TABLE OF CONTENTS

PART 16 - IONIZING RADIATION

(Statutory authority: Public Health Law, Section 225)

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.[1] Section 16.130, "Radon testing and reporting", contains provisions applicable to firms performing radon measurements in NY State. Section 16.200, "Material incorporated by reference", provides a list of Federal rules and regulations also related to the regulation of ionizing radiation.

[1] 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.

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.[2]

(b) Inapplicability.

(1) This Part does not apply to any person with respect to any radiation source to the extent that such radiation source is subject to regulation as provided for by law by the State Department of Labor. This exclusion does not apply to persons with respect to radiation sources used at industrial or commercial establishments for the application of radiation to human beings.

(2) 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.

(3) 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, 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.

(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, New York 12237, or by telephone (518) 402-7550. Registrants and licensees that are authorized pursuant to Article 28 of the Public Health Law to operate a hospital 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 these regulations, these terms have the definitions set forth below:

(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 Appendix 16-B, Table 1 of this Part.

[2] The types of installations to which this Part is generally applicable are described in the definition of "radiation installation" (Section 16.2(a)(98)).

(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 material" means any material made radioactive by a particle accelerator.

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

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

(6) "Agreement State" means any State with which the United State 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 (73 Stat. 689).

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

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

(i) In excess of the derived air concentrations (DACs) specified in Appendix 16-C, Table 1, Column 3, infra, 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.

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

(10) "Annual limit on intake" (ALI) means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent of 0.05 Sv (5 rem) or a committed dose equivalent of 0.5 Sv (50 rem) to any individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Appendix 16-C, Table 1, Columns 1 and 2, infra.

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

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

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

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

(15) Byproduct material shall include:

(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, ore bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition;

(iii) any discrete source of radium-226 that is produced, extracted, or converted after 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.

(16) "Calendar quarter" means not less than 12 consecutive weeks nor more than 14 consecutive weeks. The first calendar quarter of each year shall begin in January and subsequent calendar quarters shall be so arranged such that no day is included in more than one calendar quarter and no day in any one year is omitted from inclusion within a calendar quarter. No licensee or registrant shall change the method used to determine calendar quarters for purposes of these regulations except at the beginning of a calendar year.

(17) "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.

(18) "Certified radiation equipment safety officer" means an individual who holds an unexpired certificate as a radiation equipment safety officer issued by the department.

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

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

(b) good moral character; and

(c) 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

(d) successful completion, after meeting the requirements of clauses (a), (b), and (c) immediately above, of an examination prescribed by the department; and

(e) 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.

(ii) The department may accept in lieu of the requirements of clauses (c) and (d) of subparagraph (i) of this paragraph 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.

(iii) A person meeting all requirements of subparagraph (i) of this paragraph except the experience or experience substitute requirement of clause (e) of said subparagraph may be certified as a radiation equipment safety officer with the restriction that he/she perform surveys only under the supervision of a certified radiation equipment safety officer who meets the requirements of said clause (e).

(iv) A certification as a radiation equipment safety officer shall be issued by the department for a period not to exceed two years. 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.

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

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

(21) "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.

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

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

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

(25) "Committed effective dose equivalent" ($H_{E,50}$) 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 ($H_{E,50} = 3\ W_T\ H_{T,50}$).

(26) "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.

(27) "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. "Controlled area" as used in this Part is synonymous to "restricted area".

(28) "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} transformations per second (tps).

(29) "Declared pregnant woman" means a woman who has voluntarily informed her employer, in writing, of her pregnancy.

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

(31) "Department" means the New York State Department of Health and shall include its duly authorized representatives.

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

(33) "Derived air concentration" (DAC) means the concentration of a given radionuclide in air which, if breathed by the reference man for a working year of 2,000 hours under conditions of light work, results in an intake of one ALI. For purposes of these regulations, the condition of light work is an inhalation rate of 1.2 cubic meters of air per hour for 2,000 hours in a year. DAC values are given in Appendix 16-C, Table 1, Column 3, infra.

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

(35) "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 100 milliroentgens in one hour when the tube is operated at its maximum continuous rated current for the maximum rated tube potential.

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

(37) "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 these regulations, "radiation dose" is an equivalent term.

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

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

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

(41) "Effective dose equivalent (H_E)" means the sum of the products of the dose equivalent to each organ or tissue (H_T) and the weighting factor (W_T) applicable to each of the body organs or tissues that are irradiated ($H_E = 3\ W_T\ H_T$).

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

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

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

(45) "Exposure" means either:

(i) being exposed to ionizing radiation or to radioactive material; 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 2.58×10^{-4} coulomb per kilogram of air.

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

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

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

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

(50) "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.

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

(52) "Half value layer" (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.

(53) "Health officer having jurisdiction" means the Commissioner or his/her designee, or the chief executive officer of the appropriate county or part-county health department or the New York City department of health, or the director of a State, regional, area or district office of public health.

(54) "High radiation area" means any area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour at 30 centimeters from any source of radiation or from any surface that the radiation penetrates. For purposes of these regulations, rooms or areas in which diagnostic X-ray systems are used for healing arts purposes are not considered high radiation areas.

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

(56) "Image receptor" shall mean any device, such as fluoroscopic input phosphor or radiographic film which transforms incident X-ray photons either into a visible image or into another form which can be made into a visible image by further transformation.

(57) "Individual" shall mean any human being.

(58) "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.

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

(60) "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.

(61) "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.

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

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

(64) "Kilovolt" (kV) means a unit of electrical potential equal to 1000 volts. "Kilovolt peak" (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.

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

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

(67) "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. A "general license" means a license issued pursuant to the terms and conditions of Appendix 16-A, Table 6, infra. General licenses are effective without the filing of an application with or the issuance of a licensing document by the department. A "specific license" shall mean a license evidenced by a licensing document issued by the department to a licensee. A specific license also means a similar license issued by the State Department of Labor, the New York City Department of Health, the United States Nuclear Regulatory Commission or any agreement State. Unless otherwise specified, the type of license referred to in this Part will be a specific license.

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

(69) "Licensee" means any person who is licensed by the Department in accordance with these regulations or one who possesses any radioactive material which is subject to the licensure requirements of this Part.

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

(71) "Member of the public" means any individual, except an individual who is performing assigned duties for the licensee or registrant involving exposure to sources of radiation.

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

(73) "Monitoring" means the measurement of radiation, radioactive material concentrations, surface area activities or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses. For purposes of these regulations, radiation monitoring and radiation protection monitoring are equivalent terms.

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

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

(76) "Nuclear Regulatory Commission" (NRC) means the U.S. Nuclear Regulatory Commission or its duly authorized representatives.

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

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

(79) "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.

(80) "Package" means the packaging, together with its radioactive contents as presented for transport.

(81) "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.

(82) "Person" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this State, any other State or political subdivision or agency thereof, and any legal successor, representative, agent, or agency of the foregoing, but shall not include federal government agencies.
(83) "Personnel monitoring equipment" (See Individual monitoring devices).

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

(85) "Professional practitioner" means any person licensed or otherwise authorized under the State Education Law to practice a professional practice.

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

(87) "Protective barrier" means a barrier of radiation absorbing material(s) used to attenuate the useful beam and/or stray radiation to the degree required to assure compliance with sections 16.6 and 16.7.

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

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

(90) Reserved.

(91) "Qualified expert" means an individual having the knowledge and training to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs, for example, individuals certified in the appropriate field by the American Board of Radiology or the American Board of Health Physics, or those having equivalent training and experience. With reference to the calibration of radiation therapy equipment, an individual having, in addition to the above qualifications, training and experience in the clinical applications of radiation physics to radiation therapy, for example, individuals certified in Therapeutic Radiological Physics or X-Ray and Radium Physics by the American Board of Radiology, or those having equivalent training and experience.

(92) "Quality factor" (Q) means the modifying factor, that is used to derive dose equivalent from absorbed dose.

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

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

(93) "Quarter" (See Calendar Quarter).

Table I
Quality Factors and Absorbed Dose Equivalents

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

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

(94) "Rad" means the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 erg/gram or 0.01 joule/kilogram (0.01 gray). One millirad equals 0.001 rad.

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

(96) "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.

(97) "Radiation equipment" means any equipment or device which can emit radiation by virtue of the application thereto of high voltage.

(98) "Radiation installation" means 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, osteopathic, podiatric, or veterinarian institution, clinic or office; 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 specifically stated above, any place, facility or mobile unit where radiation is applied intentionally to a human. The limits of the radiation installation area shall be as designated by the operator.

Table II
Mean Quality Factors, Q, and Fluence per Unit Dose Equivalent for Monoenergetic Neutrons

	Neutron Energy (MeV)	Quality Factor [a] Q	Fluence per Unit Dose Equivalent [b] (neutrons/cm^2/rem)	Fluence per Unit Dose Equivalent [b] (neutrons/cm^2/Sv)
(thermal)	2.5×10^{-8}	2	980×10^6	980×10^8
	1×10^{-7}	2	980×10^6	980×10^8
	1×10^{-6}	2	810×10^6	810×10^8
	1×10^{-5}	2	810×10^6	810×10^8
	1×10^{-4}	2	840×10^6	840×10^8
	1×10^{-3}	2	980×10^6	980×10^8
	1×10^{-2}	2.5	1010×10^6	1010×10^8
	1×10^{-1}	7.5	170×10^6	170×10^8
	5×10^{-1}	11	39×10^6	39×10^8
	1	11	27×10^6	27×18^8
	2.5	9	29×10^6	29×10^8
	5	8	23×10^6	23×10^8
	7	7	24×10^6	24×10^8
	10	6.5	24×10^6	24×10^8
	14	7.5	17×10^6	17×10^8
	20	8	16×10^6	16×10^8
	40	7	14×10^6	14×10^8
	60	5.5	16×10^6	16×10^8
	1×10^2	4	20×10^6	20×10^8
	2×10^2	3.5	19×10^6	19×10^8
	3×10^2	3.5	16×10^6	16×10^8
	4×10^2	3.5	14×10^6	14×10^8

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

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

(99) "Radiation safety officer" shall mean 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.

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

(a) a professional practitioner as defined in section 16.2(a)(85) of this Part, practicing within his/her professional practice as defined in section 16.2(a)(84) of this Part: 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 radiation sources in the installation, or, an individual with equivalent training and experience.

(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: 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 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.

(100) "Radiation source" means any radioactive material or any radiation equipment.

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

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

(103) "Radiobioassay" (See Bioassay).

(104) "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.

(105) "Registrant" means any person who is registered with the Department or is legally obligated to register with the Department pursuant to these regulations.

(106) "Registration" means registration with the Department in accordance with these regulations.

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

(108) "Research and development" means:

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

(ii) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and 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.

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

(110) "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, but separate rooms in a residential building may be set apart as a restricted area.

(111) "Roentgen" means the special unit of exposure. One roentgen (R) equals 2.58×10^{-4} coulombs/kilogram of air (See Exposure).

(112) "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.

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

(114) "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.

(115) "Shallow dose equivalent" (H_s), which applies to the external exposure of the skin or an extremity, means the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm^2) averaged over an area of 1 square centimeter.

(116) "Shutter" means:

(i) in beam therapy equipment, an adjustable device, generally of lead, fixed to the X- or gamma-ray source housing to intercept or collimate the useful beam; or

(ii) in diagnostic equipment, an adjustable device used to collimate the useful beam.

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

(118) "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).

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

(120) "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.

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

(122) "Source-skin distance (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.

(123) "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 (see section 16.200 of this Part).

(124) "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.

(125) "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 or 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:

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

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

(127) "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 these regulations, probabilistic effect is an equivalent term.

(128) "Stray radiation" means the sum of leakage and scattered radiation.

(129) "Supervision" as used in radioactive materials licenses means the training of persons in the use of radioactive materials in other than medical procedures. Such training must include at least 30 hours of instruction in the principles and practices of radiation protection, radioactivity measurement standardization and monitoring techniques and instruments, mathematics and calculations basic to the use and measurement of radioactivity, and biological effects of radiation.

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

(131) "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 a distance of 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 a distance of 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.

(132) "These regulations" mean all parts of Part 16 of the State Sanitary Code.

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

(134) Reserved

(135) "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.)

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

(137) "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) interpretation of results of diagnostic procedures; and

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

(138) "Useful beam" means the radiation which passes through the source or tube-housing port and the aperture of the collimating device when the exposure switch or timer is activated.

(139) "Very high radiation area" means an area, accessible to individuals, in which radiation levels could result in an individual receiving an absorbed dose in excess of 5 Gy (500 rad) in 1 hour at 1 meter from a source of radiation or from any surface that the radiation penetrates.[3]

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

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

[3] At very high doses received at high dose rates, units of absorbed dose, gray and rad, are appropriate, rather than units of dose equivalent, sievert and rem.

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

Organ Dose Weighting Factors

Organ or Tissue	W_T
Gonads	0.25
Breast	0.15
Red Bone Marrow	0.12
Lung	0.12
Thyroid	0.03
Bone Surfaces	0.03
Remainder	0.30 [a]
Whole Body	1.00 [b]

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

[b] For purposes 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.

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

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

(145) "Working level" (WL) means any combination of short-lived radon daughters in 1 liter of air that will result in the ultimate emission of 1.3×10^5 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.

(146) "Working level month" (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.

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

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 any of the radioactive materials, radiation equipment or items containing radioactive materials listed in Appendix 16-A, Table 1, infra.

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(a)(99) 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. For licensed radioactive materials installations either the radiation safety officer, or an authorized user designated to act in his/her absence, shall be present on the premises at least 50% of the time that radioactive material is being handled or equipment containing radiation sources is being operated;

(d) provides for a radiation safety committee to administer the radiation protection program in hospitals and institutions of higher education. 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, 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 (d) of this section;

(e) provides a quality assurance program for diagnostic and therapeutic uses of radiation producing equipment and radioactive materials pursuant to section 16.23 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 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; and

(h) ensures that acceptance testing of all medical and chiropractic diagnostic equipment, and treatment and planning equipment for radiation therapy, is performed before first use of such equipment on humans by an individual competent to perform such testing.

16.6 Occupational dose limits.

(a) Occupational dose limits for adults.

(1) Except for planned special exposures pursuant to subdivision 16.6(f), 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) The 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, and to the extremities which are:

(a) An eye dose equivalent of 0.15 Sv (15 rem), and

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

(2) Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures must be subtracted from the limits for planned special exposures that the individual may receive during the current year and during the individual's lifetime. (See paragraph (6) of subdivision (f) of this section).

(3) The assigned deep dose equivalent and shallow dose equivalent shall be for the portion of the body receiving the highest exposure determined as follows:

(i) The deep dose equivalent, eye dose equivalent and shallow dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable.

(ii) When a protective apron is worn pursuant to paragraph (3) of section 16.58(b) by physicians during x-ray fluoroscopic procedures and monitoring is conducted as specified in paragraph (1) of section 16.11(b), 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.

(4) Derived air concentration (DAC) and annual limit on intake (ALI) values are presented in Appendix 16-C, Table 1, infra, and may be used to determine the individual's dose and to demonstrate compliance with the occupational dose limits.

(5) 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 16-C.)

(6) 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. (See section 16.6(e).)

(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, 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 subdivision 16.11(a) or only pursuant to subdivision 16.11(d), 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, eye dose equivalent, and shallow does equivalent from external exposure to the radioactive cloud (See Appendix 16-C, Footnotes 1 and 2).

(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, 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, 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 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 section 16.6(d), 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). 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 Appendix 16-C, 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 section 16.6(a) and in complying with the monitoring requirements in section 16.11(d), 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 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 Appendix 16-C, Table 1, infra. 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 section 16.6(a)(1)(i)(b) is met.

(e) Determination of prior occupational dose.

(1) For each individual who may enter the licensee's or registrant's restricted area and is likely to receive, in a year, an occupational dose requiring monitoring pursuant to section 16.11, the licensee or registrant shall:

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

(ii) Request in writing the records of lifetime cumulative occupational radiation dose.

(2) Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant shall determine:

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

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

(3) In complying with the requirements of paragraph (1) of this subdivision, a licensee or registrant may:

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

(ii) Accept, as the record of lifetime cumulative radiation dose, an up-to-date Department Form "Cumulative Occupational Radiation Exposure History", or equivalent, signed by the individual and countersigned by an appropriate official of the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee or registrant; and

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

(4) The licensee or registrant shall record the exposure history, as required by paragraph (1) of this subdivision, on Department Form "Cumulative Occupational Radiation Exposure History", or other clear and legible record, of all the information required on that form.

(i) The form or record shall show each period in which the individual received occupational exposure to radiation or radioactive material and shall be signed by the individual who received the exposure. For each period for which the licensee or registrant obtains reports, the licensee or registrant shall use the dose shown in the report in preparing Department Form "Cumulative Occupational Radiation Exposure History". For any period in which the licensee or registrant does not obtain a report, the licensee or registrant shall place a notation on Department Form "Cumulative Occupational Radiation Exposure History" indicating the periods of time for which data are not available.

(ii) Licensees or registrants are not required to reevaluate the separate external dose equivalents and internal committed dose equivalents or intakes of radionuclides assessed under the regulations in this Part in effect before the effective date of these regulations. Further occupational exposure histories obtained and recorded on Department Form "Cumulative Occupational Radiation Exposure History" before the effective date of these regulations, would not have included effective dose equivalent, but may be used in the absence of specific information on the intake of radionuclides by the individual.

(5) If the licensee or registrant is unable to obtain complete records of an individual's current and previously accumulated occupational dose, the licensee or registrant:

(i) When establishing administrative controls under paragraph (6) of section 16.6(a) for the current year, shall assume that the allowable dose limit for the individual is reduced by 12.5 mSv (1.25 rem) for each quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure; and

(ii) Shall not authorize the individual to receive any planned special exposures.

(6) The licensee or registrant shall retain the records on Department Form "Cumulative Occupational Radiation Exposure History" or equivalent until the Department authorizes their disposition. The licensee or registrant shall retain records used in preparing Department Form "Cumulative Occupational Radiation Exposure History" for 3 years after the record is made.

(f) Planned special exposures. A licensee or registrant may authorize an adult worker to receive doses in addition to and accounted for separately from the doses received under the limits specified in section 16.6(a) provided that each of the following conditions is satisfied:

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

(2) The licensee or registrant, and employer if the employer is not the licensee or registrant, specifically authorizes the planned special exposure, in writing, before the exposure occurs.

(3) Before a planned special exposure, the licensee or registrant ensures that each worker involved is:

(i) Informed of the purpose of the planned operation; and

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

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

(4) Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant ascertains prior doses as required by paragraph (2) of section 16.6(e).

(5) Subject to paragraph (2) of section 16.6(a), the licensee or registrant shall not authorize a planned special exposure that would cause an individual to receive a dose from all planned special exposures and all doses in excess of the limits to exceed:

(i) The numerical values of any of the dose limits in paragraph (1) of section 16.6(a) in any year; and

(ii) Five times the annual dose limits in paragraph (1) of section 16.6(a) during the individual's lifetime.

(6) The licensee or registrant maintains records of the conduct of a planned special exposure in accordance with section 16.14(e) and submits a written report in accordance with section 16.15(d).

(7) The licensee or registrant records the best estimate of the dose resulting from the planned special exposure in the individual's record and informs the individual, in writing, of the dose within 30 days from the date of the planned special exposure. The dose from planned special exposures shall not be considered in controlling future occupational dose of the individual pursuant to paragraph (1) of section 16.6(a) but shall be included in evaluations required by paragraphs (4) and (5) of this subdivision.

(g) 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 section 16.6(a).

(h) Dose to an embryo/fetus.

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

(2) The licensee or registrant shall review past exposure history and adjust working conditions so as to avoid a monthly total effective dose equivalent of more than 50 mrem to the embryo/fetus of a declared pregnant woman.

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

(i) The deep dose equivalent to the declared pregnant woman during the entire pregnancy period; and

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

(4) If by the time the woman declares pregnancy to the licensee or registrant, the dose to the embryo/fetus exceeded 4.5 mSv (0.45 rem), the licensee or registrant shall be deemed to be in compliance with paragraph (1) of this subdivision if the additional dose to the embryo/fetus does not exceed 0.50 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) Except for doses received from patients released under the provisions of section 16.123 of this Part, each licensee or registrant shall conduct operations so that:

(i) The dose in any unrestricted area from external sources 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 or registered operation, exclusive of the dose contribution from the licensee's or registrant's disposal of radioactive material into sanitary sewerage in accordance with section 16.8, does not exceed 1 mSv (0.1 rem) in a year, except where structural modifications to the building or the equipment is required of existing facilities where radiation equipment were installed prior to January 1, 1994 and the use of the radiation source does not change after January 1, 1994 and which result in a total effective dose equivalent to a member of the public which does not exceed 5 mSv (0.5 rem) in a year.

(2) 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, surveys of radiation levels in unrestricted areas and radioactive materials in effluents released to unrestricted areas, which shall be used to ascertain compliance with the dose limits for individual members of the public in section 16.7(a).

(2) A licensee or registrant shall maintain records of measurements and calculations used to demonstrate compliance with the annual dose limit in section 16.7(a).

(3) The licensee or registrant may petition the department to adjust the effluent concentration values in Appendix 16-C, Table 2, infra, for members of the public, to take into account the actual physical and chemical characteristics of the effluents, such as, aerosol size distribution, solubility, density, radioactive decay equilibrium, and chemical form.

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 shall limit any human use of radiation in diagnostic or therapeutic procedures pursuant to section 16.19 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 as to require such patient to be confined for radiation protection purposes pursuant to section 16.123 of this Part shall require that such 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 doctor who pronounces such patient as dead to notify immediately the physician in charge of the case or his/her 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 of the hospital or, if he/she is 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 department shall be notified in person, or by telephone, mailgram or facsimile within 24 hours of the death and a copy of the radioactivity report shall be sent to the department within 15 days of the death.

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 him/her to comply with other sections in this Part or as the department may direct in order to evaluate the extent of the radiation hazard that may be present.[4] 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.

(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. Except as otherwise provided in subparagraph (ii) of this paragraph, inspections shall be made at a frequency as specified in subparagraph (i) of this paragraph, with the first inspection of an installation to be made at the time of the beginning of operation and subsequent inspections not to exceed the maximum interval specified for such installation 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

[4] The specific survey requirements set forth in this section shall not be construed as relieving any person from any survey requirements specified in any registration or license.

shall be made by the department, the New York City Department of Health 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. He/she 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) Hospital, clinic, mammography and radiologist installations shall be inspected at least once every year; dental, podiatric and veterinary installations at least once every three years; and all other installations at least once every two years. Follow-up inspections shall be made at intervals of 60 days or less for the correction of any violation found during an inspection and remaining uncorrected at the conclusion thereof.

(ii) The department may establish a schedule of required inspections of any installation different from the schedule specified in this paragraph.

(iii) The 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 per 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 and shall be brought to levels not to exceed the limits specified in Appendix 16-A, Table 7, infra.

(4) Each sealed source, 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, except that each source designed for the purpose of emitting alpha particles shall be tested at intervals not to exceed three months. 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 and/or gamma emitting material or 10 microcuries or less of alpha emitting material. 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. 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. 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:

(i) the escape of radon at the rate of 0.001 microcuries or more per 24 hours for sealed radium sources; or

(ii) 0.005 microcurie or more of removable radioactivity from all other sealed sources. 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.

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

(b) Each person who possesses any radioactive material shall, no less than 30 days prior to decontrolling a controlled area or vacating, or relinquishing possession or control of premises wherein radioactive material is or has been stored or used shall have the premises surveyed and shall notify the department in writing of his intent to decontrol a controlled area or to vacate and the results of the survey. When deemed necessary by the department, such person shall decontaminate the premises to such radiation levels as the department may specify. Such person shall provide the health officer having jurisdiction, the operator of the installation housed on the premises and the landlord or subsequent tenant with a copy of a report of the results of the survey made pursuant to this subdivision.

(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.

16.11 Personnel monitoring.

(a) External radiation sources. 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); and

(2) Minors and declared pregnant women likely to receive, in one year from sources external to the body, a dose in excess of 10 percent of any of the applicable limits in sections 16.6(g) or 16.6(h); and

(3) Individuals entering a high or very high radiation area.

(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 paragraph (1) of section 16.6(h), shall be located at the waist under any protective apron worn by the woman.

(3) An individual monitoring device used for monitoring the eye 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 paragraph (1) of subdivision (d) of section 16.6 of this Part which will enable him/her 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 in Appendix 16-C, Table 1, Columns 1 and 2, infra; and

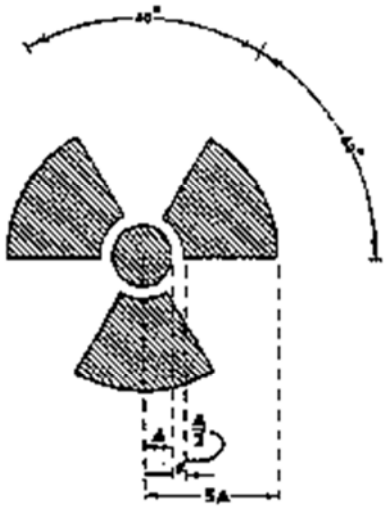
(2) Minors and declared pregnant women likely to receive, in one year, a committed effective dose equivalent in excess of 0.50 mSv (0.05 rem).

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, and

(2) The background is to be yellow.



(3) Exception to color requirements for standard radiation symbol. Notwithstanding the requirements of section 16.12(a), licensees or registrants are authorized to label sources, source holders, or device components containing sources of radiation that are subjected to high temperatures, with conspicuously etched or stamped radiation caution symbols and without a color requirement.

(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 Appendix 16-A, Table 9 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 8 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 Part 16; 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 are not required to be confined for radiation protection purposes pursuant to 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 of 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 machines.

(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 each radiation machine 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 Appendix 16-A, Table 9, infra; or

(ii) Containers holding licensed material in concentrations less than those specified in Appendix 16-C, Table 3, infra.

(iii) For 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 U. S. Department of Transportation;[5]

(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;

[5] Labeling of packages containing radioactive materials is required by the U.S. Department of Transportation if the amount and type of radioactive material exceeds the limits for an excepted quantity or article as defined and limited by U.S. Department of Transportation regulations 49 CFR 173.403(m) and (w) and 173.421.424. (See section 16.200 for reference.)

(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 subparagraph (i) of this paragraph 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 or registrant is not required to control entrance or access to rooms or other areas in hospitals solely because of the presence of patients containing radioactive material, provided that there are personnel in attendance who are taking the necessary precautions to prevent the exposure of individuals to radiation or radioactive material in excess of the established limits in Part 16 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 these regulations, 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 non-self-shielded irradiators.

(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 these regulations, such as those regulating x-ray 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 paragraph (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 subdivision 16.12(f) shall have been tested for proper functioning. (See section 16.14(h) 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 subparagraph (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.[6]

(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:

(1) 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 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 instructed to observe, to the extent within the worker's control, the applicable provisions of this Part and licenses for the protection of personnel from exposures to radiation 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.

[6] Copies of the "Notice to Employees" may be obtained from the department.

(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 (f) of section 16.14 of this Part. Each notification and report shall be in writing and include appropriate identifying data, such as the name of the licensee or registrant, the name of the individual, the individual's social security number, together with the individual's exposure information and, in addition, 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 (f) 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 planned special exposure, 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 (f) 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 controlled by a licensee or registrant for purposes of radiation protection, and who is terminating employment in such work assignment in a given calendar quarter, 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 calendar quarter or fraction thereof. 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 registrant shall afford the department or health officer having jurisdiction at all reasonable times 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, 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 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, his 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 Bureau of Environmental Radiation Protection of 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 bureau shall cause an inspection to be made as soon as practicable to determine if such alleged violation exists or has occurred. Inspection pursuant to this section need not be limited to matters referred to in the complaint.

(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 these regulations or has testified or is about to testify in any such proceeding, or because of the exercise by such worker on behalf of 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 Director, Center for Environmental Health of 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 Director, Center for Environmental Health, who will provide the complainant with a copy of such statement by certified mail. Upon the request of the complainant, the Director, Center for Environmental Health 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, the Director, Center for Environmental Health shall affirm, modify or reverse the determination of the department and furnish the complainant and the licensee or registrant a written notification of his decision and the reason therefore.

(2) If the Bureau of Environmental Radiation Protection 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 Part 16.

(2) The licensee or registrant shall make a clear distinction among the quantities entered on the records required by Part 16, such as, total effective dose equivalent, shallow dose equivalent, eye dose equivalent, deep dose equivalent, or committed effective dose equivalent.

(3) Form of records. Each record required by Part 16 shall be legible throughout the specified retention period. The record shall be the original or a reproduced copy or a microform, provided that the copy of microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period, or the record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications shall include pertinent information, such as stamps, initials, and signatures. The licensee shall maintain safeguards sufficient to prevent tampering with and loss of records.

(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.

(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 section 16.14(b) 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 section 16.14(b) for three years after the record is made.

(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). 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); 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 permanently store records on Department Form "Cumulative Occupational Radiation Exposure History" or equivalent, until disposition is authorized by the Department.

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

(d) Records of prior occupational dose.

(1) The licensee or registrant shall retain the records of prior occupational dose and exposure history as specified in section 16.6(e) on Department Form "Cumulative Occupational Radiation Exposure History" or equivalent, and the records used in preparing Department Form "Cumulative Occupational Radiation Exposure History" until disposition is authorized by the department.

(2) Upon termination of the license or registration, the licensee or registrant shall permanently store records on Department Form "Cumulative Occupational Radiation Exposure History" or equivalent, or shall make provision with the Department for transfer to the Department.

(e) Records of planned special exposures.

(1) For each of the provisions of section 16.6(f) for planned special exposures, the licensee or registrant shall maintain records that describe:

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

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

(iii) What actions were necessary; and

(iv) Why the actions were necessary; and

(v) What precautions were taken to assure that doses were maintained ALARA; and

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

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

(2) The licensee or registrant shall retain the records until disposition is authorized by the Department.

(3) Upon termination of the license or registration, the licensee or registrant shall permanently store records on Department Form "Cumulative Occupational Radiation Exposure History", or until disposition is authorized by the Department.

(f) 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, and records of doses received during planned special exposures, accidents, and emergency conditions. Assessments of dose equivalent and records made using units in effect before the effective date of Part 16 need not be changed. These records shall include, when applicable:

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

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

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

(iv) The specific information used to calculate the committed effective dose equivalent pursuant to section 16.6(d); and

(v) The total effective dose equivalent when required by section 16.6(b); 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 Department Form "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 permanently store records on Department Form "Cumulative Occupational Radiation Exposure History" or equivalent, until disposition is authorized by the Department.

(g) 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).)

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

(h) 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) 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.

(i) 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.

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 Appendix 16-A, Table 9, infra, under such circumstances that it appears to the licensee or registrant that an exposure could result to individuals in unrestricted areas; or

(ii) Within 30 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 Appendix 16-A, Table 9, infra, 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; and, for radiation equipment, the manufacturer, model and serial number, type and maximum energy of radiation emitted;

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

(iii) A statement of disposition, or probable disposition, of the licensed or registered source of radiation involved; and

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

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

(vi) Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of 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) An eye 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) An eye 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 hot-cells 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 telephone, telegram, mailgram, or facsimile to the Department.

(5) The provisions of this subdivision do not apply to doses that result from planned special exposures, provided such doses are within the limits for planned special exposures, and are reported pursuant to section 16.15(d).

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

(1) Reportable events. In addition to the notification required by section 16.15(b), 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);

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

(a) The occupational dose limits for adults in section 16.6(a);

(b) The occupational dose limits for a minor in section 16.6(g);

(c) The limits for an embryo/fetus of a declared pregnant woman in section 16.6(h);

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

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

(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 Part 16 or in the license or registration, whether or not involving exposure of any individual in excess of the limits in section 16.7(a).

(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, generally applicable environmental standards, 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, social security account number, and date of birth. With respect to the limit for the embryo/fetus in section 16.6(h), the identifiers should be those

of the declared pregnant woman. The report shall be prepared so that this information is stated in a separate and detachable portion of the report.

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

(d) Reports of planned special exposures. The licensees or registrant shall submit a written report to the Department within 30 days following any planned special exposure conducted in accordance with section 16.6(f), informing the Department that a planned special exposure was conducted and indicating the date the planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by section 16.14(e).

(e) 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 these regulations.

(2) When a licensee or registrant is required pursuant to section 16.15(c) 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 these regulations.

(f) 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.

(g) 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 (gold) jewelry.

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 Appendix 16-B, Table I of this Part, 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, 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; and 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 3 hours after the package is received during the licensee's normal working hours, or not later than 3 hours from the beginning of the next working day if it is received after working hours.

(c) The licensee shall immediately notify the final delivery carrier and the department 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 telephone as well as by telegram, mailgram or facsimile.

(1) Removable radioactive contamination in excess of 0.01 microcuries (22,000 dpm) (0.37 KBq) per 100 square centimeters on the external surfaces of the package; or

(2) Radiation levels at 1 meter from the external surface of the package in excess of 0.01 rem (10 mrem) (0.1mSV) per hour.

(d) 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; and

(2) Ensure that the procedures are followed.

16.17 Transportation.

(a) No person shall transport, package for transport, or cause to be transported, outside of the confines of his installation, any radioactive material within this State unless:

(1) such transport conforms to those regulations of the United States Department of Transportation or other agencies of the United States having jurisdiction with respect to packaging of the radioactive material and to the marking and labeling of the package and transporting vehicle which would be applicable if such transport were interstate; and

(2) procedures are established for opening and closing packages in which radioactive material is transported to provide safety and to assure that, prior to delivery to a carrier for transport, each package is properly closed for transport; and

(3) prior to delivery of a package for transport, such person shall assure that any special instructions needed to open the package are sent to, or have been made available to the consignee; or

(4) such transport complies with such requirements as have been approved by the commissioner.

(b) Transport of radioactive material is exempt from the requirements set forth in subdivision (a) of this section provided that all of the following conditions are satisfied:

(1) the package must consist of an outer container and an inner container and must be such that there can be no leakage of radioactive material under conditions normally incident to transportation;

(2) the package must contain not more than 0.01 millicurie of any alpha emitting radioactive material exclusive of fissionable material, or 0.1 millicurie of Argon 41, Barium 133, Bismuth 210, Europium 154, Krypton 87, Lead 210, Lead 212, Strontium 90, or Xenon 135, or one millicurie of any beta-gamma emitting radioactive material;

(3) the package must be such that there is no significant removable surface contamination[7] on the exterior of the package and the radiation dose rate at any point on the external surface of the package must be less than 12 milliroentgens for 24 hours; and

(4) the outside of the inner container of the package must bear the marking "RADIOACTIVE".

(c) Transport of radioactive material by a physician for use in the practice of medicine is exempt from the requirements set forth in subdivisions (a) and (b) of this section, provided that the physician is authorized to use radioactive materials by a license issued by the department under this Part.

16.18 Additional requirements; surrender of radioactive material; sealing of radiation equipment. Notwithstanding any exemption set forth in this Part:

(a) The department may, by rule, regulation 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.[8]

(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.

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[7] Removable radioactive contamination is not significant if the average amount of radioactive contamination which can be removed by wiping the external surface of the package with an absorbent material, as measured on the wiping material, does not exceed: (1) 10 picocurie per square centimeter beta-gamma (2,200 disintegrations/min. per 100 square centimeters) and 1 picocurie per square centimeter alpha (220 disintegration/min. per 100 square centimeters) for all contaminants except natural or depleted uranium and natural thorium; or (2) 100 picocurie per square centimeter beta-gamma (22,000 disintegrations/min. per 100 square centimeters) and 10 picocurie per square centimeter alpha (2,200 disintegration/min. per 100 square centimeters) where the only contaminant is known to be natural or depleted uranium or natural thorium.

[8] In evaluating the necessity for additional requirements the department will consider among other things the Federal Radiation Protection Guidance published in the Federal Register on May 13, 1960 (25FR4402) and on January 27, 1987 (52FR2822) and the recommendations of the National Council on Radiation Protection and Measurements.

16.19 Limitations on application of radiation to humans.[9]

(a) Diagnostic x-ray equipment. No person other than a professional practitioner, as defined in section 16.2(a)(85) 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, as defined in section 16.2(a)(97) of this Part to a human being. No person other than a professional practitioner; as defined in section 16.2(a)(85) of this Part; or a licensed and registered radiologic technologist, or, student currently enrolled in an approved program of study in diagnostic radiologic technology, and under direct supervision by a professional practitioner or licensed radiologic technologist; 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 of the State of New York.

(1) Unlicensed dental assistants may operate dental radiographic equipment for intraoral and panographic dental x-ray procedures only under the supervision of a licensed dentist pursuant to the applicable provisions of section 89.45 of this Title and of paragraph (4) of subdivision (c) of section 3515 of the Public Health Law of the State of New York.

(b) X-ray therapy equipment. No person other than a qualified physician shall direct or order the application of radiation from x-ray therapy equipment, as defined in paragraph (97) of section 16.2(a) of this Part, to a human being. Nor shall any person 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 person other than a physician named in a license issued pursuant to section 16.100 of this Part, or a physician under his/her tutelage shall direct or order the use of radioactive materials specified in paragraphs (1), (2), (3) and (4) of subdivision (b) of section 16.123, or in section 16.122 of this Part for human use; nor shall any person other than a physician, dentist, or podiatrist named in a license issued pursuant to section 16.100 direct or order the use of radioactive materials specified in paragraph (5) of subdivision (b) of section 16.123 for human use; nor shall anyone other than these persons, or a person working under their direction or order, administer radioactive materials or the radiation therefrom to humans. Such direction or order, or administration of radioactive materials or radiation shall be in the course of the physician's, dentist's or podiatrist's practice and shall comply with the following:

(1) The provisions of the radioactive materials license issued pursuant to section 16.100, and the provisions of the license or other authorization of the practitioner under the Education Law of the State of New York and all regulations pertinent thereto;

(2) The applicable provisions of Part 89 of this Title and Article 35 of the Public Health Law of the State of New York; and

(3) The provisions of section 16.103(b) of this Part.

[9] See also section 16.9.

16.20 Hearings.

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

(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 he/she 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 unless the prior consent of the licensee or person involved has first been obtained, 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 he/she may be present and heard at the hearing.

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 89.4 (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) Palpation and the teaching of breast self-examination shall be provided.

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

(5) 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 and/or radioactive materials procedures, excepting dental, podiatric 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 provision of the information described in subparagraphs (v), (vi), and (vii) of this paragraph to any patient upon request; and

(ix) 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.

(b) Mammography image quality. Each facility performing mammography examinations shall ensure that the mammographic system is optimized to provide consistent, high quality imaging. A mammography system includes the 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 as constituents of, and exemplified by, the model breast phantoms hereafter described:

(1) No patient mammograms shall be performed unless the minimum test object resolution established in paragraph two of this subdivision is met.

(2) The mammography system shall be capable of imaging, at the minimum, the following test objects:

(i) 0.75 millimeter (mm) mass, 0.75 mm fiber and 0.54 mm speck set using the Model 152D phantom manufactured by Radiation Measurements Inc. (RMI), or,

(ii) the 0.75 mm mass, 0.75 mm fiber, and 0.40 mm speck set using the American College of Radiology (ACR) mammography accreditation phantom; or,

(iii) the equivalent test object resolution on another approved phantom.

(3) All facilities shall optimize the mammography systems used and determine the breast equivalent phantom test object resolution of the system prior to performing patient mammograms. 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 section 16.23 of this Part, 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.

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

(i) Whenever the phantom image indicates that the mammography 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 patient mammograms.

(ii) In addition, if the imaging system resolves less than seven test objects on the RMI Model 152 D phantom, the ACR phantom, or the equivalent on another approved phantom, the investigation shall include:

(a) a review of monthly 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 mammograms 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 film 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 and maintain a quality assurance manual that includes policies and procedures that require 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 his or her practice to radiation oncology.

(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) A radiation therapy technologist, physician or other qualified health practitioner shall verify that the patient set up on the treatment machine is in accordance with the treatment plan prior to the first fraction of a course of treatment and prior to treatment for any changes to the initial treatment plan.

(v) Clinical staff 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.

(vi) Each patient's identification shall be verified by at least two different means by qualified clinical staff prior to each treatment.

(vii) 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. Unusual responses shall be evaluated as possible indications of treatment errors and recorded in the patient's medical record.

(viii) The medical records of patients undergoing fractionated treatment shall be checked for completeness and accuracy by qualified clinical staff at intervals not to exceed six fractions.

(ix) Radiation treatment plans and related calculations shall be checked by qualified clinical staff 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 300cGy or 700 monitor units; or when the output of a medical therapy accelerator exceeds 600 monitor units per minute during treatment. If a treatment plan and related calculations were originally prepared by a board certified radiation oncologist or an authorized medical physicist possessing the qualifications specified in paragraph (1) of subdivision (d) of section 16.123 of this Part, it may be rechecked by the same individual using a different calculation method. Treatment plans and related calculations prepared by other qualified clinical personnel must be checked by a second qualified person using procedures specified in the registrant's or licensee's treatment planning procedures manual required pursuant to subparagraph (2) of this paragraph, and who has received training in use of the manual pursuant to subparagraph (2) of this paragraph.

(x) All equipment and other technology used in planning and administering radiation therapy shall function properly and safely, and shall be calibrated properly and repaired and maintained in accordance with 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; 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.

(xi) 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.

(xii) Test results that exceed tolerances/limits shall be immediately reported to the authorized medical physicist.

(xiii) Records for all maintenance, repairs and upgrades of equipment and technology shall be maintained for at least five years.

(xiv) 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.

(xv) External beam therapy equipment calibration/output required by section16.60(c)(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.

(xvi) Patients with permanent brachytherapy implants shall be provided with instructions to take radiation safety precautions, as required by section 16.123(e)(4) (incorporating 10 CFR 35.75) and the licensee's radioactive materials license, after being released from the licensee's facility.

(xvii) All personnel involved in planning or implementing 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.

(xviii) 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 (4) of this subdivision and for review by the Department.

(xix) There shall be a process to ensure quick and effective response to any radiation therapy related recalls, notices, safety alerts and hazards.

(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 an authorized medical physicist possessing the qualifications specified in paragraph (1) of subdivision (d) of section 16.123 of this Part 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.

(3) Each licensee or registrant shall ensure that all equipment used in planning and administering radiation therapy is functioning properly, designed for the intended purpose, properly calibrated, and maintained in accordance with the manufacturer's instructions and the quality assurance program described in the licensee or registrant's quality assurance manual.

(4) 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 an authorized medical physicist possessing the qualifications specified in paragraph (1) of subdivision (d) of section 16.123 of this Part, 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 6 years.

(5) Blank

(6) Accreditation in Radiation Oncology.

(i) Effective 90 days from the effective date of this regulation, each registrant or licensee shall have an active application with, or be accredited in radiation oncology by, the American College of Radiology, the American College of Radiation Oncology or another accrediting organization that is equivalent as determined by the Department.

(ii) Effective 18 months from the effective date of this regulation, each registrant and licensee shall maintain accreditation in radiation oncology by the American College of Radiology, the American College of Radiation Oncology or another accrediting organization that is equivalent as determined by the Department.

(iii) The registrant or licensee shall maintain a record of accreditation, including a copy of the application, all supplemental application information and all correspondence transmitted between the accrediting body and the registrant or licensee. Records shall be maintained for at least 6 years.

(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 dose prescription.

(1) Beginning March 31, 1993, 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 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; and institute corrective actions and improvements as indicated by the audit findings.

16.25 Misadministrations.

(a) A medical misadministration 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; or

(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; or

(8) A therapeutic radiation dose in any fraction of a fractionated treatment such that the administered dose in the individual treatment or fraction differs from the dose ordered for that individual treatment or fraction by more than 50 percent, except when the administered dose is lower than the dose ordered by more than 50 percent due to machine interruption, or due to patient inability or decision to not finish the treatment.

(b) Records and Reports of Misadministrations.

(1) Diagnostic misadministrations.

(i) Records of misadministrations 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, shall be retained for three (3) years; and

(ii) If such a misadministration results in a dose to the patient exceeding 5 rem to the whole body or 50 rem 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.

(2) Therapy misadministrations.

(i) When a misadministration described in paragraphs (5), (6), or (7) of subdivision (a) of this section, in which the percentage of error is equal to or less than 20 per cent is discovered the licensee or registrant shall immediately investigate the cause and take corrective action; and

(a) The licensee shall make and retain a record of all therapy 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 misadministration described in paragraphs (a)(1), (2), (3) or (8) of this section is discovered; or when a misadministration described in paragraphs (a)(5), (6) or (7) of this section in which the percentage of error is 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 misadministration described in this subparagraph, with the exception of misadministrations 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 misadministration 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 because of this.

(iii) Within 7 days after an initial therapy misadministration report, the licensee or registrant shall send a written report to the department. 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. A separate report is not required when an incident report containing all the aforesaid information is submitted to the department pursuant to Part 405 of this Title.

(3) Each licensee or registrant shall maintain a record of each reportable misadministration 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 patient's social security 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 misadministration 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 misadministration, 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 in restricted areas.

(a) Use of process or other controls. The licensee shall use, to the extent practicable, process or other engineering controls, such as, containment or ventilation to control the concentrations of radioactive material in air.

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

(1) Control of access; or

(2) Limitation of exposure times; or

(3) Use of respiratory protection equipment; or

(4) Other controls.

(c) Use of individual respiratory protection equipment.

(1) If the licensee or registrant uses respiratory protection equipment to limit intakes pursuant to subdivision (b) of this section:

(i) Except as provided in subparagraph (ii) of this paragraph the licensee or registrant shall use only respiratory protection equipment that is tested and certified or had certification extended by the National Institute for Occupational Safety and Health Administration and the Mine Safety and Health Administration.

(ii) If the licensee wishes to use equipment that has not been tested or certified by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration, has not had certification extended by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration, or for which there is no schedule for testing or certification, the licensee or registrant shall submit an application for authorized use of that equipment, including a demonstration by testing, or a demonstration on the basis of reliable test information, that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use.

(iii) The licensee shall implement and maintain a respiratory protection program that includes:

(a) Air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate exposures; and

(b) Surveys and bioassays, as appropriate, to evaluate actual intakes; and

(c) Testing of respirators for operability immediately prior to each use; and

(d) Written procedures regarding selection, fitting, issuance, maintenance, and testing of respirators, including testing for operability immediately prior to each use; supervision and training of personnel; monitoring, including air sampling and bioassays; and recordkeeping; and

(e) Determination by a physician prior to initial fitting of respirators, and at least every 12 months thereafter, that the individual user is physically able to use the respiratory protection equipment.

(iv) The licensee or registrant shall issue a written policy statement on respirator usage covering:

(a) The use of process or other engineering controls, instead of respirators; and

(b) The routine, nonroutine, and emergency use of respirators; and

(c) The length of periods of respirator use and relief from respirator use.

(v) The licensee or registrant shall advise each respirator user that the user may leave the area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other conditions that might require such relief.

(vi) The licensee or registrant shall use equipment within the equipment manufacturer's expressed limitations for type and mode of use and shall provide proper visual, communication, and other special capabilities, such as adequate skin protection, when needed.

(2) When estimating exposure of individuals to airborne radioactive materials, the licensee or registrant may make allowance for respiratory protection equipment used to limit intakes pursuant to subdivision (b) of section 16.26, provided that the following conditions, in addition to those in subdivision (c) of section 16.26, are satisfied:

(i) The licensee selects respiratory protection equipment that provides a protection factor greater than the multiple by which peak concentrations of airborne radioactive materials in the working area are expected to exceed the values specified in Appendix 16-C, Table 1, Column 3, infra. However, if the selection of respiratory protection with a protection factor greater than the peak concentration is inconsistent with the goal specified in subdivision (b) of this section of keeping the total effective dose equivalent ALARA, the licensee or registrant may select respiratory protection equipment with a lower protection factor provided that such a selection would result in total effective dose equivalent that is ALARA. The concentration of radioactive material in the air that is inhaled when respirators are worn may be initially estimated by dividing the average concentration in air, during each period of uninterrupted use, by the protection factor. If the exposure is later found to be greater than initially estimated, the corrected value shall be used; if the exposure is later found to be less than initially estimated, the corrected value may be used.

(ii) The licensee or registrant shall obtain authorization from the Department before assigning respiratory protection factors in excess of those specified in Appendix 16-A, Table 8, infra. The Department may authorize a licensee or registrant to use higher protection factors upon receipt of an application that:

(a) Describes the situation for which a need exists for higher protection factors, and

(b) Demonstrates that the respiratory protection equipment provides these higher protection factors under the proposed conditions of use.

(3) In an emergency, the licensee shall use as emergency equipment only respiratory protection equipment that has been specifically certified or had certification extended for emergency use by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration.

(4) The licensee shall notify the Department in writing at least 30 days before the date that respiratory protection equipment is first used pursuant to subdivision (c) of section 16.26.

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 or any person that holds a radioactive material license issued by the New York City Department of Health, pursuant to section 16.50(j) and section 16.1(b)(3), respectively, 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. A late payment charge will be assessed at the rate of one and one half percent for each 30 day late period or part thereof.

(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. Provided that a written schedule of the registration fees to be charged by the New York City Department of Health, not to exceed $50 per year per installation, has been submitted, in the manner prescribed, to, and approved by, the State Commissioner of Health, the New York City Department of Health 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 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)(3) 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 with the department pursuant to section 16.50(a) of this Part is $50.

(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), computed tomography and particle accelerators, 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:	$1,370
Category II radiation installations:	$1,030
Category III radiation installations:	$ 690
Category IV radiation installations:	$ 275
Category V radiation installations:	$ 140
Category VI radiation installations:	$ 75

(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:	$ 425
Category II radiation installations:	$ 320
Category III radiation installations:	$ 210
Category IV radiation installations:	$ 85
Category V radiation installations:	$ 45
Category VI radiation installations:	$ 15

(e) Fee categories for 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:	$5,265
Category II:	$3,510
Category III:	$1,400
Category IV:	$ 880
Category V:	$ 350
Category VI:	$ 50

(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.

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.[10]

(b) Application for the registration of a radiation installation 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. The times for making application shall be as follows:

(1) for an installation not in registered status, between 60 and 30 days prior to the establishment of the installation;

(2) for an installation in registered status with a current certificate of registration, between 60 and 30 days prior to the expiration of such certificate unless the certificate is revoked or the installation is discontinued upon or before the expiration of the certificate;

(3) for an installation with respect to which either the operator or location is changed, between 60 and 30 days prior to such change.

(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. The length of such period of time shall not exceed two years except that the department may issue a certificate of registration for a longer period of time in order to stagger expiration dates for administrative purposes.

[10] Radiation equipment exempted from the requirements of this Part under section 16.4 is exempt from the registration requirement.

(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.

(f) A certificate of registration shall not be transferable or assignable.

(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. Acceptance of registration may be done only for radiation installations surveyed under an inspection program conducted by the New York City Department of Health 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.

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 16.50-16.63), and all possession or use thereof shall comply with the requirements of sections of this Part set forth under the heading "General Provisions" (section 16.1-16.20), 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:

(1) non-image intensified fluoroscopic equipment which has not been certified in accordance with 21 CFR Part 1020. (See section 16.200 of this Part);

(2) shoe-fitting fluoroscopic devices;

(3) intra-oral fluoroscopy used in dental examinations;

(4) photofluorographic equipment; and

(5) the sale of gold jewelry which is known by the owner to be contaminated with radioactive materials, except for sale to the department.

(c) Precedence of Federal performance standard. Wherever any requirement of this Part relating to radiation equipment conflicts with the Federal performance standard for diagnostic X-ray systems and their major components (21 CFR 1020.-30), the Federal performance standard, when effective, shall take precedence over and supersede any conflicting requirement of this Part.

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 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) 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) For intra-oral radiography 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 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

(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 can not 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 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 hand held 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).

(6) Gonadal shielding of not less than 0.5 mm lead equivalent shall be used for patients who have not passed the reproductive age during radiographic procedures in which the gonads are in the useful beam.

(c) Special installations.

(1) Panoramic installations are dental installations which consist of a tube head with a collimator providing a narrow (1-2mm) 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 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

(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.

16.54 Veterinary radiographic and fluoroscopic installations.

(a) Fixed 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 films used as the recording medium during the x-ray examination 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 films shall be held only under extreme conditions when clinically necessary. Individuals holding animal patients or films 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/her 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 film used as the recording medium during the X-ray examination 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) Collimaters, 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.

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 films used as the recording medium during the X-ray examination 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 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

(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.

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 films used as the recording medium during the X-ray examination 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 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

(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) 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 films during exposures nor shall such duty be performed by any individual occupationally exposed to radiation during the course of his/her other duties. When it is necessary to restrain the patient, mechanical supporting or restraining devices shall be used whenever possible. If patients or films 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.

(3) Gonadal shielding of not less than 0.5 mm lead equivalent shall be used for patients who have not passed the reproductive age during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.

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 films used as the recording medium during the X-ray examination 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 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

(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 one location it shall be considered a fixed installation, and shall meet the requirements of section 16.56.

(c) Conditions for operation of equipment.

(1) No person shall be regularly employed to hold patients or films during exposures nor shall such duty be performed by any individual occupationally exposed to radiation during the course of his/her other duties. When it is necessary to restrain the patient, mechanical supporting or restraining devices shall be used. If patient or films 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.

(2) Gonadal shielding of not less than 0.5 mm lead equivalent shall be used for patients who have not passed the reproductive age during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.

16.58 Fluoroscopic installations excluding veterinary installations.

(a) Equipment.

(1) The protective tube housing shall be of the diagnostic type.

(2) Equipment shall be constructed so 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 below:

(i) for equipment manufactured prior to August 1, 1974:

Operating kVp	Minimum total filtration (Inherent plus added)
Below 50 kVp	0.5 mm aluminum
50-70 kVp	1.5 mm aluminum
Above 70 kVp	2.5 mm aluminum

(ii) for equipment manufactured after August 1, 1974.

Designed Operating Range (kVp)	Measured Operating Potential (kVp)	Minimum HVL mm of Al
Below 51	30	0.3
	40	0.4
	50	0.5
51 to 70	51	1.2
	60	1.3
	70	1.5
Above 70	71	2.1
	80	2.3
	90	2.5
	100	2.7
	110	3.0
	120	3.2
	130	3.5
	140	3.8
	150	4.1

(4) Fluoroscopic exposure switch shall be of the dead-man type.

(5) The source-tabletop distance shall not be less than 12 inches (30 cm) and should not be less than 15 inches (38 cm).

(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 a signal audible to the operator or by temporary interruption of the irradiation.

(7)) (i) The fluoroscopic exposure rate when measured under the following conditions shall not exceed 5 Roentgens per minute:

(a) the controls are set to the dose rate mode used for the fluoroscopic procedure most commonly performed on that fluoroscopic unit;

(b) the image intensifier is set to the largest field of view;

(c) the image intensifier is at 12 inches (30 cm) above the tabletop or the overtable fluoro tube is at a source to image distance normally used for an average patient;

(d) a patient phantom composed of 1 and ½ inch (3.8 cm) thickness of Type 1100 aluminum and 0.02 inch (0.5 mm) thickness of copper or an equivalent device is completely intercepting the useful beam; and

(e) the measurement is made at the measurement location specified in 21 CFR Section 1020.32(d)(3) (see section 16.200 of this part).

(ii) If the exposure rate cannot be measured, the exposure integrated for one minute under the same conditions as subsection (7)(i) shall not exceed 5 Roentgens.

(8) Using the measurement locations specified in 21 CFR Section 1020.32(d)(3) (see section 16.200 of this part), the maximum exposure rate measured in air shall not exceed 10 roentgens per minute except as follows:

(i) Equipment manufactured before May 19, 1995 and certified in accordance with 21 CFR Part 1020 (see section 16.200 of this Part) and having an optional high level control is limited to a maximum output of 5 Roentgens per minute unless the high level control is activated and an audible signal to that effect is provided. When the high level 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.

(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 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 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 20 Roentgens per minute.

(9) With the system configured for the most frequently performed procedure, the fluoroscopic and fluorographic, if the system is equipped for image acquisition, exposure rates shall be measured with each of the following attenuators in the beam:

0.75 inches (19 mm) of aluminum (pediatric patient -- 25 kg.),

1.50 inches (38 mm) of aluminum (small adult patient -- 50 kg.),

1.50 inches (38 mm) of aluminum and 0.02 inches (0.5 mm) of copper (average adult patient -- 75 kg.),

1.50 inches (38 mm) of aluminum and 0.08 inches (2.0 mm) of copper (large adult patient -- 100 kg.),

1.50 inches (38 mm) of aluminum and 0.08 inches (2.0 mm) of copper and 0.12 inches (3.0 mm) of lead (for maximum fluoroscopic exposure rate only).

The fluoroscopic exposure rates for the most frequently performed procedure shall be posted so that they are conspicuous to the operator.

(10) Primary protective barriers shall provide the following protection:

(i) for uncertified equipment, with the image intensifier 14 inches (36 cm) from the tabletop, the exposure rate two inches (5 cm) beyond the image intensifier shall not exceed 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 two milliroentgens per hour at four inches (10 cm) from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute or entrance exposure rate.

(11) In the absence of a tabletop, a cone or spacer frame shall limit the source-to-skin distance to not less than 12 inches (30 cm) for all mobile fluoroscopic equipment. Units intended for specific surgical application may be used at shorter source skin distances but in no case less than 8 inches (20 cm).

(12) The spatial resolution of the fluoroscopic system shall be measured using a test tool composed of a line pair (lp) plate with discreet line pair groups and a maximum lead foil thickness of 0.1 mm or an equivalent device. The test tool shall be placed on a 0.75 inch (19 mm) thickness of type 1100 aluminum, large enough to completely intercept the useful beam, with the test tool 12 inches (30 cm) from the entrance surface of the image receptor assembly. If the system has variable source-to-image distance (SID), the measurement SID shall not exceed 40 inches (100 cm). The image receptor of the fluoroscopic system shall be operated in the largest available field of view (FOV) that does not exceed six inches (15 cm). If all the fluoroscopic system's FOVs exceed six inches (15 cm), the system shall be operated in the smallest FOV. The minimum spatial resolution at center of the beam for all FOVs shall be determined by the following equation:

2 lp/mm x (6 inches (15cm)/size of FOV used) = minimum number of lp/mm.

(13) 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 phantom composed of a 1 and ½ inch (3.8 cm) thickness of Type 1100 aluminum large enough to completely intercept the useful beam or an equivalent device. The test tool shall be 12 inches (30 cm) from the entrance surface of the image receptor assembly. The image receptor of the fluoroscopic system shall be operated in the largest available field of view (FOV) that does not exceed six inches (15 cm). If all the fluoroscopic system's FOVs exceed six inches (15 cm), the system shall be operated in the smallest FOV.

(14) 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 exposure and exposure rate measurements made pursuant to paragraph (a)(7) and (8) 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) Unless measurements indicate that they are not needed protective garments of at least 0.25 mm lead equivalent each shall be worn by all persons within the fluoroscopic room except for the patient.

(3) Only persons needed in the fluoroscopic room shall be present during irradiation.

(4) The cumulative fluoroscopic time must be reset for each new patient.

16.60 Therapy equipment operated at potentials up to 10 million volts.[11]

(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 (5 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.

[11] See section 16.61 for special requirements for equipment operating below 60 kVp.

(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 be fixed to the wall of the building.

(2) The control panel for all therapy equipment operating at voltages above 150 kVp installed after January 1, 1963, shall be located outside the treatment room.

(c) 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 a person qualified pursuant to subdivision (f) of section 16.122 of this Part. 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 X-ray therapy room while the X-ray generator is in operation.

(3) Every entrance to an X-ray 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. They 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.

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 a person qualified pursuant to subdivision (f) of section 16.122 of this Part and experienced in the calibration of such units. 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.

16.62 Television receivers and other household appliances.

(a) No home television receiver or other household equipment, whether used in the home or elsewhere, which emits radiation on application of high voltage, shall be offered, transferred, or consigned for sale or use in the State of New York unless it be constructed to prevent radiation therefrom at a level greater than 0.5 milliroentgen per hour, measured two inches or five centimeters from its surface, and averaged over an area of 1.55 square inches or 10 square centimeters.

(b) No replacement part which on being installed would cause the assembled unit for which it is intended to exceed the radiation limit allowed under this section shall be offered, transferred, or consigned for sale or use in the State of New York.

(c) No person shall alter or adjust any home television receiver or other household equipment, whether used in the home or elsewhere, which can emit radiation, in such manner as to increase the radiation emission level thereof, unless the level thereby achieved be within the emission limit allowed under this section.

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, 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.

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 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 paragraphs (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.[12] General licenses provided in Appendix 16-A, Table 6, infra, are effective without the filing of an application with or the issuance of a licensing document by the department.

16.102 Applications for specific licenses.

(a) An application for a license for any radioactive material shall be filed in triplicate on, and shall contain completely and accurately all information called for by, a written 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.

[12] Radioactive material possessed or used under a general license is subject to the requirements of sections 16.6 through 16.17 set forth under the heading "General Provisions" of this Part.

16.103 General requirements for issuing specific licenses. The department will 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:

(a) 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;

(b) the applicant's radiation detection and measuring instrumentation is appropriate for the uses of radioactive materials requested in the application;

(c) 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

(d) the applicant submits sufficient information to support a determination that the requirements of this section are satisfied.

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 State 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 his 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 State Department of Labor, the New York City Department of Health, 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(14)) (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.

(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 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.

16.106 Renewal or amendment of specific licenses. Any application by a licensee for the renewal or amendment of his license shall be considered as an application for a license and shall be filed in accordance with section 16.102; 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 as appropriate corrective amendment of a license may be issued by the department at any time upon its initiative.

16.107 Amendment, suspension or revocation of licenses. Specific and general licenses shall be subject to amendment, suspension or revocation by reason of amendment of the State Public Health Law, enactment or amendment of any other applicable law, amendment of the State Sanitary Code (Chapter I of this Title) or amendment or promulgation of any other applicable rule, regulation, or order. The department may amend, revoke or suspend any license in whole or in part, for:

(a) any material misstatement in the application therefor or in any supplementary statement thereto;

(b) 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

(c) any violation or failure to observe any of the applicable terms or provisions of such license, the State Public Health Law, this Part, or any other applicable rule, regulation, code or order now or hereafter in effect.

16.108 Reserved.

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 (3) 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;[13]

(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, 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:

[13] A license may transfer material to the department only after receiving prior approval from the department.

(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 Fingerprinting and criminal background check requirements.

(a) Applicability.

This section applies to any licensee who possesses, or is authorized to possess, radioactive material that is: (1) listed in Table 1 (“Radionuclides of Concern”) of this Section and (2) in a quantity equal to or exceeding that listed in Table 1.

(b) Definitions

(1) Trustworthiness and Reliability (T&R) Official means an individual appointed by the licensee who is responsible for determining the trustworthiness and reliability of another individual requiring unescorted access to one or more radioactive materials identified in Table 1 of this section.

(2) "Affected individual" means an individual who has or is seeking unescorted access to radioactive material identified in Table 1 of this section in a quantity equal to or exceeding that listed in Table 1.

(3) "Unescorted access" means access without an escort to radioactive material identified in Table 1 of this section which is in a quantity equal to or exceeding that listed in Table 1.

(c) The T&R Official, if he/she does not require unescorted access, must be deemed trustworthy and reliable by the Licensee in accordance with its Increased Controls license conditions before making a determination regarding the trustworthiness and reliability of another individual. If the T&R Official requires unescorted access, the Licensee must consider the results of the Federal Bureau of Investigation (FBI) identification and criminal history records check before approving a T&R Official.

(d) Prior to requesting fingerprints from any individual, the Licensee shall provide a copy of this section to that person.

(e) Upon receipt of the results of FBI identification and criminal history records checks, the Licensee shall control such information as specified in subdivision (i) of this section and its Increased Controls license conditions.

(f) Specific Requirements Pertaining to Fingerprinting and Criminal History Records Checks

(1) Each Licensee subject to the provisions of this section shall fingerprint each affected individual.

(2) For affected individuals employed by the Licensee for three years or less, and for affected individuals who are nonlicensee personnel, such as physicians, physicists, house-keeping personnel, and security personnel under contract, trustworthiness and reliability shall be determined, at a minimum, by verifying employment history, education, personal references, and fingerprinting and the review of an FBI identification and criminal history records check.

(3) The Licensee shall also obtain independent information to corroborate that provided by the employee (e.g. seeking references not supplied by the individual). For an affected individual employed by the Licensee for longer than three years, trustworthiness and reliability shall be determined, at a minimum, by a review of the employee's employment history with the Licensee and fingerprinting and an FBI identification and criminal history records check.

(4) Service provider Licensee employees who are affected individuals shall be escorted unless they are determined to be trustworthy and reliable by a NRC-required background investigation. Written verification attesting to or certifying the person’s trustworthiness and reliability shall be obtained by the Licensee from the Licensee providing the service.

(5) The Licensee must submit one completed, legible standard FBI fingerprint card (Form FD-258,ORIMDNRCOOOZ)[1] for each affected individual, to the NRC's Division of Facilities and Security. The name and address of the individual (T&R Official) to whom the criminal history records should be returned must be included with the submission.

(6) The Licensee shall review and use the information received from the FBI identification and criminal history records check as part of its trustworthiness and reliability determination required by its Increased Controls license conditions.

(7) The Licensee shall notify each affected individual that his/her fingerprints will be used to secure a review of his/her criminal history record and inform the affected individual of the procedures for revising the record or including an explanation in the record, as specified in subdivision (h) of this section.

(8) Fingerprints for unescorted access need not be taken if an employed individual

(e.g., a Licensee employee, contractor, manufacturer, or supplier) is:

(i) An employee of the United States (U.S.) Nuclear Regulatory Commission (NRC) or of the Executive Branch of the U.S. Government who has undergone fingerprinting for a prior U.S. Government criminal history check;

(ii) A Member of Congress;

(iii) An employee of a member of Congress or Congressional committee who has undergone fingerprinting for a prior U.S. Government criminal history check;

(iv) The Governor or his or her designated State employee representative;

(v) Federal, State, or local law enforcement personnel;

(vi) State Radiation Control Program Directors and State Homeland Security Advisors or their designated State employee representatives;

(vii) Representatives of the International Atomic Energy Agency (IAEA) engaged in activities associated with the U.S./IAEA Safeguards Agreement who have been certified by the NRC; or

(viii) documentation is provided which demonstrates that the employed individual has been favorably-decided by a U.S. Government program involving fingerprinting and an FBI identification and criminal history records check within the last five calendar years of the effective date of this regulation, or documentation is provided which demonstrates that any person has an active federal security clearance. Written confirmation from the agency/employer which granted the federal security clearance or reviewed the FBI criminal history records results based upon a fingerprint identification check must be provided. The Licensee must retain this documentation for a period of three (3) years from the date the employed individual no longer requires unescorted access associated with the Licensee's activities.

(9) All fingerprints obtained by the Licensee pursuant to this section must be submitted to the NRC. Additionally, the Licensee shall submit a certification of the trustworthiness and reliability of the T&R Official as determined in accordance with 16.112(c) to the NRC with each submission of fingerprints.

(10) The Licensee shall review and use the information received from the FBI identification and criminal history records check and consider it as part of its trustworthiness and reliability determination, in conjunction with the trustworthiness and reliability requirements set forth in its Increased Controls license conditions, in making a determination whether to grant an affected individual unescorted access. The Licensee shall use any information obtained from a criminal history records check solely for the purpose of determining an affected individual's suitability for unescorted access.

(11) The Licensee shall document the basis for its determination whether to grant, or continue to allow, an affected individual unescorted access.

(12) Licensees shall notify the Department and the U.S. NRC Headquarters Operations Office by telephone within 24 hours if the results from a FBI identification and criminal history records check indicate an individual is listed on the FBI Terrorist Screening Data Base.

(g) Prohibitions

(1) A Licensee shall not base a final determination to deny an affected individual unescorted access solely on the basis of information received from the FBI involving:

(i) an arrest more than one (1) year old for which there is no information regarding the disposition of the case, or
(ii) an arrest that resulted in dismissal of the charge or an acquittal.

(2) A Licensee shall not use information received from a criminal history records check obtained pursuant to this section in a manner that would infringe upon the rights of any individual under the First Amendment to the Constitution of the United States or Article 1 of the New York State Constitution, nor shall the Licensee use the information in any way which would discriminate among individuals on the basis of race, religion, national origin, sex, or age.

(h) Right to Correct and Complete Information

Prior to any final adverse determination, the Licensee shall make available to the affected individual the contents of any criminal records obtained from the FBI for the purpose of assuring correct and complete information. Written confirmation by the individual of receipt of this notification must be maintained by the Licensee for a period of one (1) year from the date of the notification. If, after reviewing the record, an affected individual believes that it is incorrect or incomplete in any respect and wishes to change, correct, or update the alleged deficiency, or to explain any matter in the record, the individual may initiate challenge procedures. These procedures include either a direct application by the individual challenging the record to the agency (i.e., law enforcement agency) that contributed the questioned information, or a direct challenge as to the accuracy or completeness of any entry on the criminal history record to the FBI Identification Division.[2] The Licensee must provide at least ten (10) days for an individual to initiate an action challenging the results of a FBI criminal history records check after the record is made available for his/her review. The Licensee may make a final unescorted access determination based upon an individual's criminal history record only upon receipt of the FBI's confirmation or correction of the record. Upon a final adverse determination on unescorted access the Licensee shall provide the individual its documented basis for denial. Unescorted access shall not be granted to an individual during the review process.

(i) Protection of Information

(1) Each Licensee who obtains a criminal history record on an affected individual pursuant to this section shall establish and maintain a system of files and procedures for protecting the record and the personal information in the record from unauthorized disclosure.

(2) The Licensee may not disclose the record or personal information collected and maintained to persons other than the affected individual, his/her representative, or to those who have a need

to access the information in performing assigned duties in the process of determining unescorted access. No individual authorized to have access to the information may disseminate the information to any other individual whose job duties do not require such information.

(3) The personal information obtained on an affected individual from a criminal history record check may be transferred to another Licensee if the Licensee holding the criminal history record check receives the affected individual's written request to provide the information contained in his/her file, and the receiving Licensee verifies information such as the affected individual's name, date of birth, social security number, sex, and other applicable physical characteristics for identification purposes.

(4) The Licensee shall make criminal history records, obtained under this section, available for examination by an authorized representative of the Department to determine compliance with this section.

(5) The Licensee shall retain all fingerprint and criminal history records from the FBI, or a copy if the affected individual's file has been transferred, for three (3) years after termination of employment or determination of unescorted access (whether unescorted access was approved or denied). After the required three (3) year period, these documents shall be destroyed by a method that will prevent reconstruction of the information in whole or in part.

[1]. Copies of these forms may be obtained from NRC. The Licensee shall establish procedures to ensure that the quality of the fingerprints taken results in minimizing the rejection rate of fingerprint cards due to illegible or incomplete cards. Licensees must have fingerprints taken by local law enforcement (or a private entity authorized to take fingerprints) because an authorized official must certify the identity of the person being fingerprinted. If the FBI advises the fingerprints are unclassifiable based on conditions other than poor quality, the Licensee must submit a request to NRC for alternatives. When those search results are received from the FBI, no further search is necessary. The NRC will receive and forward to the submitting Licensee all data from the FBI as a result of the Licensee's application(s) for criminal history records checks, including the FBI fingerprint record(s).

[2]. In the latter case, the FBI forwards the challenge to the agency that submitted the data and requests that agency to verify or correct the challenged entry. Upon receipt of an official communication directly from the agency that contributed the original information, the FBI Identification Division makes any changes necessary in accordance with the information supplied by that agency (see 28 CFR Part 16.30 through 16.34).

Table 1: Radionuclides of Concern

Radionuclide	Quantity of Concern[1] (TBq)	Quantity of Concern[2] (Ci)
Am-241	0.6	16
Am-241/Be	0.6	16
Cf-252	0.2	5.4
Cm-244	0.5	14
Co-60	0.3	8.1
Cs-137	1	27
Gd-153	10	270
Ir-192	0.8	22
Pm-147	400	11,000
Pu-238	0.6	16
Pu-239/Be	0.6	16
Ra-226	0.4	11
Se-75	2	54
Sr-90 (Y-90)	10	270
Tm-170	200	5,400
Yb-169	3	81
Combinations of radioactive materials listed above[3]	See Footnote Below[4]	

[1] The aggregate activity of multiple, collocated sources of the same radionuclide should be included when the total activity equals or exceeds the quantity of concern.

[2] The primary values used for compliance with this Order are tera becquerel (TBq).

[3] Radioactive materials are to be considered aggregated or co-located if breaching a common physical security barrier (e.g., a locked door at the entrance to a storage room) would allow access to the radioactive material or devices containing the radioactive material.

[4] If several radionuclides are aggregated, the sum of the ratios of the activity of each source, *i* of radionuclide, *n*, $\mathbf{A}_{(i,n)}$, to the quantity of concern for radionuclide *n*, $\mathbf{Q}_{(n)}$, listed for that radionuclide equals or exceeds one. That is:

$$\sum_{n} \left\{ \sum_{i} \frac{Ai,n}{Q_n} \right\} \geq 1$$

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 regulation that references paragraph (b) shall be deemed to reference paragraph (d).

(b) Definitions. Whenever used in this section, or in federal regulations incorporated herein, the following terms shall have the following meanings:

(1) "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 definition and the training requirements for an authorized medical physicist set forth in 10 CFR §§ 35.2, 35.51 and 35.57; or

(ii) is named as a radiation therapy physicist on a medical use radioactive materials

license issued by the Department and meets the requirements set forth in 10 CFR § 35.59.

(2) "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 in 10 CFR § 35.55(a) and § 35.59; 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.

(3) "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 in 10 CFR §§ 35.59 and 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), or 35.690(a); 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.

(4) "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.

(5) "Positron emission tomography facility" is a facility operating a cyclotron or accelerator for the purpose of producing PET radionuclides.

(6) "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. Further details concerning this referenced code are contained in subdivision (c) of this section.

(7) "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.

(8) "Radiation safety officer" means an individual who:

(i) meets the requirements set forth in 10 CFR §§ 35.50(a) or (c)(1) and 35.59; or

(ii) is identified as a radiation safety officer on a specific medical use license issued by the Nuclear Regulatory Commission or Agreement State or a medical use permit issued by a Nuclear Regulatory Commission master material licensee.

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

(10) "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, with the same force and effect as if fully set forth at length herein: Title 10 of the Code of Federal Regulations, Part 35, Medical Use of Byproduct Material. 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, New York 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 Subpart L (Records) of Part 35 of 10 CFR. 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 Subpart M (Reports) of Part 35 of 10 CFR as revised herein as follows: (i) in § 35.3045(c) and §35.3047(c), replace phrase "NRC Operations Center" with "Department"; (ii) in §35.3045(d) and § 35.3047(d), 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, §36.67, §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 with10 CFR §§ 35.100 and 35.190 and all 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 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 Subpart E (Unsealed Byproduct Material-Written Directive Required) of Part 35 of 10 CFR 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 Subpart F (Manual Brachytherapy) of Part 35 of 10 CFR.

(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 Subpart G (Sealed Sources for Diagnosis) of Part 35 of 10 CFR and other applicable provision of this Part.

(k) Use of sealed source 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 Subpart H (Photon Emitting Remote Afterloader Units, Teletherapy Units and Gamma Stereotactic Radiosurgery Units) of Part 35 of 10 CFR and other applicable provisions of this Part.

(l) 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 paragraphs 1 through 6 of subdivision (b) of this section if the licensee submits to the department information required by 10 CFR §35.12(b) through (d) 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) General Use License. Any licensee who is licensed for one or more of the types of medical uses specified in paragraphs (1) through (6) of subdivision (b) of this section also is authorized to use radioactive material under the general license in Appendix 16-A, Table 6, Item (i) infra, for the

specified "in vitro" uses without filing Form GEN 373 as required by Appendix 16-A, Table 6, Item (i), subdivision (2), infra, provided, however, that the licensee is subject to the other provisions of Appendix 16-A, Table 6, Item (i), infra.

16.130 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 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.

(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(a)(145) 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) 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, New York 12237:

(1) 49 CFR Parts 170 through 189;

(2) 10 CFR Parts 20, 21, 30, 32, 35, 39, 40, 70, 71 and 73;

(3) 21 CFR Part 1020.

(b) Availability of documents. All the Code of Federal Regulations (CFR) documents are available from the Superintendent of Documents, US Government Printing Office, Washington, D.C. 20402.