(e)(1)-(4), 30.37, 30.38, 30.39, 30.41 (b)(6), 30.50(c)(3), 30.51(c), 30.52, 30.53, 30.55, 30.61, 30.62, 30.63, 30.64, 40.2a, 40.4 definitions of "Commencement of Construction", "Construction", "Foreign obligations", "Reconciliation", "Residual radioactive material", and "Uranium milling", 40.5 – 40.9, 40.12(b), 40.13(c)(5)(iv), 40.14, 40.20 40.23, 40.26, 40.27, 40.28, 40.31(a)-h) and (j)-(m), 40.32 (d) with respect to "common defense and security", 40.32, (e) and (g), 40.33, 40.35 (d)-(f), 40.38, 40.41(d), (e), (g) and (h), 40.43, 40.44, 40.45, 40.51(b)(6), 40.52, 40.53, 40.56, 40.64 – 40.82, criterion 11A. through F of appendix A to Part 40, 70.1, 70.2, 70.10(b), 70.13, 70.14, 70.17, 70.20a, 70.20b, 70.21, 70.22, 70.24, 70.25(a)(1), (c), (d), f), and (h), 70.31 are excluded.

(2) Any reference to the "commission", "NRC", "US NRC", "NRC regional office", "United States nuclear regulatory commission", "administrator of the appropriate regional office", "Director of the Office of Nuclear Material Safety and Safeguards", "NRC Operations Center" or any other office or person thereof, shall be deemed to be a reference to the New York State Department of Health, except for when used in: sections 30.12, 30.21(c), 30.34(h)(1), 30.50(c)(1), 40.11. 70.11, 70.19(a)(1) and (2), 70.39(b), 70.40(b)-(d).

(3) Any reference to “Department” in 10 CFR40.11 means the United States Department of Energy.

(4) Any reference to “Parts 19, 20, and 21 of this Chapter” shall be deemed to be a reference to Title 10 of the CFR.

(5) Any reference to “an appropriate method listed in 10 CFR 30.6(a), 40.5(a) and 70.5(a)” shall be deemed to be a reference to “a means specified in section 16.1(c) of this Part”.

(6) Any reference to an “NRC Form” shall been deemed to reference “a form prescribed by the Department.”

16.104 Conditions of specific licenses.

(a) It is hereby made a condition of each specific license:

(1) that the licensee thereunder shall comply with all applicable provisions of the Public Health Law, of all other laws now or hereafter in effect, and with all applicable rules, regulations, codes and orders now or hereafter in effect of the department and of all appropriate regulatory agencies;

(2) that neither such license, nor any right, title or interest in, of or to such license, shall be disposed of by assignment, transfer or otherwise, either voluntarily or involuntarily, either directly or indirectly, unless the department shall, after securing complete and accurate pertinent information, have approved in writing of such disposal;

(3) that the licensee shall confine their possession and use of licensed radioactive material to such location or locations and for such purpose or purposes as the license may authorize; provided, however, that except as otherwise provided in such license or this Part, such license shall be deemed to authorize the licensee to transfer the material covered by such license to any

other person authorized to receive it by the department, the New York City Department of Health and Mental Hygiene, the United States Nuclear Regulatory Commission or any Agreement State; and

(4) that the licensee shall notify the department by letter within 30 days if an authorized user, radiation safety officer or radiation therapy physicist permanently discontinues performance of duties under the license; and

(5)(i) that each licensee shall notify the department in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of Title 11 (Bankruptcy) of the United States Code by or against:

(*a*) the licensee;

(*b*) an entity (as that term is defined in 11 U.S.C. 101(15) (see section 16.200 of this Part) controlling the licensee or listing the license or licensee as property of the estate; or

(*c*) an affiliate (as that term is defined in 11 U.S.C. 101(2)) (see section 16.200 of this Part) of the licensee.

(ii) This notification must indicate:

(*a*) the bankruptcy court in which the petition for bankruptcy was filed; and

(*b*) the date of the filing of the petition.

(6) that any license covering the use of special nuclear material in the course of which licensed use additional special nuclear material is produced, shall be deemed to cover any such special nuclear material so produced; provided, however, that the total quantity of special nuclear material possessed by the licensee is not sufficient to form a critical mass.

(7) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall

test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with 10 CFR35.204, as revised and implemented in full on July 16, 2018. The licensee shall record the results of each test and retain each record for three years after the record is made.

(8) Security requirements for portable gauges, excluding X-ray Fluorescence devices.

Each portable gauge licensee shall use a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal, whenever portable gauges are not under the control and constant surveillance of the licensee.

(9) Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under 10 CFR 35.

(i) Authorization under 10 CFR 30.32(j) as revised and implemented in full on September 30, 2014, to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other federal, and State requirements governing radioactive drugs.

(ii) Each licensee authorized under 10 CFR 30.32(j) as revised and implemented in full on September 30, 2014, to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:

(*a*) Satisfy the labeling requirements in 10 CFR 32.72(a)(4), as revised and implemented in full on August 24, 2023,for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium.

(*b*) Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural,

radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in 10 CFR 30.32(j) as revised and implemented on September 30, 2014, to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radioactive drugs shall be:

(*1*) an authorized nuclear pharmacist that meets the requirements in 10 CFR 32.72(b)(2) as revised and implemented on August 24, 2023, or

(*2*) an individual under the supervision of an authorized nuclear pharmacist as specified in 10 CFR35.27, as revised and implemented in full on November 14, 2022.

(iii) A pharmacy, authorized under 10 CFR 30.32(j) as revised and implemented on September 30, 2014, to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirements of 10 CFR 32.72(b)(5) as revised and implemented on August 24, 2023.

(b) The department may at any time set forth in any license or incorporate by reference therein, additional conditions, restrictions or requirements applicable to the licensee's transfer, receipt, possession or use of the radioactive material covered by such license in order to protect the public health and safety and to minimize danger to life and property from radiation hazards.

16.105 Duration, expiration and termination of specific licenses.

(a) Except as otherwise provided in this subdivision, each specific license will expire at the end of the expiration date stated in such license. If any licensee duly files with the department not less than 30 days prior to such expiration date, an application in accordance with section 16.102 of this Part for the renewal of his license or for a new and superseding license, such license shall not be deemed to have expired until the department has finally determined such application.

(b) The department may terminate any specific license upon the written request of the licensee

(c) Each specific license continues in effort, beyond the expiration date if necessary, with respect to possession of radioactive material until the commissioner notified the licensee in writing that the license is terminated. During this time, the licensee shall:

(1) limit actions involving radioactive material to those related to decommissioning; and

(2) continue to control entry to restricted areas until they are suitable for release in accordance with department requirements.

16.106 Renewal or amendment of specific licenses.

Any application by a licensee for the renewal or amendment of the license shall be considered as an application for a license and shall be filed in accordance with section 16.102 of this Part; and any such application for amendment shall set forth the reasons for such requested amendment. In considering any such application for renewal or amendment, the department will apply the requirements set forth in section 16.103 of this Part as appropriate. Corrective amendments to a license may be issued by the department at any time upon its initiative.

16.107 Amendment, suspension or revocation of licenses.

(a) Specific and general licenses may be subject to amendment, suspension or revocation by reason of amendment of the Public Health Law, enactment or amendment of any other applicable law, amendment of this Part or amendment or promulgation of any other applicable rule, regulation, or order.

(b) The department may amend, revoke or suspend any license in whole or in part, for:

(1) any material misstatement in the application therefor or in any supplementary statement thereto;

(2) any condition revealed by such application, supplementary statement, report, record, inspection or other means, which would warrant the department to refuse to grant a license on an original application; or

(3) any violation or failure to observe any of the applicable terms or provisions of such license, the Public Health Law, this Part, or any other applicable rule, regulation, code or order now or hereafter in effect.

16.108 Recognition of Agreement State and U.S. NRC Licenses.

(a) The holder of a specific license or permit issued by the State Department of Health, the New York City Department of Health, the United States Nuclear Regulatory Commission, and any Agreement State, or any licensing nonagreement state, may bring, possess or use radioactive material covered by such license or permit within the commissioner's jurisdiction for a period not in excess of 180 days in any calendar year without obtaining a specific license from the commissioner, and is granted a general license to conduct the same activity within areas of exclusive State jurisdiction within New York State, provided that:

(1) such license or permit does not limit the holder's possession or use of such material to a specific installation or installations;

(2) such holder shall, at least 3 days before engaging in each activity for the first time in a calendar year, file a submittal containing a completed form specified by the department, a copy of its U.S. Nuclear Regulatory Commission or Agreement State specific license, and the appropriate fee as prescribed in sections 16.40 and 16.41 of this Part with the New York State

Department of Health. If a submittal cannot be filed 3 days before engaging in activities under reciprocity, because of an emergency or other reason, the department may waive the 3-day time requirement provided the licensee:

(i) informs the department by telephone, facsimile, a completed form specified by the department, or a letter of initial activities or revisions to the information submitted on the initial form specified by the department;

(ii) receives oral or written authorization for the activity from the department; and

(iii) within 3 days after the notification, files a completed form specified by the department, a copy of the U.S. Nuclear Regulatory Commission or Agreement State license, and the fee payment;

(3) such holder, at least three days prior to engaging in such activities within the commissioner's jurisdiction, files with the commissioner a notice indicating the period, type and location of proposed possession and use within the commissioner's jurisdiction and a copy of the license or permit. At the discretion of the commissioner, oral notification of the commissioner or notification of the commissioner less than three days prior to engaging in such activities may be accepted in lieu of the filing requirement under this paragraph;

(4) such holder supplies such additional information as the commissioner may reasonably request;

(5) such holder, during the period of his possession and use of such material within the commissioner's jurisdiction, complies with all relevant provisions of this Part, and any additional requirements which the commissioner may impose, and which are reasonable under the circumstances;

(6) such holder, is engaged in licensable activities exclusive to the use, possession, or temporary storage of x-ray fluorescence devices, portable gauges, industrial radiography, well logging, decontamination and decommissioning services, waste brokerage, packaging of radioactive materials for transport, possession of radioactive material for training purposes, installation, manufacture, or service radioactive devices or equipment unless stated otherwise under subdivision (b) of this section, or other uses as deemed applicable by the department.

(b) Any holder of a license or permit issued by the State Department of Health, the New York City Department of Health and Mental Hygiene, the United States Nuclear Regulatory Commission, any Agreement State, or any licensing nonagreement state which authorizes the holder to manufacture, install or service a device of the type which is generally licensed and specified in section 16.101 of this Part may install or service such device without obtaining a license from the department, provided that:

(1) such person shall file a report with the department within 30 days after the end of each calendar quarter in which any device is transferred to or installed within the department's jurisdiction. Such report shall contain the name and address of each person receiving such a device, shall identify the type of device or devices so transferred, and shall state the quantity and type of radioactive material contained in such device or devices;

(2) any such device is installed and serviced in accordance with the terms of the license or permit issued to such person;

(3) such person shall assure that any labels required to be affixed to any such device shall bear a statement that reads "Removal of this label is prohibited"; and

(4) the person to whom such holder transfers any such device or on whose premises such holder installs or services any such device has a copy of the general license requirements or equivalent requirements outlined in section 16.103 of this Part.

16.109 Licensees and contractors of the United States Nuclear Regulatory Commission and the United States Department of Energy within the State.

(a) Each person who holds a license from the United States Nuclear Regulatory Commission authorizing activities within the State shall be exempt from the requirements of this Part with respect to such activities during the period that such license is valid, provided, however, that such person:

(1) shall afford the department and health officer having jurisdiction access to all records which such person is required to maintain pursuant to the United States Nuclear Regulatory Commission's rules and regulations or pursuant to the provisions of the United States Nuclear Regulatory Commission license,

(2) shall afford the department and health officer having jurisdiction opportunity to sample effluents, and to conduct such measurement or survey of levels of radiation and radioactive contamination as will not substantially interfere with or interrupt any activities licensed by the United States Nuclear Regulatory Commission, and

(3) shall afford the department and health officer having jurisdiction access to the facilities of such person in order to accomplish the foregoing review of records, sampling of effluents and conduct of measurements or surveys.

(b) Each United States Nuclear Regulatory Commission contractor or subcontractor and each United States Department of Energy contractor and subcontractor of the following categories

operating within the State shall be exempt from the requirements of this Part to the extent that such contractor or subcontractor under such contract transfers, receives, possesses, or uses sources of radiation:

(1) prime contractors performing work for the United States Department of Energy at United States government-owned or controlled sites, including the transportation of sources of radiation to or from such sites and the performance of contract services during temporary interruptions of such transportation;

(2) prime contractors performing research in, or development, manufacture, storage, testing or transportation of, atomic weapons or components thereof;

(3) prime contractors using or operating nuclear reactors or other nuclear devices in a United States government-owned vehicle or vessel; and

(4) any other prime contractor or subcontractor when the State and the United States Nuclear Regulatory Commission or the United States Department of Energy jointly determine that:

(i) under the terms of the contract or subcontract there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety; and

(ii) the exemption of such contractor or subcontractor is otherwise appropriate.

16.110 Licensure and inspection of radioactive materials; fees authorized. Provided that a written schedule of the licensing and inspection fees to be charged has been submitted to and approved by the State Commissioner of Health, any county, part-county or city health district having a population of more than 2,000,000 which has established substitute licensure requirements acceptable to the State Department of Health pursuant to the provisions of paragraph (2) of subdivision (b) of section 16.1 of this Part is authorized to charge adequate and

reasonable fees for the licensing and inspection of radioactive materials not exceeding the estimated cost of such services except that, with the approval of the State Commissioner of Health, one or more of such services may be rendered without charge.

16.111 Transfer of radioactive material.

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

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

(1) to the department, only after receiving prior approval from the department;

(2) to the United States Nuclear Regulatory Commission;

(3) to any person exempt from the regulations in this Part to the extent permitted under such exemption;

(4) to any person authorized to receive such material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the department, the United States Nuclear Regulatory Commission, or any Agreement State, or to any person otherwise authorized to receive such material by the Federal Government or any agency thereof, the Department of Energy, or any Agreement State; or

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

(c) Before transferring radioactive material to a specific licensee of the department, the United States Nuclear Regulatory Commission or the licensing agency of an Agreement State, or to a general licensee who is required to register with the department, the United States Nuclear Regulatory Commission or the licensing agency of an Agreement State prior to receipt of the

radioactive material, the licensee transferring the material shall verify that the transferee's license authorizes the receipt of the type, form and quantity of radioactive material to be transferred.

(d) The following methods for the verification required by subdivision (c) of this section are acceptable:

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

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

(3) for emergency shipments the transferor may accept oral certification by the transferee that he is authorized by license or registration certificate to receive the type, form and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency and expiration date; provided that the oral certification is confirmed in writing within 10 days;

(4) the transferor may obtain other sources of information compiled by a reporting service from official records of the department, the United States Nuclear Regulatory Commission or the licensing agency of an Agreement State as to the identity of licensees and the scope and expiration dates of licenses and registrations; or

(5) when none of the methods of verification described in paragraphs (1) through (4) of this subdivision are readily available, or when a transferor desires to verify that information received by one of such methods is correct or up-to-date, the transferor may obtain and record confirmation from the department, the United States Nuclear Regulatory Commission or the

licensing agency of an Agreement State that the transferee is licensed to receive the radioactive material.

(e) Preparation for shipment and transport of radioactive material shall be in accordance with the provisions of section 16.17 of this Part.

16.112 Physical protection of category 1 and category 2 quantities of radioactive material, fingerprinting and criminal background check requirements.

(a) This section contains the requirements for the physical protection program for any licensee that possesses an aggregated category 1 or category 2 quantity of radioactive material, which provide reasonable assurance of the security of such material from theft or diversion. Specific requirements for access to material, use of material, transfer of material, and transport of material are included.

(b) The licensee shall comply with 10 CFR 71.97, July 1, 2018, version.

(c)The licensee shall comply with the 10 CFR 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material," August 9, 2021, version, except as follows:

(1) Sections 37.1, 37.3, 37.7, 37.9, 37.11(a-b), 37.13, 37.105, 37.107, and 37.109 are excluded.

(2) Any reference to the Commission or NRC shall be deemed to be a reference to the New York State Department of Health, except:

(i) section 37.5 Definitions: "Agreement State", "Byproduct material", "Commission", "Fingerprint orders", "Person";

(ii) section 37.25(b);

(iii) section 37.27(a) and (c);

(iv) section 37.29(a);

(v) section 37.71 referring to NRC's license verification system.

(3) License required reports of events or notifications in sections 37.41, 37.45, 37.57, 37.77(a)-(d), 37.81, shall be reported to the department by means specified in section 16.1(c) of this Part instead of to the NRC.

16.113 Decommissioning.

(a) Decommissioning Plan.

(1) A licensee must submit a decommissioning plan: if otherwise required by this Part; if required by license condition; or if 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 may 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) must include:

(i) a description of the conditions of the facility or site sufficient to evaluate the acceptability of the plan;

(ii) a description of planned decommissioning activities;

(iii) a description of methods used to ensure protection of workers and the environment against radiation hazards during decommissioning;

(iv) a description of the radiation survey planned to demonstrate compliance with paragraphs (f)(4) and (g)(1) of this section; and,

(v) an updated detailed cost estimate for decommissioning, comparison of that estimate with existing 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 may 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.

(5) DFP (Decommissioning Funding Plan) Reviewed and Revised at least on a three (3) year basis

(b) Timeliness of Decommissioning.

(1) Each licensee or person in possession of a non-exempt source of radioactive material 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 radioactive material or which may be contaminated by residual radioactivity shall, no less than 30 days before vacating or relinquishing possession or control of a restricted area, 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:

(i) 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 this Part; or,

(ii) no principal activities under the license have been conducted for a period of 24 months; or,

(iii) 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 this Part.

(c) From the date of notification of the department required in subdivision (a) of this section, the licensee shall either:

(1) begin decommissioning activities; or

(2) within 12 months of notification submit a decommissioning plan, if required by subdivision (a) of this section, and begin decommissioning upon department approval of that plan.

(d) Coincident with the notification of the department required in subdivision (b) of this section, the licensee shall maintain in effect all decommissioning financial assurances established by the licensee in conjunction with a license issuance or renewal or as required by this Part. The amount of the financial assurance must be increased, or may be decreased, as appropriate, to

cover the detailed cost estimate for decommissioning established pursuant to section 16.113(a)(3)(v) of this Part.

(e) The department may approve an alternate schedule for the submission of plans and for the completion of decommissioning as required pursuant to subdivisions (a) and (c) of this section 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 request must be submitted no later than 30 days before notification pursuant to subdivision (b) of this section. The schedule for decommissioning may not commence until the department has made a determination on the request.

(f) 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 paragraph (3) of this subdivision 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:

(i) whether it is technically feasible to complete decommissioning within the allotted 24-month period;

(ii) whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 24-month period;

(iii) whether a significant volume reduction in wastes requiring disposal will be achieved by allowing short-lived radionuclides to decay;

(iv) whether a significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay; and,

(v) 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, ground-water 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:

(i) 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:

(*a*) 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,

(*b*) specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.

(ii) Certify the disposition of all licensed material including accumulated wastes, by submitting a form approved by the department.

(g) Termination of a License and Release of a Site Without Restriction.

(1) A site will 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 0.25 millisievert (25 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). When calculating TEDE to the average member of the critical group, the licensee shall determine the peak annual TEDE dose expected within the first 1000 years after decommissioning. 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) Specific licenses, including expired licenses, will be terminated upon written notice to the licensee when the department determines that:

(i) radioactive material has been properly disposed;

(ii) reasonable effort has been made to eliminate residual radioactive contamination, if present; and

(iii) documentation is provided to the department that:

(*a*) a radiation survey has been performed which demonstrates that the premises are suitable for release in accordance with department requirements; or

(*b*) other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with department requirements.

(iv) The licensee has complied with applicable sections of the New York State Environmental Conservation Law regarding radiological decommissioning.

(h) Applicability of Decommissioning Criteria Following License Termination. After a site has been decommissioned and the license terminated in accordance with the criteria in this Part, the department will require additional cleanup only if, based on new information, it determines that the criteria of this Part were not met and residual radioactivity remaining at the site could result in significant threat to public health and safety.

16.114 Financial assurance and record keeping for decommissioning.

(a) Any person issued a specific license to possess and use radioactive material shall comply with the provisions of the following federal regulations, which are hereby incorporated by reference, with the same force and effect as if fully set forth at length herein: 10 CFR 30, Rules of General Applicability to Domestic Licensing of Byproduct Material, Section 35, Financial Assurance and Recordkeeping for Decommissioning, December 19, 2014, version. Any reference to the "Commission" or "NRC" shall be deemed to be a reference to the New York State Department of Health.

16.115 RESERVED.

16.116 RESERVED.

16.117 RESERVED.

16.118 RESERVED.

16.119 RESERVED.

16.120 Specific licenses for the use of radioactive materials on human beings.

An application seeking a specific license for use of radioactive materials on human beings shall be

approved if all of the following criteria are satisfied:

(a) The application is completed, signed by an appropriate individual, and submitted to the department.

(b) The applicant is an individual, corporation, partnership or other entity that is legally authorized to do business in New York State. If the applicant is seeking a specific license pursuant to section 16.123 of this Part, the applicant shall be legally authorized to practice medicine in New York State or operate a hospital as defined in section 2801 of the Public Health Law.

(c) The applicant satisfies the requirements set forth in section 16.103 of this Part.

(d) The applicant demonstrates to the satisfaction of the department that it has adequate facilities for clinical care of patients.

(e) The applicant demonstrates to the satisfaction of the department that its facilities will be appropriately equipped and staffed and will be operated as required by this Part.

(f) The applicant provides additional information as requested by the department.

16.121 RESERVED.

16.122 RESERVED.

16.123 Specific licenses for certain medical uses of byproduct materials.

(a) Purpose and scope. This section contains requirements for the medical uses of byproduct materials that are subject to specific licenses. These requirements are in addition to, and not a substitute for, other requirements in this Part. Any license issued prior to the effective date of this section that references subdivisions (b) or (c) shall be deemed to reference the equivalent medical use category in 10 CFR 35 as follows:

Previous designation(s)	10 CFR 35 equivalent
16.123(b)(1) or 16.123(c)(1)……	35.100
16.123(b)(2) or 16.123(c)(2)……	35.200
16.123(b)(3) or 16.123(c)(3)……	35.300
16.123(b)(4) or 16.123(c)(4)…….	35.400
16.123(b)(5) or 16.123(c)(5)…….	35.500
16.123(c)(6)……	35.600
16.123(c)(7)……..	35.1000

(b) Definitions. Whenever used in this section, or in federal regulations incorporated herein, the following terms shall have the following meanings:

(1) “Associate Radiation Safety Officer”

(i) meets the requirements of 10 CFR 35.50 and 35.59, as revised and implemented in full on November 14, 2022;

(ii) Is currently identified as an Associate Radiation Safety Officer for the types of use of byproduct material for which the individual has been assigned duties and tasks by the Radiation Safety Officer on:

(*a*) a specific medical use license issued by the Commission or an Agreement State; or

(*b*) a medical use permit issued by a Commission master material license.

(2) "Authorized medical physicist" means an individual who is authorized to practice medical physics pursuant to article 166 of the Education Law and:

(i) meets the requirements for an authorized medical physicist set forth in 10 CFR 35.51, 35.57 and 35.59, as revised and implemented in full on November 14, 2022; or

(ii) is identified as an authorized medical physicist or teletherapy physicist on:

(*a*) a specific medical use license issued by the Nuclear Regulatory Commission or Agreement State;

(*b*) a medical use permit issued by a Nuclear Regulatory Commission master material licensee;

(*c*) a permit issued by a Nuclear Regulatory Commission or Agreement State broad scope medical use licensee; or

(*d*) a permit issued by a Nuclear Regulatory Commission master material license broad scope medical use permittee.

(3) "Authorized nuclear pharmacist" means an individual who is authorized to practice pharmacy pursuant to article 137 of the Education Law and:

(i) meets the requirements for an authorized nuclear pharmacist set forth in 10 CFR 35.55 and 35.59, as revised and implemented in full on November 14, 2022; or

(ii) is identified as an authorized nuclear pharmacist on:

(*a*) a specific license issued by the Nuclear Regulatory Commission or Agreement State that authorizes medical use or the practice of nuclear pharmacy;

(*b*) a permit issued by a Nuclear Regulatory Commission master material licensee that authorizes medical use or the practice of nuclear pharmacy;

(*c*) a permit issued by a Nuclear Regulatory Commission or Agreement State broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or

(*d*) a permit issued by a Nuclear Regulatory Commission master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy; or

(iii) is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or

(iv) was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material, and the individual practiced at a pharmacy at a federal government agency or federally recognized Indian Tribe before November 30, 2007, or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the Nuclear Regulatory Commission.

(4) "Authorized user" means an individual who is authorized to practice medicine pursuant to article 131 of the Education Law and:

(i) meets the applicable requirements for an authorized user set forth in 10 CFR 35.59 and 35.190, 35.290, 35.390, 35.392, 35.394, 35.490, 35.590, or 35.690 as revised and implemented in full on November 14, 2022; or

(ii) is identified as an authorized user on:

(*a*) a Nuclear Regulatory Commission or Agreement State license that authorizes the medical use of byproduct material;

(*b*) a permit issued by a Nuclear Regulatory Commission master material licensee that is authorized to permit the medical use of byproduct material;

(*c*) a permit issued by a Commission or Agreement State specific licensee of broad scope that is authorized to permit the medical use of byproduct material; or

(*d*) a permit issued by a Commission master material license broad scope permittee that is authorized to permit the medical use of byproduct material.

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

(6) “Ophthalmic physicist”

(i) meets the requirements in 10 CFR 35.433(a)(2) and 35.59 as revised and implemented in full on November 14, 2022; and

(ii) is identified as an ophthalmic physicist on a:

(*a*) specific medical use license issued by the Commission or an Agreement State; or

(*b*) permit issued by a Commission or Agreement State broad scope medical use license; or

(*c*) medical use permit issued by a Commission master material licensee; or

(*d*) permit issued by a Commission master material licensee board scope medical use permittee.

(7) "Positron emission tomography facility" is a facility operating a cyclotron or accelerator for the purpose of producing PET radionuclides.

(8) "Prescribed dosage" means the specified activity or range of activity of unsealed byproduct material as documented in a written directive, or in accordance with the directions of the authorized user for procedures performed pursuant to 10 CFR 35.100 and 35.200 as revised and implemented in full on November 14, 2022. Further details concerning this referenced code are contained in subdivision (c) of this section.

(9) "Prescribed dose" means:

(i) for gamma stereotactic radiosurgery, the total dose as documented in the written directive;

(ii) for teletherapy, the total dose and dose per fraction as documented in the written directive;

(iii) for manual brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or

(iv) for remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

(10) "Radiation safety officer" means an individual who:

(i) meets the requirements for a radiation safety officer set forth in 10 CFR 35.50 and 35.59 as revised and implemented in full on November 14, 2022; or

(ii) is identified as a radiation safety officer on:

(*a*) a specific medical use license issued by the Nuclear Regulatory Commission or Agreement State; or

(*b*) a medical use permit issued by a Nuclear Regulatory Commission master material licensee.

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

(12) "Treatment site" means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

(c) Approved medical uses of byproduct materials. A licensee may use byproduct materials on human beings for the particular uses set forth below, provided that the licensee meets all applicable requirements of this Part:

(1) use of unsealed byproduct material for uptake, dilution and excretion studies;

(2) use of unsealed byproduct material for imaging and localization studies;

(3) use of unsealed byproduct material for which a written directive is required;

(4) use of sources for manual brachytherapy;

(5) use of sealed sources for diagnosis;

(6) use of sealed source in a remote afterloader unit, teletherapy unit or gamma stereotactic radiosurgery unit; or

(7) other specific medical uses of byproduct material or radiation from byproduct material, as licensed by the department.

(d) Federal Standards. All licensees shall comply with the provisions of the following federal regulations, which are hereby incorporated by reference in paragraphs (e)(1)-(4) and subdivisions (f)-(m) of this section, with the same force and effect as if fully set forth at length. All referenced provisions are found within 10 CFR 35, Medical Use of Byproduct Material, as revised and implemented in full on November 14, 2022. This code is published by the Office of the Federal Register National Archives and Records Administration. Copies may be obtained from the Superintendent of Documents, United States Government Printing Office, Washington D.C. 20402. This code is available for copying and inspection at the Regulatory Affairs Unit, New York State Department of Health, Corning Tower, Empire State Plaza, Albany, NY 12237. Notwithstanding any provision herein to the contrary, if a conflict occurs between the above referenced CFR and other provisions in this Part, compliance with the more restrictive regulation is required.

(e) General requirements applicable to all licensees authorized to use byproduct materials for medical purposes.

(1) Record Keeping Requirements. A licensee shall comply with all record keeping requirements set forth in 10 CFR 35 subpart L (Records), as revised and implemented in full on November 14, 2022. Further details concerning this referenced code are contained in subdivision (c) of this section.

(2) Reporting requirements: A licensee shall comply with all reporting requirements set forth in 10 CFR 35 subpart M (Reports), as revised and implemented in full on November 14, 2022 as revised herein as follows: (i) in 35.3045(c)35.3047(c), and35.3204(a) replace phrase "NRC Operations Center" with "Department"; (ii) in35.3045(d), 35.3047(d),35.3067 and35.3204(b) replace “By an appropriate method listed in 30.6(a) of this chapter, the licensee shall submit a

written report to the appropriate NRC Regional Office listed in 30.6 of this chapter" with "shall submit a written report to the Department"; (iii) in 35.3045(g)(1) and 35.3047(f)(1), replace the term "NRC" with "Department"; and, (iv) in 35.3067 replace "The report must be filed with the appropriate NRC Regional Office listed in 30.6 of this chapter, by an appropriate method listed in 30.6(a) of this chapter, with a copy to the Director, Office of Federal and State Materials and Environmental Management Programs." with "The report shall be filed with the Department".

(3) Training and experience requirements. A licensee shall ensure that all staff who are involved in the use of byproduct material pursuant to a specific license have the training and experience required by this Part.

(4) Other General Requirements. A licensee shall comply with requirements set forth in 10 CFR 35.5,35.6, 35.11(a) and (b),35.24(b), (e), (f) and (g),35.27,35.40,35.41,35.49,35.60,35.61,35.63,35.65,35.67,35.69,35.70,35.75,35.80,35.92 as modified herein as follows: in 35.27(a)(1) and (b)(1), replace "19.12 of this chapter" with "16.13(c) of this Part".

(f) Requirements for the use of unsealed byproduct material for uptake, dilution and excretion studies. A licensee shall use unsealed byproduct material for uptake dilution and excretion studies only if authorized to do so by a specific license issued by the department and provided that the licensee complies with 10 CFR 35.100 and 35.190 as revised and implemented in full on November 14, 2022, and other applicable provisions of this Part.

(g) Requirements for the use of unsealed byproduct material for imaging and localization studies. A licensee shall use unsealed byproduct material for imaging and localization studies only if authorized to do so by a specific license issued by the department and provided that the licensee

complies with 10 CFR 35.200, 35.204 and 35.290 as revised and implemented in full on November 14, 2022, and other applicable provisions of this Part.

(h) Requirements for the use of unsealed byproduct material for which a written directive is required. A licensee shall use unsealed byproduct material for which a written directive is required only if authorized to do so by a specific license issued by the department and provided that the licensee complies with 10 CFR 35 subpart E (Unsealed Byproduct Material-Written Directive Required), as revised and implemented in full on November 14, 2022, and other applicable provisions of this Part.

(i) Requirements for the use of sources for manual brachytherapy. A licensee may use sources for manual brachytherapy only if authorized to so by a specific license issued by the department and provided that the licensee complies with 10 CFR 35 subpart F (Manual Brachytherapy), as revised and implemented in full on November 14, 2022.

(j) Requirements for the use of sealed sources for diagnosis. A licensee may use sealed sources for diagnosis only if authorized to do so by a specific license issued by the department and provided that the licensee complies with 10 CFR 35 subpart G (Sealed Sources for Diagnosis) , as revised and implemented in full on November 14, 2022, and other applicable provision of this Part.

(k) Requirements for the use of sealed sources in a remote afterloader unit, teletherapy unit or gamma stereotactic radiosurgery unit. A licensee may use a sealed source in a remote afterloader unit, teletherapy unit or gamma stereotactic radiosurgery unit only if authorized to so by a specific license issued by the department and provided that the licensee complies with 10 CFR 35 subpart H (Photon Emitting Remote Afterloader Units, Teletherapy Units and Gamma

Stereotactic Radiosurgery Units), as revised and implemented in full on November 14, 2022, and other applicable provisions of this Part.

(l) Requirements for the use of other medical uses of byproduct material or radiation from byproduct material. A licensee may use byproduct material or a radiation source approved for medical use which is not specifically addressed in subdivisions (f) through (k) of this section if the licensee submits to the department information required by 10 CFR 35.12(b) through (d) as revised and implemented in full on November 14, 2022, and the licensee has received written approval from the department in a specific license or license amendment and uses the material in accordance with specific conditions that the department deems necessary or desirable for the safest medical use of the material.

(m) Notwithstanding the requirements of this Part, physically present for the use of high dose rate afterloader units, teletherapy units, and gamma stereotactic radiosurgery units means that the authorized medical physicist and physician is located at the console, unobstructed from visually viewing and communicating with the patient and able to provide face-to-face services immediately in the event of an emergency requiring immediate medical intervention.

(n) General Use License. Any licensee who is licensed for one or more of the types of medical uses specified in subdivisions (f) through (k) of this section also is authorized to use radioactive material under the general license in paragraph 16.101(a)(1) of this Part for the specified "in vitro" uses without registering with the department, provided, however, that the licensee is subject to the other provisions of 10 CFR 31.11 as revised and implemented on November 14, 1968.

16.124 Licenses to manufacture or transfer certain items containing radioactive material.

(a)(1) This section contains requirements for the issuance of specific licenses to persons who manufacture or initially transfer items containing radioactive material for sale or distribution to:

(i) persons exempted from the licensing requirements of this Part, or equivalent regulations of an Agreement State, the NRC; or

(ii) persons generally licensed under this Part or equivalent regulations of an Agreement State or the NRC; or

(iii) persons licensed under section 16.123 of this Part.

(2) This section prescribes requirements for the issuance of specific licenses to persons who introduce radioactive material into a product or material owned by or in the possession of a licensee or another, and regulations governing holders of such licenses.

(3) This section prescribes certain requirements governing holders of licenses to manufacture or distribute items containing byproduct material.

(4) This section describes procedures and prescribes requirements for the issuance of certificates of registration (covering radiation safety information about a product) to manufacturers or initial transferors of sealed sources or devices containing sealed sources.

(b) The provisions and requirements of this section are in addition to, and not in substitution for, other requirements of this Part.

(c) Any person who manufactures or transfers items containing radioactive material shall comply with the provisions of the following federal regulations, which are hereby incorporated by reference, with the same force and effect as if fully set forth at length herein: 10CFR 32, Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material as revised and implemented in full on August 24, 2023, except as follows:

(1) Sections 32.1, 32.11, 32.12, 32.14 through 32.23, 32.25 through 32.32, 32.301, and 32.303 are excluded.

(2) Any reference to the "Commission", "NRC", or "NRC Regional Office" or any other office thereof shall be deemed to be a reference to the New York State Department of Health, except for when used in 10 CFR 32.51(a)(3)(iii), 32.54(a), 32.58, 32.71(d), 32.72(b)(5), and 32.74(a)(3).

(3) Reporting required in 10 CFR32.56(a) shall be submitted to the department by means specified in section 16.1(c) of this Part, instead of to the NRC.

16.125 Additional Requirements for the Manufacture, preparation, or transfer for commercial distribution of drugs containing radioactive material for medical use under 10 CFR 35 or the equivalent regulations of any state.

(a) An application for a specific license to manufacture, prepare, or transfer for commercial distribution radioactive drugs containing radioactive material for use by persons authorized pursuant to 10 CFR 35 or the equivalent regulations of any state may be approved if:

(1) the applicant satisfies the general requirements specified in section 16.103 of this Part.

(2) the applicant submits evidence that the applicant is registered or licensed by the New York State Board of Pharmacy as a drug manufacturer or a pharmacy, as appropriate to their practice;

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

(4) the applicant satisfies the following labeling requirements:

(i) a label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words “Caution, Radioactive Material” or “Danger, Radioactive Material”; the name of the radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half-life greater than 100 days, the time may be omitted; and

(ii) a label is affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words “Caution, Radioactive Material” or “Danger, Radioactive Material” and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

(b) A licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radioactive drugs prior to transfer for commercial distribution. In addition, the licensee shall:

(1) perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary;

(2) check each instrument for constancy and proper operation at the beginning of each day of use; and

(3) use differing activity concentrations in preparing different radiopharmaceuticals and ensure that any discrepancy between the calculated volume of a dosage and the volume found to be

required by measurement to achieve the prescribed activity, is resolved before the dosage is dispensed. Records of actions taken to resolve any such discrepancy shall be maintained for three years.

(c) A licensee shall possess and use instrumentation for performing surveys and analyses for radioactive contamination, and for making such measurements of radiation levels and radiation dose as may be necessary to demonstrate compliance with all requirements of this Part. In addition, the licensee shall:

(1) provide appropriate instrumentation for each application. This must include but is not limited to: a microrem or microR meter for surveying non-radioactive trash before disposal, and for surveying workers' skin and clothing for contamination; a thyroid uptake system with a reproducible geometry and an adequate lower limit of detection; and analytical instruments for identifying and quantifying radioactive contamination; and

(2) calibrate all instruments in accordance with the manufacturer's specifications and calibrate all meters at least every 12 months.

(d) (1) A licensee shall provide a radiation safety officer who is a health physicist with qualifications listed in paragraph (3) of this subdivision.

(2) a licensee shall only allow persons who are certified by the New York State Board of Pharmacy as nuclear pharmacists to act as pharmacists in a facility licensed pursuant to this section. A licensee may also propose such a certified nuclear pharmacist as radiation safety officer provided that the nuclear pharmacist will be assisted in the administration of the radiation protection program by a health physicist with the qualifications listed in subparagraph (iii) of this paragraph, and who will be present at the licensee's facility for the equivalent of one working day per month at a minimum, and who will provide the following services:

(i) provide classroom instruction to non-professional personnel who will perform work under the license;

(ii) review personnel monitoring reports and recommend methods to reduce exposures exceeding ALARA levels;

(iii) review survey records and make confirmatory measurements;

(iv) review air monitoring and emission levels and ensure compliance with limits;

(v) assist in thyroid bioassays and review absorbed dose calculations;

(vi) observe operations and make recommendations for improvements;

(vii) assist in response to, and in the evaluation of root causes and impacts of, incidents and accidents in order to minimize their impact and prevent their recurrence; and

(vii) generally consult with the RSO and provide health physics support as needed. The services to be provided must be documented in a contractual agreement between the licensee and the health physicist, and the department must be given a minimum of thirty days advance notice of the licensee's intent to retain a different health physicist.

(3) A health physicist who will act as radiation safety officer, or who will provide the services described in paragraph (2) of this subdivision, must have the following qualifications:

(i) experience in performing radiation protection services, or the duties of a radiation safety officer for programs of similar type, size and scope as the licensee's program; and

(ii) a bachelor's degree in health physics or radiological health and four years of the experience as described in clause (a) of this subparagraph; or certification by the American Board of Health Physics (Comprehensive), the American Board of Radiology in Medical Nuclear Physics, the American Board of Science in Nuclear Medicine in Radiation Protection or the American Board

of Medical Physics in Medical Health Physics, and two years of the experience as described in clause (a) of this subparagraph.

(e) (1) A licensee shall only locate a nuclear pharmacy in a building that is zoned for commercial use, and which is not in a heavy public traffic area such as a large shopping center.

(2) A licensee who proposes to locate within a multi-tenant building must demonstrate that:

(i) there are no areas above or below the proposed facility which are not under the licensee's control, and to which the licensee does not have the authority to restrict access; and

(ii) there are no neighboring tenants on the same level with walls contiguous to the proposed radioactive materials use and storage areas. There must be a buffer zone of unrestricted area within the licensee's proposed facility along any walls that are common walls with a neighboring tenant.

16.126 Sealed source and device registration.

(a) Purpose. The requirements of this section apply to any manufacturer or initial distributor of a sealed source or device containing a sealed source to submit a request to the New York State Department of Health for evaluation of radiation safety information about its product and for its registration.

(b) Specific requirements. Each manufacturer or initial distributer of a sealed source or device shall comply with the provisions of 10 CFR 32, "Subpart D- Sealed Source and Device Information," Sections 32.210 and 32.211, December 19, 2014 edition.

16.127 Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations.

(a) This section contains requirements for the issuance of a license authorizing the use of sealed sources containing radioactive materials for persons using these sealed sources in industrial radiography, and for depleted uranium shielding in a radiographic exposure device. This section also contains radiation safety requirements for industrial radiography. The requirements of this section are in addition to other requirements of this Part.

(b) Any person that possesses or uses sealed sources for industrial radiography shall comply with the provisions of the following federal regulations, which are hereby incorporated by reference, with the same force and effect as if fully set forth at length herein: 10 CFR 34, Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations as revised and implemented in full on October 16, 2020, except as follows:

(1) Sections 34.1, 34.5, 34.8, 34.11, 34.43(a)(2), 34.45(a)(9), 34.111, 34.121 and 34.123 are excluded.

(2) Any reference to the "Commission", "NRC", "NRC Regional Office" or any office or individual thereof shall be deemed to be a reference to the New York State Department of Health, except for 34.20(a)(1), 34.27 (a)-(c) and (e), 34.41(c) and 34.43(a)(1).

(3) Reports and notifications required by 34.27(d) and 34.101 shall be reported to the Department by a means specified in 16.1(c) of this Part instead of to the NRC Director, Office of Nuclear Material Safety and Safeguards.

(4) In section 34.20 "10 CFR part 71" is replaced with "section 16.17".

(5) In section 34.25 "10 CFR 20" is replaced with "this Part".

(6) In section 34.33 (a)(1) "20.1601(a)(1) of this chapter" is replaced with "16.12(d)(1)(i) of this Part".

(7) In section 34.42 (c)(1) “current 10 CFR part 20 of this chapter” and “10 CFR part 20” are replaced with “this Part”.

(8) In section 34.42 (c)(4) “20.2203 of this chapter” is replaced with “16.15(c) of this Part”.

(9) In section 34.43 (b)(1) and (c)(1) “10 CFR parts 19 and 20, of this chapter” is replaced with “this Part”.

(10) In section 34.43 (g)(4) is replaced to read: “The requirements of pertinent State and Federal regulations; and”.

(11) In section 34.45 (a)(1), “10 CFR part 20 of this chapter ‘Standards for Protection Against Radiation’” is replaced with “this Part”, and the word “person” is replaced with “individual”.

(12) In section 34.53, “20.1902 of this chapter” is replaced with “16.12(b)(1) of this Part” and “20.1903 of this chapter” is replaced with “16.12(b)(2) of this Part”.

(13) In section 34.89(a)(2) “10 CFR parts 19 and 20” is replaced with “this Part”.

(14) In section 34.101(b) “10 CFR 20.2203” is replaced with “section 16.15(c) of this Part”.

16.128 Well-Logging.

(a) Any person conducting well-logging operations shall comply with the provisions of the following federal regulations, which are hereby incorporated by reference, with the same force and effect as if fully set forth at length herein: 10 CFR 39, Licenses and Radiation Safety Requirements for Well Logging as revised and implemented in full on March 18, 2020, except as follows:

(1) Sections 39.1, 39.5, 39.8, 39.11, 39.45, 39.91, 39.101, and 37.103 are excluded.

(2) Any reference to the “Commission” or “NRC” shall be deemed to be a reference to the New York State Department of Health, except in sections:

(i) 39.35 (b) and (d);

(ii) 39.41(f);

(iii) 39.43 (c) - (e); and

(iv) 39.51.

(3) Any reference to parts 19 and 20 shall be deemed to be a reference to this Part.

(4) Any reference to section 20.1901(a) shall be deemed to be a reference to section 16.12(a) of this Part.

(5) Section 39.63(h) “20.1906 of this chapter” is replaced with “16.16 of this Part”.

(6) Section 39.71(b) “20.1003 of this chapter” is replaced with “16.2 of this Part”.

(7) Section 39.75(d) “71.5 of this chapter” is replaced with “16.17 of this Part”.

(8) Section 39.77(b) “20.2201-20.2202, 20.2203” is replaced with “16.15 of this Part”.

(9) Reports of events or notifications in sections 39.35(d)(2), 39.63(l), and 39.77 shall be reported to the department by means specified in section 16.1(c) of this Part instead of to the NRC.

(b) The requirements in this section do not relieve any person from the requirements in New York State Department of Environmental Conservation (NYSDEC) regulations (6 NYCRR Part 380) for the use of unsealed radioactive material for tracer studies in the environment.

16.129 Specific requirements for irradiators.

(a) This section contains requirements for the issuance of a license authorizing the use of sealed sources containing radioactive materials in irradiators used to irradiate objects or materials using gamma radiation. This section also contains radiation safety requirements for operating irradiators. These requirements are in addition to other requirements of this Part. Nothing in this

section relieves the licensee from complying with other applicable federal, State, and local regulations governing the siting, zoning, land use, and building code requirements for industrial facilities.

(b) This section applies to panoramic irradiators that have either dry or wet storage of the radioactive sealed sources and to underwater irradiators in which both the source and the product being irradiated are under water. Irradiators whose dose rates exceed 5 grays (500 rads) per hour at 1 meter from the radioactive sealed sources in air or in water, as applicable for the irradiator type, are covered by this Part.

(c) This section does not apply to self-contained dry-source-storage irradiators (those in which both the source and the area subject to irradiation are contained within a device and are not accessible by personnel), medical radiology or teletherapy, radiography (the irradiation of materials for nondestructive testing purposes), gauging, or open-field (agricultural) irradiations.

(d) Any person conducting irradiator operations shall comply with the provisions of the following federal regulations, which are hereby incorporated by reference, with the same force and effect as if fully set forth at length herein: 10CFR 36, Licenses and Radiation Safety Requirements for Irradiators, as revised and implemented in full on March 18, 2020, except as follows:

(1) Section 36.2 definitions of “commencement of construction” and “construction”, sections 36.5. 36.8. 36.11, 36.15, 36.17, 36.19, 36.91 and 36.93 are excluded.

(2) Section 36.21 (a)(1) is amended to add “or equivalent Agreement State Regulations” following “10 CFR 32.210”.

(3) Section 36.23(g) is amended to replace “10 CFR 20.1902” with “this Part”.

(4) Section 36.51(a)(2) is amended to replace" Parts 19 and 36 of NRC regulations" with "this Part".

(5) Section 36.83(b) is amended to read: "The report must include a telephone report within 24 hours as described in 10 CFR 30.50(c)(1), and a written report within 30 days as described in 10 CFR 30.50(c)(2), except that such reports shall be made to the Department by means specified in section 16.1(c) of this Part instead of to the NRC Operation Center."

(6) Any reference to the "Commission", "NRC", or "NRC Regional Office" shall be deemed to be a reference to the New York State Department of Health, except for 10 CFR 36.59(a) and (c).

16.140 Radon testing and reporting.

(a) Definitions. As used in this Part:

(1) "Radon" means the radioactive noble gas radon-222.

(2) "Radon testing firm" means a commercial business which uses equipment or provides detectors for testing for radon or radon decay products, or analyzes radon measurement devices, including continuous radon monitors, and which provides the results of such tests to customers.

(3) "Radon mitigation firm" means a commercial business which evaluates buildings for the purpose of developing plans for reducing indoor air radon levels, and/or implements measures designed to reduce such levels within existing buildings. This includes contractors who install passive mitigation systems in new construction.

(b) General requirements.

(1) A radon testing firm shall report to the department in writing, within 30 days following the end of a reporting period, a summary of all indoor air radon screening and long-term radon tests performed in the State during that reporting period. Reporting periods shall be from January 1st

to June 30th and July 1st to December 31st of each year. The report shall include the dates for which the report is made and the number of such measurements performed for the reporting period in each county or ZIP code area in the State.

(2) When any radon screening or long-term testing result exceeds 20 pCi/l or 0.1 working level as defined in section 16.2 of this Part, the radon testing firm shall advise the customer, if a resident of this State, in writing to contact the New York State Department of Health, Bureau of Environmental Radiation Protection, for further technical advice and assistance.

(3) When any radon screening or long-term testing result exceeds 100 pCi/l or 0.5 working level as defined in section 16.2 of this Part, the radon testing firm shall provide telephone and written notification of measured radon concentrations to the department within two working days.

(4) Pursuant to Public Health Law Section 502 and Subpart 55-2 of this Title, no environmental laboratory may perform any examination on samples collected in the State of New York for which the commissioner issues a certificate of approval for such examination unless the laboratory has been issued such certificate of approval. Approval must be obtained through the department's Environmental Laboratory Approval Program.

(5) A radon mitigation firm shall report to the department in writing, within 30 days following the end of a reporting period, a summary of the number of homes mitigated in the State during that reporting period. Reporting periods shall be from January 1st to June 30th and July 1st to December 31st of each year. The report shall include the dates for which the report is made and the number of buildings for which mitigation was performed for the reporting period in each county or ZIP code area in the State.

16.200 Material incorporated by reference.

(a) Documents. The following documents, referenced in this Part, are available for review and copying through the Records Access Officer, New York State Department of Health, Corning Tower, Empire State Plaza, Albany, NY 12237:

(1) Except as set forth in paragraph (2) of this subdivision, Title 10 of the Code of Federal Regulations, Chapter I (Nuclear Regulatory Commission) Parts 19 (as revised and implemented in full on October 16, 2020), 20 (as revised and implemented in full on March 14, 2023), 30 (as revised and implemented in full on October 16, 2020), 31 (as revised and implemented in full on July 23, 2008), 33 (as revised and implemented in full on March 19, 2013), 35 (as revised and implemented in full on November 14, 2022), 37 (as revised and implemented in full on November 30, 2021), 71 (as revised and implemented in full on November 30, 2021) and 40.13 (revised as of May 29, 2013), 40.21 (revised as of October 3, 1980) and 40.22 (revised as of November 30, 2021) are hereby incorporated by reference with the same force and effect as if fully set forth in this Part. The CFR provisions incorporated by reference herein may be obtained from the department at the address provided above, or from the following:

(i) The United States Government Publishing Office (GPO), 710 North Capitol Street, N.W., Washington, DC 20401 (866) 512-1800, or GPO online at http://www.gpo.gov/fdsys, or

(ii) The U.S. Nuclear Regulatory Commission online at http://www.nrc.gov/reading-rm/doc-collections/cfr/.

(2) The following sections from Title 10 Chapter I of the CFR are not incorporated:

(i) Part 19: 19.1, 19.2, 19.4, 19.5, 19.8, 19.18, 19.30, 19.31, 19.32, and 19.40.

(ii) Part 20: 20.1001, 20.1002, 20.1006 through 20.1009, 20.1405, 20.1406(b), 20.1905(g), 20.2203(c), 20.2401, 20.2402, part 20 appendix D.

(iii) Part 30: 30.1, 30.2, 30.5 through 30.8, 30.21(c), 30.37 through 30.39, 30.41(b)(6), 30.53, 30.55, 30.62, 30.63, 30.64.

(iv) Part 31: 31.1, 31.2, 31.4, 31.22, and 31.23.

(v) Part 33: 33.1, 33.8, 33.11(b-c), 33.14, 33.15, 33.16, 33.21, 33.23, 33.100 Schedule A.

(vi) Part 35: 35.1, 35.8, 35.4001, and 35.4002.

(vii) Part 37: 37.1, 37.3, 37.7, 37.9, 37.11(a-b), 37.13, 37.105, 37.107, and 37.109.

(viii) Part 71: 71.2, 71.6, 71.11, 71.14(b), 71.19, 71.31 through 71.45, 71.51 through 71.77, 71.99, 71.100, 71.101(c)(2), 71.101(d)-(f), 71.107 through 71.125.

(3) To reconcile differences between this Part and the incorporated sections of the CFR, the following meanings shall be substituted for certain terms in the incorporated language of the CFR:

(i) Any reference to ‘‘NRC’’ or ‘‘Commission’’ in the incorporated CFR regulations means the department, unless the context clearly indicates otherwise. Notifications and correspondence indicated in the incorporated sections of the CFR should be sent to the department, except as required by 10 CFR37.27 (relating to requirements for criminal history records checks of individuals granted unescorted access to category 1 or category 2 quantities of radioactive material), which should be sent to the NRC.

(ii) References to forms in the incorporated CFR regulations mean the appropriate forms prescribed by the department.

(iii) Any reference to ‘‘NRC or Agreement State’’ in the incorporated CFR regulations means this department, NRC, or Agreement State.

(iv) Any reference to “Type A specific license of broad scope” in the incorporated CFR regulations means “specific license of broad scope” as defined in this Part

(v) Any reference to “byproduct material” in sections 30.31 through 30.62, and 31.9 of the incorporated CFR regulations means “radioactive material” as defined in this Part.

(4) Title 21 of the Code of Federal Regulations, Food and Drugs Parts 900 (as revised and implemented in full on July 14, 2023) and 1020 (as revised and implemented in full on January 20, 2023) are hereby incorporated by reference with the same force and effect as if fully set forth in this Part. The CFR provisions incorporated by reference herein may be obtained from the department at the address provided in paragraph (1) of this subdivision, or from the following:

(i) The United States Government Publishing Office (GPO), 710 North Capitol Street, N.W., Washington, DC 20401 (866) 512-1800, or GPO online at http://www.gpo.gov or https://www.ecfr.gov/current/title-10.

(5) The National Fire Protection Association (NFPA) 70, National Electrical Code - International Electrical Code Series, 2023 Edition, as incorporated by reference herein may be obtained from the department at the address provided in paragraph (1) of this subdivision, or online at https://www.nfpa.org/product/nfpa-70-code/p0070code.

(b) All persons subject to the requirements of this Part are required to comply with the specific regulations of Title 10 of the Code of Federal Regulations (CFR) as incorporated into this Part pursuant to subdivision (a) of this section.

REGULATORY IMPACT STATEMENT

Statutory Authority:

Section 7 of Part B of Chapter 58 of the Laws of 2006 sets forth the authority for the Commissioner of Health to modify or abrogate the regulations found in Part 38 of Title 12 (Labor) of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) pertaining to the radiation control program.

The Public Health and Health Planning Council is authorized by § 225(4) of the Public Health Law (PHL) to establish, amend, and repeal provisions of the State Sanitary Code (SSC), subject to the approval of the Commissioner of Health. PHL §§ 225(5)(p) & (q) and 201(1)(r) authorize SSC regulations to protect the public from the adverse effects of ionizing radiation. Pursuant to such statutory authority and as set forth in 10 NYCRR Part 16, the Department of Health (Department), licenses or registers health care providers to use radioactive materials or ionizing radiation emitting equipment on patients.

The federal Atomic Energy Act of 1954 (the Act), codified at 42 USC §§ 2021, et. seq., authorizes the United States Nuclear Regulatory Commission (NRC) to regulate the use of radioactive materials. The Act also authorizes "Agreement States," to regulate the use of radioactive materials in lieu of the NRC, provided that the "Agreement State" promulgates regulations that are comparable to or exceed NRC's regulatory standards. New York State is an "Agreement State" within the meaning of the Act. New York's regulatory standards for the use of radioactive materials in 10 NYCRR Part 16 must therefore meet or exceed comparable NRC regulatory standards. The Act governs only the use of radioactive materials: it does not apply to x-rays or radiation therapy equipment that emit only x-rays.

Legislative Objectives:

Chapter 58 of the Laws of 2006 transferred the radiation control program from the Department of Labor (DOL) to the Department of Health, effective July 1, 2006. The law specifically sets forth that the regulations (12 NYCRR Part 38) would remain in effect until "duly modified or abrogated by the Commissioner of Health." The amendments being made by this regulation to 10 NYCRR Part 16 will incorporate and update the regulatory provisions currently found in 12 NYCRR Part 38. It is therefore appropriate to repeal 12 NYCRR Part 38 in its entirety.

The legislative intent of PHL §§ 225(5) and 201(1)(p) and (q) are to protect the public from the adverse effects of ionizing radiation. Promulgating regulations to ensure safe and effective uses of radioactive material and radiation producing equipment is consistent with this legislative objective. Section 225(5)(q) of the Public Health law also authorized the Department to recover the cost of the programs by charging adequate and reasonable fees for its regulatory activities. Such fees enable the program to maintain the staffing level required to meet the legislative mandate. By establishing the Special Revenue Operating fund in 1999 the Legislature intended the program to be funded through fees.

Needs and Benefits:

The US Nuclear Regulatory Commission (NRC) has relinquished its authority to regulate the use of radioactive materials in New York State to the State. The Atomic Energy Act of 1954 (the Act) (codified at 42 USC § 2021 et. seq.) requires New York to adopt and enforce regulatory standards for the use of radioactive materials that are comparable to or exceed federal regulatory standards that apply to the use of radioactive materials. The Department regulates approximately 1,100 facilities that use radioactive material and approximately 10,000 facilities that use x-ray

equipment. The proposed regulations incorporate by reference many of the NRC regulatory standards that govern the use of radioactive materials in medical and commercial settings. In recent years the technology and equipment used to deliver radiation therapy to cancer patients, including systems used to plan and execute radiation therapy treatment, have become significantly more complex. Recently developed radiation therapy systems more effectively deliver high-dose rate treatments to precisely defined three-dimensional tumor volumes while sparing doses to healthy tissue. Patients benefit significantly when, as is the case in most of such radiation treatments, the dose is delivered as intended.

Schedules for licensing and registration fees currently being assessed by the Bureau of Environmental Radiation Protection (BERP) are published under two separate Titles of the NYCRR. Title 12 NYCRR section 82.8 contains the fee schedule for radioactive materials licenses and radiation equipment registrations issued to industrial and commercial facilities formerly regulated by DOL under Industrial Code Rule number 38 (12 NYCRR 38). Title 10 NYCRR section 16.41 contains the corresponding schedule for radioactive sources regulated by the Department under 10 NYCRR Part 16. The current proposal combines these into one fee schedule to be published in 10 NYCRR § 16.41. Regulated parties would benefit from having a single fee schedule in one location for all radiation sources regulated by the Department.

The current fee schedules were established in 2001 (for the Department) and 2005 (for DOL). The costs of the Department's program have increased due to increased salary, equipment, and travel costs. In addition to these cost increases, increased security measures have been adopted requiring closer tracking and more frequent inspection by the Department of certain radiation sources that are of concern for national security reasons. The increased costs from these additional measures must be recovered through fees.

Finally, the proposed rule establishes an annual fee for reciprocity. Reciprocity is required under federal rules as it allows an entity licensed in another state to operate temporarily in New York based on their radioactive materials license in their home state. New York is currently one of only two states that does not charge a reciprocity fee (the other is Alabama). Other states' fees (including 48 other state programs) range from $100 to $1,400 with an average fee of about $900 per year.

The NRC audited New York State in August 2022 to review the overall status of the agreement state program. A significant finding of the last two such audits was that the New York State program is failing to meet compatibility standards. Since this is the third audit where NYS was deemed not compatible with NRC regulations, NRC placed NYS on heightened oversight. This status will be maintained until these regulations are updated and NRC completes another audit.

Costs:

Costs for the Implementation of, and Continuing Compliance with the Regulation to the Regulated Entity:

This regulation updates the fees charged to facilities that use radioactive materials or x-ray equipment. On average the fee increases are 68% over existing fees. These fees are still significantly less than the corresponding fees charges by the NRC which, depending on facility type range from $12,300 to over $53,800, or two to six times higher than the proposed fees. Geographically adjacent states (PA, NJ, and MA) have different fee structures that are more variable, but in general their fees are slightly higher than what the Department is proposing in this rule.

Fee Category	Current fee	Proposed fee	Count
Radiation Equipment Category I (i.e., Hospital)	$1,420	$2,600	75
Radiation Equipment Category II (i.e., Clinic)	$1,080	$1,800	200
Radiation Equipment Category III (i.e., Large Private practice)	$740	$1,250	200
Radiation Equipment Category IV (i.e., Small Practice)	$325	$550	600
Radiation Equipment Category V (i.e., Small Practice Low Volume)	$190	$325	1,400
Radiation Equipment Category VI (i.e., Dental/Vet/Podiatry)	$65	$100	7,400
Radioactive Materials Category I (i.e., Medical Broadscope)	$5,265	$9,600	6
Radioactive Materials Category II (i.e., Academic Broadscope)	$3,510	$6,200	9
Radioactive Materials Category III (i.e., Nuc Pharm, Brachytherapy)	$1,400	$2,400	37
Radioactive Materials Category IV (i.e., Nuclear Medicine, LINAC)	$880	$1,500	502
Radioactive Materials Category V (i.e., Clinical Labs, XRF)	$350	$600	78
Radioactive Materials Category VI (i.e., Gas Chromatograph)	$50	$120	2
Radioactive Materials Commercial 1 (i.e., Industrial Radiography)	$2,500	$3,600	52
Radioactive Materials Commercial 2 (i.e., Manufacturing)	$1,833	$3,000	23
Radioactive Materials Commercial 3 (i.e., R&D, Irradiators)	$1,333	$2,400	148
Radioactive Materials Commercial 4 (i.e., Gauges)	$1,000	$1,800	182

Radioactive Materials Commercial 5 (i.e., GC, analytic Equipment)	$500	$600	5
Radioactive Materials General (i.e., General License)	$33	$120	146
Totals (count x fee)	$2,555,458	$4,291,760	11,065

Additionally, these regulations will impose new costs on Cone-Beam CT units (CBCTs). These units, like all other CT units, will have to be accredited within 18 months of the adoption of this rule. They will also be subject to annual quality assurance testing. Accreditation costs are approximately $3,000 every three years, and the annual Quality Assurance (QA) testing will be $800 to $1,200 per year.

C**osts to State and Local Governments:**

Government agencies are exempt from the fees in these regulations, except for government operated hospitals and higher education institutions. This will include about 30 hospitals (including Nassau County Medical Center, Westchester County Medical Center, and Erie County Medical Center) and State University of New York (SUNY) colleges who will have an approximately 60% to 75% increase in fees.

The cost increase to the three county run health care facilities are listed below:

County	Current Fees	Proposed Fees	Net increase
Nassau	2300	4100	+1800
Westchester	3635	5875	+2240
Erie	1960	3300	+1340

There are approximately 25 SUNY facilities that have X-ray equipment or a radioactive materials license. The sum of all SUNY fees will increase from approximately $36,000 currently to a total of $63,000 spread over the 25 regulated facilities. These fee increases are incidental costs for programs of this size.

Costs to the Department of Health:

These regulations make numerous technical changes and updates to the radiation safety rules. These changes will require the Department to update guidance, forms, and Standard Operating Procedures. These activities are done periodically and will not incur significant extra costs for the Department.

Local Government Mandates:

These proposed regulations apply to hospitals operated by public benefit corporations including Nassau, Erie and Westchester Medical centers. The increased annual fees will apply to these facilities. Registrants and licensees, including the hospitals operated by state and local governments, are currently required to retain all quality assurance documents for review by the Department. As such, no other additional costs or mandates are associated with implementation of these regulations.

Paperwork:

Department regulations (10 NYCRR Part 16) require registrants and licensees to maintain a variety of records relating to the use of ionizing radiation for review by the Department. The

Department estimates that licensees and registrants may have a small amount of additional documentation to create, maintain, or file these records. These regulations change the content of those records (ex. different quality assurance requirements) but do not significantly increase any required documentation over the current standards.

Duplication:

There is no duplication of the proposed regulatory requirements by any federal, state, or local agency for licensees, registrants, or authorized users subject to 10 NYCRR Part 16. New York State entered into an agreement with the federal government on October 15, 1962, by which the federal government discontinued its regulatory authority over the use of radioactive materials and New York assumed such authority.

Alternatives:

Many of the regulatory changes are required to meet federal standards. The alternative to the present fee proposal is to leave the current fees unchanged. This would require a proportional reduction in the scope of the Department's regulatory program to offset the effects of inflation and increased security measures. Failure to implement these changes would jeopardize the agreement state status and could also jeopardize public health.

Federal Standards:

New York State’s agreement with the NRC requires it to promulgate regulations consistent with the NRC’s rules, either by incorporation by reference or by developing state rules that are

nearly identical. These regulations incorporate by reference many federal standards developed by the U.S. NRC.

Compliance Schedule:

Except for the Cone-Beam CT accreditation requirements, there is no compliance schedule imposed by these regulations, which shall be effective upon publication of the Notice of Adoption in the State Register. The Cone-Beam accreditation rule requires that facilities apply to an accrediting body within 90 days of the regulations going into effect and that they complete the process with 18 months.

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REGULATORY FLEXIBILITY ANALYSIS FOR SMALL BUSINESSES AND LOCAL GOVERNMENTS

Effect of Rule:

These regulations will apply to two State University hospitals, one county hospital and three hospitals operating as a public benefit corporation. There are approximately 200 other facilities operated by local government agencies, mostly jails and community clinics that will be affected by these regulations but that are exempt from the fees set forth in regulation.

Of the roughly 11,000 licenses and registrations currently issued under 10 NYCRR Part 16, it is estimated that approximately two-thirds constitute small business, or roughly 6,400 throughout the state. This figure does not include any hospitals, educational facilities or government operated entities.

Compliance Requirements:

This rule change will affect small businesses and local government facilities that use ionizing radiation, including healthcare facilities, colleges, and commercial services. This is a repeal and replace of the entire existing regulation. Significant changes and updates include the following:

- Radioactive material licensing is updated to incorporate federal standards by reference and to include NYS Department of Labor regulations that were previously turned over to the Department of Health.
- Radioactive materials license and x-ray equipment registration fees are increased an average of 68%, fees for reciprocity are added, and late fees are removed. Commercial

license fees were converted to annual fees from triannual which will reduce the initial burden on applicants.

- The proposed rules include a requirement for accreditation and quality assurance (QA) testing on Cone-Beam CT units used on people, most of which are used in dentistry.
- QA requirements for diagnostic imaging have been updated to reflect the current technologies, in particular the replacement of film with digital imaging modalities. The regulations have been developed based on American College of Radiology (ACR) and American Association of Physicists in Medicine (AAPM) guidance documents that the Department of Health (Department) has used as a standard for facilities for the past decade.
- Definitions have been added for compatibility and clarity purposes. Other sections of the regulations have had out of date language or unclear phrasing reworded based on discussions with regulated entities and NRC staff.
- Updates require recording of high patient doses from fluoroscopy and notification of referring physician and instructions to patient.

Regulated facilities will need to become familiar with the updated rules and may need to modify their radiation safety program and quality assurance policies and procedures accordingly. Those facilities with Cone Beam CT units that are not accredited will need to do so within 18 months of the effective date of the rule.

Professional Services:

Many large facilities have in-house staff that perform quality assurance testing and operate radiation emitting technology. Smaller offices and private practices employ consultants

to provide QA services and assistance in the development of policies and procedures relating to radiation safety. The QA related changes will not require significant time and the Department will provide updated guidance and references to current professional and national standards as applicable.

The Department does not expect that it will be necessary for licensees to use additional professional services for completion of applications for accreditation or to implement the quality assurance requirements other than the operators of Cone-Beam equipment who will have to develop QA plans and become accredited.

Compliance Costs:

The Cone-Beam CT accreditation will cost the registrant about $3,000 dollars for a three-year period and the Cone Beam CT QA testing will cost approximately $800 to 1,200 per year. In addition, radioactive materials license and x-ray equipment registration fees are increased an average of 68%, fees for reciprocity are added, and late fees are removed. This fee increase is needed to cover program cost as the fees have not increased since 2001. Program used the US Bureau of Labor Statistics Consumer Price Index Calculator to determine average increases from 2002 to 2023. This program is a partial cost recovery program and staff salaries, and other program operation expenses are covered through the fees. Commercial license fees were converted to annual fees from triannual which will reduce the initial burden on applicants.

Economic and Technology Feasibility

There are no capital costs or new technology required to comply with the proposed rule. Most of the facilities affected will be dental, veterinary, and podiatric facilities and they will

have a $35 increase in registration fee which is still a low-cost relative to many other states annual fees. Large hospitals, universities and other large corporate entities will see larger amounts proportional to the cost to inspect and regulate these facilities. Therefore, the proposal should be economically and technologically feasible for regulated entities.

Minimizing Adverse Impact:

Most facilities will not need a substantial amount of time to comply with these updates. Mitigating the fee increase for commercial licensees will be the fact that they only pay a 1-year fee instead of a 3-year fee. Late fees for all regulated facilities are dropped. Facilities will have 90 days to apply for accreditation and 18 months to become accredited. This will allow a facility adequate time to select the accreditation body of their choice, complete an application, and budget funds for the accreditation fee. Most users of Cone Beam CT equipment already charge patients a fee for the images made by this equipment and will be able to recoup the increased cost associated with the increased QA requirements.

Small Business and Local Government Participation:

The diagnostic quality assurance testing changes were reviewed by NYS medical and health physics societies for technical content during the past several years. The therapy regulation updates have been developed with input from radiation oncology facilities, based on current professional standards and practices. The Department of Health will provide notice of rulemaking to organizations that represent the interested parties including the dental, veterinary, podiatry, medical (MSSNY) and healthcare (HANYS) and other interested parties. In addition, the proposed regulations will be published in the State Register to provide Small Business and

Local Government a review and comment period, which is an opportunity for comment and to participate in the regulatory process. Some sections of the regulations have had out of date language or unclear phrasing reworded based on discussions with regulated entities and NRC staff and many of their suggestions have been included.

For Rules That Either Establish or Modify a Violation or Penalties Associated with a Violation

Violations that had previously been cited by 12 NCYRR Part 38 may now be cited under 10 NYCRR Part 16 as the NYS Department of Labor regulations are transcribed into Title 10 NYCRR Part 16. There are no changes to any violations or penalties, however late fees have been removed from the fee schedule and will no longer be charged.

Rural Area Flexibility Analysis

Types and Estimated Numbers of Rural Areas:

This rule applies uniformly throughout the state, including rural areas. Rural areas are defined as counties with a population less than 200,000 and counties with a population of 200,000 or greater that have towns with population densities of 150 persons or fewer per square mile. The following 44 counties have a population of less than 200,000 based upon the United States Census estimated county populations for 2020 (https://www.census.gov/quickfacts/). Approximately 17% of small health care facilities are located in rural areas.

Allegany County	Greene County	Schoharie County
Broome County	Hamilton County	Schuyler County
Cattaraugus County	Herkimer County	Seneca County
Cayuga County	Jefferson County	St. Lawrence County
Chautauqua County	Lewis County	Steuben County
Chemung County	Livingston County	Sullivan County
Chenango County	Madison County	Tioga County
Clinton County	Montgomery County	Tompkins County
Columbia County	Ontario County	Ulster County
Cortland County	Orleans County	Warren County
Delaware County	Oswego County	Washington County
Essex County	Otsego County	Wayne County
Franklin County	Putnam County	Wyoming County
Fulton County	Rensselaer County	Yates County
Genesee County	Schenectady County	

The following counties have a population of 200,000 or greater and towns with population densities of 150 persons or fewer per square mile. Data is based upon the United States Census estimated county populations for 2020.

Albany County	Niagara County	Orange County
Dutchess County	Oneida County	Saratoga County
Erie County	Onondaga County	Suffolk County
Monroe County		

There are just over 11,000 regulated facilities that possess and use x-ray equipment or radioactive materials. Approximately 20% are in the 44 counties defined as rural based on population and an additional 46% are in those counties defined as rural by population density. As of January 1, 2022, there are just under 7,200 facilities in rural areas. Approximately 50% of the regulated facilities are dental, 10% are veterinarians, 9% are physician's office, 8% are non-human use (academic, commercial, or industrial), 7% are hospitals, clinics or imaging centers, and the rest are a mix of podiatrists, chiropractors, and other specialty providers.

Reporting, Recordkeeping and Other Compliance Requirements and Professional Services:

There are no new reporting requirements to the State contained in the proposed regulations for most regulated facilities. However, certain medical users of fluoroscopy will have to report to the patient and maintain records of high patient exposure. This will affect hospitals and ambulatory surgery sites that perform interventional fluoroscopic procedures. No additional professional service costs are anticipated. Facilities are currently required to maintain records of quality assurance test results and accreditation documents for review by the Department's inspectors. The content of these tests is specified in sections 16.23 and 16.24 of these regulations. Compliance with the recordkeeping requirements will require only a minor incremental amount of time and effort for affected facilities.

Cost:

Fees are increased an average of 68% for all license and registration categories. Specifically, operators of Cone-Beam CT units will also have to get accredited which will cost them $3,000 for a three-year period. These units will now be subject to quality assurance testing

requirements that will cost an additional $800-1,200 per year. This will affect approximately 10% of the dental practices in the state, principally oral surgeons, and other specialty practices.

Schedules for licensing and registration fees currently being assessed by the Bureau of Environmental Radiation Protection (BERP) are published under two separate Titles of the NYCRR. Title 12 NYCRR section 82.8 contains the fee schedule for radioactive materials licenses and radiation equipment registrations issued to industrial and commercial facilities formerly regulated by DOL under Industrial Code Rule number 38 (12 NYCRR 38). Title 10 NYCRR section 16.41 contains the corresponding schedule for radioactive sources regulated by the Department under 10 NYCRR Part 16. The current proposal combines these into one fee schedule to be published in 10 NYCRR § 16.41. Regulated parties would benefit from having a single fee schedule in one location for all radiation sources regulated by the Department.

The current fee schedules were established in 2001 (for the Department) and 2005 (for DOL). The costs of the Department's program have increased due to increased salary, equipment, and travel costs. In addition to these cost increases, increased security measures have been adopted requiring closer tracking and more frequent inspection by the Department of certain radiation sources that are of concern for national security reasons. The increased costs from these additional measures must be recovered through fees.

Finally, the proposed rule establishes an annual fee for reciprocity. Reciprocity is required under federal rules as it allows an entity licensed in another state to operate temporarily in New York based on their radioactive materials license in their home state. New York is currently one of only two states that does not charge a reciprocity fee (the other is Alabama). Other states' fees (including 48 other state programs) range from $100 to $1,400 with an average fee of about $900 per year.

Minimizing Adverse Impact:

Most facilities will not need to take a substantial amount of time to comply with these updates. Mitigating the fee increase for commercial licensees is the fact that they will now only pay a 1-year fee instead of a 3-year fee. In addition, late fees for all regulated facilities are dropped. Cone Beam CT facilities will have 90 days to apply for accreditation and 18 months to become accredited. This will allow a facility adequate time to select the accreditation body of their choice, complete an application and budget funds for the accreditation fee. Most users of Cone Beam CT equipment already charge patients a fee for the images made by this equipment and therefore should be able to recoup the increased costs associated with the new regulatory requirements.

Rural Area Participation:

Regulated facilities are invited to comment during the Codes and Regulations Committee meeting of the Public Health and Health Planning Council and as part of the formal public comment process. The diagnostic quality assurance testing changes were reviewed by NYS medical physics and health physics societies for technical content during the past several years. The therapy regulation updates have been developed with input from radiation oncology facilities, based on current professional standards and practices. The majority of the changes are based on existing guidance, published federal regulations, merge DOL regulations into DOH regulations, or were clarifications and modernizations of language. DOH has communicated the nature of these updates with interested professional organizations over the past few years.

JOB IMPACT STATEMENT

Nature of Impact:

It is anticipated that no jobs will be adversely affected by this rule. Medical providers of diagnostic imaging and radiation therapy will need to become familiar with the new quality assurance requirements.

Categories and Numbers Affected:

There are approximately 10,000 facilities registered to use radiation producing equipment (x-ray machines), and more than 1,100 facilities authorized by license to use radioactive material. Approximately 5,500 of the x-ray facilities are dental practices.

Regions of Adverse Impact:

No areas will be adversely affected.

Minimizing Adverse Impact:

There are no alternatives to the proposed regulations. Many of these changes are required for the State to maintain compatibility with federal regulations. Non-compatibility updates reflect technological change, especially the change from film-based imaging to digital x-ray systems. The Department will revise guidance to assist all licensees, including those in rural areas, with implementation of the proposed regulations.

Self-Employment Opportunities:

The rule may have impact on some dental practices. It imposes an additional cost and a quality assurance requirement on facilities that have Cone-Beam CT units (CBCT). The Department estimates that there are between 500 and 600 practices that have CBCT units.