Rules of the City of New York

Title 24

Department of Health

§175.01 **Applicability and inapplicability, communications.**

(a) *Applicability.* (1) Except as provided in §175.01(b), this Code applies to any person who sells, transfers, assembles, receives, produces, possesses, or uses any radiation source in this City.

(b) *Inapplicability.* (1) This Code does not apply to any person with respect to any radiation source subject to regulation, as provided for by law, by the New York State Department of Labor. This exclusion does not apply to:

(A) the use of such sources in places where the general public may be exposed; or

(B) to persons with respect to radiation sources used at industrial or commercial establishments for the application of radiation to human beings.

(2) This Code does not apply to any common or contract carrier or any shipper operating within this City to the extent that such carrier or shipper is subject to regulation as provided for by law by the U.S. Department of Transportation or other agencies of the United States or agencies of the State or City of New York, except for compliance with provisions relating to transportation of radioactive materials set forth in §175.105.

(3) Foreign military aircraft. - This Code does not apply to persons who carry special nuclear material (other than plutonium) in aircraft of the armed forces of foreign nations subject to 49 U.S.C. 40103(d).

(c) *Communications.* (1) Except as otherwise provided for in this Code, or as authorized by the Department, all applications, notifications, reports or other communications filed pursuant to this Code shall be addressed to the Department at:

Office of Radiological Health, 2 Lafayette Street, 11th Floor New York, New York 10007

§175.02 **Definitions.**

(a) As used in this Code, the following definitions shall apply:

…

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

(9) "Agreement State" means any State with which the U.S. Nuclear Regulatory Commission or the U.S. Atomic Energy Commission has entered into an effective agreement under subsection 274b. of the Atomic Energy Act of 1954, as amended (73 Stat. 689).

…

(14) "Area of use" means a portion of [a physical structure, or a specified out-of-doors location,] an address of use that has been set aside for the purpose of receiving, [producing,] preparing, using, or storing [radioactive] byproduct material.

…

§175. 02(a)(18) "Authorized medical physicist" means an individual who—(a) Meets the requirements in §§175.103(j)(2)(a) and 175.103(j)(15); or, before October 24, 2005, meets the requirements in §§35.961(a), or (b), and 175.103(j)(15); or

(b) Is identified as an authorized medical physicist or teletherapy physicist on—
(i) A specific medical use license issued by the Commission or Agreement State;
(ii) A medical use permit issued by a Commission master material licensee;
(iii) A permit issued by a Commission or Agreement State broad scope medical use licensee; or
(iv) A permit issued by a Commission master material license broad scope medical use permittee.

§175. 02(a) (19) "Authorized nuclear pharmacist" means a pharmacist who-
(a) Meets the requirements in §§175.103(j)(3)(a) and 175.103(j)(15); or
(b) Is identified as an authorized nuclear pharmacist on—
(i) A specific license issued by the Commission or Agreement State that authorizes medical use or the practice of nuclear pharmacy;
(ii) A permit issued by a Commission master material licensee that authorizes medical use or the practice of nuclear pharmacy;
(iii) A permit issued by a Commission or Agreement State broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or
(iv) A permit issued by a Commission master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy; or

(b) Is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or

(c) Is designated as an authorized nuclear pharmacist in accordance with § 32.72(b)(4).

§175.02(a)[(18)](20) "Authorized user" means [an individual] a physician, dentist, or podiatrist who --

(i) Meets the requirements in §§ 175.103(j)(15) and 175.103(j)(4)(a), 175.103(j)(5)(a), 175.103(j)(6)(a), 175.103(j)(7)(a), 175.103(j)(8)(a), 175.103(j)(10)(a), 175.103(j)(15)(a), or 175.103(j)(13)(a); or

(ii) is identified as an authorized user on---

(A) a Department, Agreement State, or U.S. Nuclear Regulatory Commission license that authorizes the use of radioactive material; or

(B) A permit issued by a Commission master material licensee that is authorized to permit the medical use of byproduct material; or

(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; or

(iii) who is named as an authorized user on a certified registration issued by the Department.

...

(27) "Brachytherapy" means a method of radiation therapy in which sealed sources are utilized to deliver a radiation dose at a distance of up to a few centimeters[,] by surface, intracavitary, intraluminal or interstitial application. Brachytherapy includes radiation therapy using electronic remote after-loading devices.

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

…

(42) "Client's address" means the area of use or a temporary job site for the purpose of providing mobile medical service in accordance with § 175.103(c)(12).

...

(45) "Commission" means the United States Nuclear Regulatory Commission.

...

(57) "Dedicated check source" means a [radiation] radioactive source that is used to assure the constant operation of a radiation detection or measurement device over several months or years.

…

(59) "Dentist" means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice dentistry.

…

(99) "High dose-rate remote afterloader" as used in this Code, means a brachytherapy device that remotely delivers a dose rate in excess of 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

…

(122) "Low dose-rate remote afterloader" as used in this Code, means a brachytherapy device that remotely delivers a dose rate of less than or equal to 2 gray (200 rads) per hour at the point or surface where the dose is prescribed.

…

(126) "Management" means the chief executive officer or [that individual's designee or designees.] other individual having the authority to manage, direct, or administer the licensee's activities, or those persons' delegate or delegates.

(127) "Manual brachytherapy" as used in this Code, means a type of brachytherapy in which the brachytherapy sources (e.g., seeds, ribbons) are manually placed topically

on or inserted either into the body cavities that are in close proximity to a treatment site or directly into the tissue volume.

(128) Medical event means an event that meets the criteria in §175.03(l)(8)(a) or (b).

[(132) "Medical misadministration" means the administration of:

(i) a radiopharmaceutical, radiobiologic or radiation from a source other than the one ordered;

(ii) a radiopharmaceutical, radiobiologic or radiation to the wrong person;

(iii) a radiopharmaceutical, radiobiologic or radiation by a route of administration, or to a part of the body, other than that in the order of the prescribing physician;

(iv) an activity of a diagnostic radiopharmaceutical or radiobiologic differing from the prescribed activity by more than 50 percent;

(v) an activity of a therapeutic radiopharmaceutical or radiobiologic differing from the prescribed activity by more than 10 percent;

(vi) a therapeutic radiation dose from any source other than a radiopharmaceutical, radiobiologic 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 prescribed total treatment dose ordered by more than 10 percent;

(vii) 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

(viii) 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.]

(130) "Medical use" means the intentional internal or external administration of radiation[to humans in the practice of the healing arts in accordance with a license issued by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.], byproduct material or the radiation from byproduct material to patients or human research subjects under the supervision of an authorized user. For purposes of this Code, "human use" is an equivalent term.

(131) "Medium dose-rate remote afterloader" as used in this Code, means a brachytherapy device that remotely delivers a dose rate of greater than 2 gray (200 rads) per hour, but less than or equal to 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

…

(134) "Mobile medical service" means the transportation of byproduct material to and its medical use at the client's address.

(143) "Output" means the exposure rate, dose rate, or a quantity related in a known manner to these rates [of ionizing radiation from an external beam therapy] from a brachytherapy source or a teletherapy, remote afterloader, or gamma stereotactic radiosurgery unit for a specified set of exposure conditions.

(146) " Patient intervention " means actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration.

…

(151) "Pharmacist" means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice pharmacy.

(152) "Physician" means a medical doctor or doctor of osteopathy licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine.

(152) "Podiatrist" means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice podiatry.

(153) "Preceptor" means an individual who provides, directs, or verifies training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, or a Radiation Safety Officer.

(154) Prescribed dosage means the specified activity or range of activity of unsealed byproduct material as documented--

(i) In a written directive; or

(ii) In accordance with the directions of the authorized user for procedures performed pursuant to §§ 175.103(d)(1) and 175.103(d)(2).

(155) 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.

…

(161) "Pulsed dose-rate remote afterloader", as used in this Code, means a special type of remote afterloading brachytherapy device that uses a single source capable of delivering dose rates in the "high dose-rate" range, but—

(i) Is approximately one-tenth of the activity of typical high dose-rate remote afterloader sources; and

(ii) Is used to simulate the radiobiology of a low dose-rate treatment by inserting the source for a given fraction of each hour.

…

[(174) "Radiation safety officer" means an individual who, under the authorization of the operator of a radiation installation, administers a radiation protection program in accordance with §175.03 of this Code 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.]

(174) "Radiation safety officer" means an individual who —

(1) Meets the requirements in §§ 175.103(j)(1)(a) or (c)(1) and 175.103(j)(15); or

(2) Is identified as a Radiation Safety Officer on--

(i) A specific medical use license issued by the Department, the Commission or Agreement State; or

(ii) A medical use permit issued by a Commission master material licensee.

…

…

(198) ["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.]

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

(199) Sealed Source and Device Registry means the national registry that contains all the registration certificates, generated by both NRC and the Agreement States, that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product.

…

(216) "Stereotactic radiosurgery" means the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a therapeutic dose to a tissue volume.

…

(217) "Structured educational program" means an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.

…

(218) "Supervision" means:

(i) for radioactive materials licenses which do not authorize human use, the training of persons in the use of radioactive materials in other than medical procedures. Such training shall include at least thirty (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; and

(ii) for radioactive materials licenses which do authorize human use[,]

(A) the training of a physician in the use of radioactive materials in the clinical treatment or diagnosis of disease. Such training shall provide that specified in [§175.102(j)] §175.103(j), as applicable.

(B) the oversight of a licensed radiologic technologist by a licensed practioner acting within the limits specified in the law under which the practioner is licensed.

(iii) "Direct supervision" means a physician must be present in the section of the facility where the procedure is being performed and is not concurrently encumbered by responsibilities that would preclude the physician from responding to a request for assistance within a timeframe that poses no risk to the patient. The physician shall be immediately available to furnish assistance and direction throughout the performance of the procedure, and is professionally responsible for the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed.

(iv) "Personal supervision" means the physician must be in attendance in the room during the performance of the procedure.

(220) "Teletherapy", as used in this Code, means a method of radiation therapy [utilized to deliver a radiation dose] in which the source (sources) of radiation is (are)] collimated gamma rays are delivered at a distance from the [body] patient or human research subject. For the purposes of this Code "external beam radiation therapy" is an equivalent term.

(222) "Temporary job site" means a location where mobile medical services are conducted other than those location(s) of use authorized on the license.

…

(223) "Therapeutic dosage" means a dosage of unsealed byproduct material that is intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.

(223) "Therapeutic dose" means a radiation dose delivered from a source containing byproduct material to a patient or human research subject for palliative or curative treatment.

…

(229) "Treatment site" means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

…

(235) "Type of use" means use of byproduct material under §§10CFR 35.100{§175.103(d)(1)}; 35.200{§175.103(d)(2)}; 35.300{§175.103(e)}; 35.400{§175.103(f)}; 35.500{§175.103(g)}; 35.600{§175.103(h)}; or 35.1000{§175.103(i)(1)}.

(236) "Unit dosage" means a dosage prepared for medical use for administration as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared.

…

(252) "Written directive" means an authorized user's written order for the administration of byproduct material or radiation from byproduct material to a specific patient or human research subject, as specified in § 175.103(b)(4).

…

§175.03 **Standards for protection against radiation.**

…

(b) *Radiation protection programs.* (1) *Radiation Protection Programs.*

…

(2) Radiation protection program changes.

(a) A licensee may revise its radiation protection program without Departmental approval if--

(1) The revision does not require a license amendment under § 175.103(a)(7);

(2) The revision is in compliance with the regulations and the license ;

(3) The revision has been reviewed and approved by the Radiation Safety Officer and licensee management; and

(4) The affected individuals are instructed on the revised program before the changes are implemented.

(b) A licensee shall retain a record of each change in accordance with § 175.03(k)(4).

…

[(2)] (3) *Radiation safety officer.* The radiation safety officer specified in §175.03(b)(1)(iii) shall be:

(i) For human use radiation equipment installations:

(A) a physicist certified by the American Board of Health Physics, the American Board of Radiology or the American Board of Medical Physics in a branch of physics related to the type of use of radiation sources in the installation; or

(B) a person satisfying the radiation safety officer qualifications set forth in §175.103(j) of this Code; or

(C) a professional practitioner as defined in §175.02(a)(157), practicing within such person's professional practice as defined in §175.02(a)(156).

(ii) For human use radiation equipment installations requiring a certified registration pursuant to §175.64:

(A) a physicist certified by the American Board of Health Physics, the American Board of Radiology or the American Board of Medical Physics in a branch of physics related to the type of use of radiation sources in the installation; or

(B) a person satisfying the radiation safety officer qualifications set forth in §175.103(j) of this Code; or

(C) an authorized user named on the facility's certified registration issued by the Department.

(iii) For non-human use radiation equipment installations:

(A) a veterinarian for veterinary installations; or

(B) a physicist certified by the American Board of Health Physics, the American Board of Radiology or the American Board of Medical Physics; or

(C) a person with equivalent training and experience as determined by the Department; or

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

(iv) For non-human use radioactive materials installations:

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

(B) a person with equivalent training and experience as determined by the Department; or

(C) an authorized user named on the radioactive materials license issued by the Department.

…

…

(e) *Testing for leakage or contamination of sealed sources.*

(1) *Testing for leakage or contamination of sealed sources.* (i) The licensee or registrant in possession of any sealed source shall assure that:

(A) each sealed source, except as specified in §175.03(e)(1)(ii), is tested for leakage or contamination and the test results are received before the sealed source is put into use unless the licensee or registrant has a certificate from the transferor indicating that the sealed source was tested within 6 months before transfer to the licensee or registrant; and

…

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

(A) The presence of 185 Bq (0.005 [m]μCi) or more of removable contamination on any test sample.

(B) Leakage of 37 Bq (0.001 [m]μCi) of radon-222 per 24 hours for brachytherapy sources manufactured to contain radium.

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

(D) Leakage of 185 Bq (0.005 [m]μCi) of iodine-125 per 24 hours for sealed sources containing iodine-125.

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

(vii) Reports of test results for leaking or contaminated sealed sources shall be made pursuant to §175.03(l)(7).

…

§175.03(k) *Records.* (1) *General provisions.* (i) Each licensee or registrant shall use SI units (becquerel, gray, sievert and coulomb per kilogram) or special units (curie, rad, rem and roentgen) including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by this Code.

(ii) The licensee or registrant shall make a clear distinction between the quantities entered on the records required by this section, such as, total effective dose equivalent, total organ dose equivalent, shallow dose equivalent, eye dose equivalent, deep dose equivalent, or committed effective dose equivalent.

(2) *Records of radiation protection programs.* (i) Each licensee or registrant shall maintain records of the radiation protection program, including:

(A) the provisions of the program; and

(B) audits and other reviews of program content and implementation.

(ii) The licensee or registrant shall retain the records required by §175.03(k)(2)(i)(A) until the Department terminates each pertinent license, certified registration or registration requiring the record. The licensee or registrant shall retain the records required by §175.03(k)(2)(i)(B) for 3 years after the record is made.

(3) Records of authority and responsibilities for radiation protection programs.

(a) A licensee shall retain a record of actions taken by the licensee's management in accordance with § 175.103(b)(2)(a) for 5 years. The record must include a summary of the actions taken and a signature of licensee management.

(b) The licensee shall retain a copy of both authority, duties, and responsibilities of the Radiation Safety Officer as required by § 175.103(b)(2)(e), and a signed copy of each Radiation Safety Officer's agreement to be responsible for implementing the radiation safety program, as required by § 175.103(b)(2)(b), for the of the license. The records must include the signature of the Radiation Safety Officer and licensee management.

(4) Records of radiation protection program changes.

A licensee shall retain a record of each radiation protection program change made in accordance with § 175.03(b)(2)(a) for 5 years. The record must include a copy of the old and new procedures; the effective date of the change; and the signature of the licensee management that reviewed and approved the change.

[(3)](5) *Records of receipt, use and disposition of radioactive material.* (i) Each licensee shall maintain records of the receipt, use and disposition of radioactive material in units of becquerels or microcuries

and shall include from whom such materials were received and the ultimate disposition.

(ii) The licensee shall retain the records required by §175.03(k)(3)(i) for 3 years after the record is made.

[(4)](6) *Records of surveys.* (i) Each licensee or registrant shall maintain records showing the results of surveys and calibrations required by §175.03(f) and §175.03(j)(6)(ii). The licensee or registrant shall retain these records for 3 years after the record is made.

…

[(6)](7) *Records of prior occupational dose.* (i) The licensee or registrant shall retain the records of prior occupational dose and exposure history as specified in §175.03(c)(5) on form RAD-4, "Cumulative Occupational Radiation Exposure History" or equivalent, and the records used in preparing form RAD-4 until the Department authorizes their disposition.

…

[(7)](8) *Records of planned special exposures.* (i) For each use of the provisions of §175.03(c)(6) for planned special exposures, the licensee or registrant shall maintain records that describe:

…

[(8)](9) *Records of individual monitoring results.* (i) Recordkeeping Requirement. Each licensee or registrant shall maintain records of doses received by all individuals for whom monitoring was required pursuant to §175.03(f)(2), 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 these requirements need not be changed. These records shall include, when applicable:

…

[(9)](10) *Records of dose to individual members of the public.* (i) Each licensee or registrant shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public as specified in §175.03(d).

…

[(10)](11) *Records of testing entry control devices for very high radiation areas.*

(i) Each licensee or registrant shall maintain records of tests made pursuant to §175.03(g)(3)(ii)(I) on entry control devices for very high radiation areas. These records must include the date, time, and results of each such test of function.

…

(12) Records of written directives.

A licensee shall retain a copy of each written directive as required by § 175.103(b)(4) for 3 years.

(13) Records for procedures for administrations requiring a written directive.

A licensee shall retain a copy of the procedures required by § 175.103(b)(5)(a) for the duration of the license.

(14) Records of calibrations of instruments used to measure the activity of unsealed byproduct material.

A licensee shall maintain a record of instrument calibrations required by § 175.103(c)(2) for 3 years. The records must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

(15) Records of radiation survey instrument calibrations.

A licensee shall maintain a record of radiation survey instrument calibrations required by § 175.103(c)(3) for 3 years. The record must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

(16) Records of dosages of unsealed byproduct material for medical use.

(a) A licensee shall maintain a record of dosage determinations required by § 175.103(c)(4) for 3 years.

(b) The record must contain--

(1) The radiopharmaceutical, generic name, trade name, or abbreviation of the radiopharmaceutical, its lot number, and expiration dates and the radionuclide;

(2) The patient's or human research subject's name, or identification number if one has been assigned;

(3) The prescribed dosage, the determined dosage, or a notation that the total activity is less than 1.1 MBq (30 µCi);

(4) The date and time of the dosage determination; and

(5) The name of the individual who determined the dosage

(17) Records of tests for leakage or contamination and inventory of sealed sources and brachytherapy sources.

[(a) Records of tests for leakage or contamination of sealed sources required by §175.03(e)(1) shall be kept in units of becquerel or microcurie and maintained for inspection by the Department for 5 years after the records are made.] (a) A licensee shall retain records of leak tests required by §175.03(e)(1) and § 175.103(c)(6)(b) for inspection by the Department for 5 years after the records are made. The records must include the model number, and serial number if one has been assigned,

of each source tested; the identity of each source by radionuclide and its estimated activity; the results of the test in units of becquerel or microcurie; the date of the test; and the name of the individual who performed the test.

(b) A licensee shall retain records of the semi-annual physical inventory of sealed sources and brachytherapy sources required by § 175.103(c)(6)(g) for 5 years. The inventory records must contain the model number of each source, and serial number if one has been assigned, the identity of each source by radionuclide and its nominal activity, the location of each source, and the name of the individual who performed the inventory.

(18) Records of surveys for ambient radiation exposure rate.

A licensee shall retain a record of each survey required by § 175.103(c)(8) for 3 years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

(19) Records of the release of individuals containing unsealed byproduct material or implants containing byproduct material.

(a) A licensee shall retain a record of the basis for authorizing the release of an individual in accordance with § 103(c)(9), if the total effective dose equivalent is calculated by--

(1) Using the retained activity rather than the activity administered;

(2) Using an occupancy factor less than 0.25 at 1 meter;

(3) Using the biological or effective half-life; or

(4) Considering the shielding by tissue.

(b) A licensee shall retain a record that the instructions required by § 103(c)(9)(b) were provided to a breast-feeding female if the radiation

dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 5 mSv (0.5 rem).

(c) The records required by paragraphs (a) and (b) of this section must be retained for 3 years after the date of release of the individual.

(20) Records of mobile medical services.

(a) A licensee shall retain a copy of each letter that permits the use of byproduct material at a client's address, as required by § 175.103(c)(12)(a)(1). Each letter must clearly delineate the authority and responsibility of the licensee and the client and must be retained for 3 years after the last provision of service.

(b) A licensee shall retain the record of each survey required by § 175.103(c)(12)(a)(4) for 3 years. The record must include the date of the survey, the results of the survey, the model and serial number of the instrument used to make the survey, and the name of the individual who performed the survey.

(21) Records of decay-in-storage.

A licensee shall maintain records of the disposal of licensed materials, as required by § 103(c)(11), for 3 years. The record must include the date the radioactive material was placed in storage, the date of the disposal, the model and serial number of the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the survey.

(22) Records of molybdenum-99, strontium-82, and strontium-85 concentrations.

A licensee shall maintain a record of the molybdenum-99 concentration or strontium-82 and strontium-85 concentration tests required by § 175.103(d)(3)(b) and (c) for 3 years. The record must include:

(a) For each measured elution of technetium-99m, the ratio of the measures expressed as kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (or microcuries of molybdenum per millicurie of technetium), the time and date of the measurement, and the name of the individual who made the measurement; or

(b) For each measured elution of rubidium-82, the ratio of the measures expressed as kilobecquerel of strontium-82 per megabecquerel of rubidium-82 (or microcuries of strontium-82 per millicurie of rubidium), kilobecquerel of
strontium-85 per megabecquerel of rubidium-82 (or microcuries of strontium-85 per millicurie of rubidium), the time and date of the measurement, and the name of the individual who made the measurement.

(23) Records of safety instruction.

A licensee shall maintain a record of safety instructions required by §§ 175.103(e)(2), 175.103(f)(4), and 175.103(h)(5) for 3 years. The record must include a list of the topics covered, the date of the instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

(24) Records of surveys after source implant and removal.

A licensee shall maintain a record of the surveys required by §§ 175.103(f)(2) and 175.103(h)(2) for 3 years. Each record must include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey.

(25) Records of brachytherapy source accountability.

(a) A licensee shall maintain a record of brachytherapy source accountability required by § 175.103(f)(3) for 3 years.

(b) For temporary implants, the record must include--

(1) The number and activity of sources removed from storage, the time and date they were removed from storage, the name of the individual who removed them from storage, and the location of use; and

(2) The number and activity of sources returned to storage, the time and date they were returned to storage, and the name of the individual who returned them to storage.

(c) For permanent implants, the record must include--

(1) The number and activity of sources removed from storage, the date they were removed from storage, and the name of the individual who removed them from storage;

(2) The number and activity of sources not implanted, the date they were returned to storage, and the name of the individual who returned them to storage; and

(3) The number and activity of sources permanently implanted in the patient or human research subject.

(26) Records of calibration measurements of brachytherapy sources.

(a) A licensee shall maintain a record of the calibrations of brachytherapy sources required by § 175.103(f)(7) for 3 years after the last use of the source.

(b) The record must include—

(1) The date of the calibration;

(2) The manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source;

(3) The source output or activity;

(4) The source positioning accuracy within the applicators; and

(5) The name of the individual, the source manufacturer, or the calibration laboratory that performed the calibration.

(27) Records of decay of strontium-90 sources for ophthalmic treatments.

(a) A licensee shall maintain a record of the activity of a strontium-90 source required by § 175.103(f)(8) for the life of the source.

(b) The record must include--

(1) The date and initial activity of the source as determined under § 175.103(f)(7); and

(2) For each decay calculation, the date and the source activity as determined under § 175.103(f)(8).

(28)Records of installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units as required by § 175.103(h)(3) for the duration of the license. For each installation, maintenance, adjustment and repair, the record must include the date and description of the service, and name(s) and license number(s) of the individual(s) who performed the work. For teletherapy unit source exchanges, the manufacturer's name, model number and serial number for both the teletherapy unit and source shall be recorded.

(29) Records of safety procedures

A licensee shall retain a copy of the procedures required by §§ 175.103(h)(5)(a)(4) and (d)(2) until the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery unit..

(30) Records of dosimetry equipment used with remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

(a) A licensee shall retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment done in accordance with § 175.103(h)(8) for the duration of the license.

(b) For each calibration, intercomparison, or comparison, the record must include--

(1) The date;

(2) The manufacturer's name, model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by paragraphs (a) and (b) of § 175.103(h)(8);

(3) The correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison; and

(4) The names of the individuals who performed the calibration, intercomparison, or comparison

(5) and evidence that the intercomparison meeting was sanctioned by a calibration laboratory or radiologic physics center accredited by AAPM.

(31) Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations.

(a) A licensee shall maintain a record of the teletherapy unit, remote afterloader unit, and gamma stereotactic radiosurgery unit full calibrations required by §§ 175.103(h)(9), 175.103(h)(10), and 175.103(h)(11) for 3 years.

(b) The record must include--

(1) The date of the calibration;

(2) The manufacturer's name, model number, and serial number of the teletherapy, remote afterloader, and gamma stereotactic radiosurgery unit(s), the source(s), and the instruments used to calibrate the unit(s);

(3) The results and an assessment of the full calibrations;

(4) The results of the autoradiograph required for low dose-rate remote afterloader units; and

(5) The signature of the authorized medical physicist who performed the full calibration.

(32) Records of periodic spot-checks for teletherapy units.

(a) A licensee shall retain a record of each periodic spot-check for teletherapy units required by § 175.103(h)(12) for 3 years.

(b) The record must include--

(1) The date of the spot-check;

(2) The manufacturer's name, model number, and serial number of the teletherapy unit, source and instrument used to measure the output of the teletherapy unit;

(3) An assessment of timer linearity and constancy;

(4) The calculated on-off error;

(5) A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;

(6) The determined accuracy of each distance measuring and localization device;

(7) The difference between the anticipated output and the measured output;

(8) Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each source exposure indicator light, and the viewing and intercom system and doors; and

(9) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(c) A licensee shall retain a copy of the procedures required by § 175.103(h)(12)(b) until the licensee no longer possesses the teletherapy unit.

(33) Records of periodic spot-checks for remote afterloader units.

(a) A licensee shall retain a record of each spot-check for remote afterloader units required by § 175.103(h)(13) for 3 years.

(b) The record must include, as applicable--

(1) The date of the spot-check;

(2) The manufacturer's name, model number, and serial number for the remote afterloader unit and source;

(3) An assessment of timer accuracy;

(4) Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, and clock and decayed source activity in the unit's computer; and

(5) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(c) A licensee shall retain a copy of the procedures required by § 175.103(h)(13)(b) until the licensee no longer possesses the remote afterloader unit.

(34) Records of periodic spot-checks for gamma stereotactic radiosurgery units.

(a) A licensee shall retain a record of each spot-check for gamma stereotactic radiosurgery units required by § 175.103(h)(14) for 3 years.

(b) The record must include--

(1) The date of the spot-check;

(2) The manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit;

(3) An assessment of timer linearity and accuracy;

(4) The calculated on-off error;

(5) A determination of trunnion centricity;

(6) The difference between the anticipated output and the measured output;

(7) An assessment of source output against computer calculations;

(8) Notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, and stereotactic frames and localizing devices (trunnions); and

(9) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(c) A licensee shall retain a copy of the procedures required by § 175.103(h)(14)(b) until the licensee no longer possesses the gamma stereotactic radiosurgery unit.

(35) Records of additional technical requirements for mobile remote afterloader units.

(a) A licensee shall retain a record of each check for mobile remote afterloader units required by § 175.103(h)(15) for 3 years.

(b) The record must include--

(1) The date of the check;

(2) The manufacturer's name, model number, and serial number of the remote afterloader unit;

(3) Notations accounting for all sources before the licensee departs from a facility;

(4) Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators, source transfer tubes, and transfer tube applicator interfaces, and source positioning accuracy; and

(5) The signature of the individual who performed the check.

(36) Records of surveys of therapeutic treatment units.

(a) A licensee shall maintain a record of radiation surveys of treatment units made in accordance with § 175.103(h)(16) for the duration of use of the unit.

(b) The record must include--

(1) The date of the measurements;

(2) The manufacturer's name, model number and serial number of the treatment unit, source, and instrument used to measure radiation levels;

(3) Each dose rate measured around the source while the unit is in the off position and the average of all measurements; and

(4) The signature of the individual who performed the test.

(37) Records of 5-year inspection for teletherapy and gamma stereotactic radiosurgery units.

(a) A licensee shall maintain a record of the 5-year inspections for teletherapy and gamma stereotactic radiosurgery units required by § 175.103(h)(19) for the duration of use of the unit.

(b) The record must contain--

(1) The inspector's radioactive materials license number;

(2) The date of inspection;

(3) The manufacturer's name and model number and serial number of both the treatment unit and source;

(4) A list of components inspected and serviced, and the type of service; and

(5) The signature of the inspector.

(38) Maintenance of records.

(i) Each record required by this section must be legible throughout the retention period specified by each Departmental regulation. The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy

throughout the required retention period. 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, specifications, must include all pertinent information such as stamps, initials, and signatures.

(ii) The licensee shall maintain adequate safeguards against tampering with and loss of records.

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

(l) *Reports.* (1) *Reports of stolen, lost, or missing licensed or registered sources of radiation.* (i) *Telephone reports.* Each licensee or registrant shall report to the Department by telephone as follows:

…

(7)[(8)] *Event reporting.* (i) *Immediate report.* Each licensee or registrant shall notify the Department as soon as possible, but not later than four (4) hours, after the discovery of an event that prevents immediate preventive actions necessary to avoid exposures to radiation or radioactive material that could exceed regulatory limits or releases of licensed material that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, *etc.*).

…

(8) Report and notification of a medical event.

(a) A licensee shall report any event, except for an event that results from patient intervention, --

(1) in which the administration of byproduct material or radiation from byproduct material results in a dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an

organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and

(i) The total dose delivered differs from the prescribed dose by 20 percent or more;

(ii) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

(iii) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

(2) in which the administration of byproduct material or radiation from byproduct material results in a dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following--

(i) An administration of a wrong radioactive drug containing byproduct material;

(ii) An administration of a radioactive drug containing byproduct material by the wrong route of administration;

(iii) An administration of a dose or dosage to the wrong individual or human research subject;

(iv) An administration of a dose or dosage delivered by the wrong mode of treatment; or

(v) A leaking sealed source.

(3) in which the administration of byproduct material or radiation from byproduct material results in a dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

(4) in which a therapeutic radiation dose in any fraction of a fractionated treatment is 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.

(i) a licensee/certified registrant shall be required to make a record of, but not report, as described in §175.07(e), a therapeutic radiation dose from any source other than a radiopharmaceutical, radiobiologic 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 prescribed total treatment dose ordered by more than 10 percent.

(b) A licensee/certified registrant shall report any event resulting from intervention of a patient or human research subject in which the administration of radiation, byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

(c) The licensee/certified registrant shall notify by telephone the Department no later than the next calendar day after discovery of the medical event.

(d) The licensee/certified registrant shall submit a written report to the Department within 15 days after discovery of the medical event.

(1) The written report must include--

(i) The licensee's/certified registrant's name;

(ii) The name of the prescribing physician;

(iii) A brief description of the event;

(iv) Why the event occurred;

(v) The effect, if any, on the individual(s) who received the administration;

(vi) What actions, if any, have been taken or are planned to prevent recurrence; and

(vii) Certification that the licensee/certified registrant notified the individual (or the individual's responsible relative or guardian), and if not, why not.

(2) The report may not contain the individual's name or any other information that could lead to identification of the individual.

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

(f) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees/certified registrants and

physicians in relation to each other, to individuals affected by the medical event, or to that individual's responsible relatives or guardians.

(g) A licensee/certified registrant shall:

(1) Annotate a copy of the report provided to the Department with the:

(i) Name of the individual who is the subject of the event; and

(ii) Social security number or other identification number, if one has been assigned, of the individual who is the subject of the event; and

(2) Provide a copy of the annotated report to the referring physician, if other than the licensee/certified registrant, no later than 15 days after the discovery of the event.

(h) Records and reports of medical events.

(1) Diagnostic medical events.

(i) Records of medical events which involve diagnostic procedures and the corrective actions taken pursuant to §175.07(b)(1)(ix) shall be retained for three (3) years; and

(ii) if such a medical event results in a dose to the patient exceeding 50 millisieverts (5 rem) to the whole body or 500 millisieverts (50 rem) to any individual organ, or involves the administration of iodine-125 or iodine-131 in the form of iodide in a quantity greater than 1 megabecquerel (30 microcuries), the licensee or registrant shall notify the Department in writing within fifteen (15) days and make and retain a record for six (6) years.

(2) Therapy medical events.

(i) When a medical events described in §175.02(a) (129)(v), (vi) or (vii), in which the percentage of error is equal to or less than 20 percent is discovered, the licensee or registrant shall immediately investigate the cause and take corrective action; and

(ii) the licensee or registrant shall make and retain a record of all therapy misadministrations described in §175.07(e)(2). The record shall contain all the information required by §175.07(e)(3) and shall be retained for six (6) years.

(9) Report and notification of a dose to an embryo/fetus or a nursing child.

(a) A licensee shall report any dose to an embryo/fetus that is greater than 50 mSv (5 rem) dose equivalent that is a result of an administration of byproduct material or radiation from byproduct material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.

(b) A licensee shall report any dose to a nursing child that is a result of an administration of byproduct material to a breast-feeding individual that--

(1) Is greater than 50 mSv (5 rem) total effective dose equivalent; or

(2) Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

(c) The licensee shall notify by telephone the Department no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in paragraphs (a) or (b) in this section.

(d) The licensee shall submit a written report to the Department within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in paragraphs (a) or (b) in this section.

(1) The written report must include--

(i) The licensee's name;

(ii) The name of the prescribing physician;

(iii) A brief description of the event;

(iv) Why the event occurred;

(v) The effect, if any, on the embryo/fetus or the nursing child;

(vi) What actions, if any, have been taken or are planned to prevent recurrence; and

(vii) Certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.

(2) The report must not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

(e) The licensee shall provide notification of the event to the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of an event that would require reporting under paragraph (a) or (b) of this section, unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this paragraph, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(f) A licensee shall:

(1) Annotate a copy of the report provided to the Department with the:

(i) Name of the pregnant individual or the nursing child who is the subject of the event; and

(ii) Social security number or other identification number, if one has been assigned, of the pregnant individual or the nursing child who is the subject of the event; and

(2) Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

(10) Report of a leaking source.

[A licensee or registrant shall file a report within five (5) days with the Department if the test for leakage or contamination required pursuant to §175.03(e)(1)]

A licensee shall file a report with the Department within 5 days if a leak test required by § 175.103(c)(6) reveals the presence of 185 Bq (0.005 µCi) or more of removable contamination. The written report must include the model number and serial number, if assigned, of the leaking source; the radionuclide and its estimated activity; the results of the test; the date of the test; and the action taken.

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

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§175.04 **Notices, instructions and reports to workers; inspections.**

…

§175.04(d) *Notification and reports to workers.* (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 herein. The information reported shall include data and results obtained pursuant to this Code or license or certified registration conditions as shown in records maintained by the licensee and/or registrant pursuant to §175.03(k)[(8)](9) of this Code. Each notification and report shall:

(i) be in writing;

(ii) include appropriate identifying data such as the name of the licensee and/or registrant, the name of the individual and the individual's social security number;

(iii) include the individual's exposure information; and

(iv) contain the following statement: "This report is furnished to you under the provisions of §175.04 of the New York City Health Code. You should preserve this report for further reference."

(2) Each licensee and/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 and/or registrant pursuant to §175.03(k)[(8)](9).

…

§175.06 **Professional practitioners and related provisions.**

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§175.07 **Quality assurance programs [and misadministration records and reports].**

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§175.07(c) *External beam and brachytherapy.* A quality assurance program for external beam therapy and brachytherapy is a system of plans, actions, reviews, reports and records, the purpose of which is to ensure a consistent and safe fulfillment of the dose prescription to the target volume, with minimal dose to normal tissue.

(1) Each licensee or registrant who uses external beam therapy and/or brachytherapy in humans shall implement a quality assurance program which includes at a minimum: (i) the adoption of a quality assurance manual containing written policies and procedures designed to ensure effective supervision, safety, proper performance of equipment, effective communication and quality control. These must include policies and procedures to ensure that:

…

(I) final plans of treatment and related calculations are checked for accuracy before 25 percent of the prescribed dose for external beam therapy or 50 percent of the prescribed dose for brachytherapy is administered. If a treatment plan and related calculations were originally prepared by [a radiation therapy] <u>an authorized medical</u> physicist possessing the qualifications specified in §175.64(c)(2) or §175.103(j)(2), it may be checked by the same person using a different calculational method. Treatment plans and related calculations prepared by all other personnel must be checked by a second person using procedures specified in the treatment planning procedures manual required pursuant to §175.07(c)(2), and who has received training in the use of such manual;

…

§175.07(c)(2) Each licensee or registrant shall ensure that [a radiation therapy] <u>an authorized medical</u> physicist possessing the qualifications specified in §175.64(c)(2) or §175.103(j)(2), prepares a procedures manual describing how radiation therapy treatment planning is to be performed at the licensee's or registrant's facility. The treatment planning manual may be part of the quality assurance manual required by

§175.07(c)(1) and shall include 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 by §175.07(c)(1). The treatment planning manual shall be reviewed annually by [a radiation therapy] an authorized medical physicist and shall be included in training given pursuant to §175.04(c) of this Code to facility staff who will participate in treatment planning.

…

§175.07(c)(4) Each licensee or registrant shall implement procedures for auditing the effectiveness of the radiation therapy quality assurance program as specified below. Audit procedures must specify either that:

(i) external audits will be conducted at intervals not to exceed twelve (12) months by [radiation therapy] authorized medical physicists possessing the qualifications specified in §175.64(c)(2) or §175.103(j)(2) and by physicians who are active in the practice of the type of radiation therapy conducted by the licensee or registrant. These shall be individuals who are not involved in the therapy program being audited; and

…

§175.07(d)[*Therapy with radiopharmaceuticals and/or radiobiologics.*] *Usealed byproduct material for which a written directive is required.* A quality assurance program for [radiopharmaceutical/radiobiologic therapy] unsealed byproduct material for which a written directive is required is a system of plans, actions, reviews, reports and records, the purpose of which is to ensure a consistent and safe fulfillment of the dose prescription.

(1) Each licensee who uses [radiopharmaceuticals and/or radiobiologics for therapy] unsealed byproduct material for which a written directive is required 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;

…

(F) each patient's response to treatment is assessed by an authorized user physician, or a physician under the supervision of an authorized user physician, for [radiopharmaceutical/radiobiologic therapy] unsealed byproduct material for which a written directive is required and that unusual responses are evaluated as possible indications of treatment errors; and

…

(2) Each licensee shall ensure that all equipment used in planning and administering [radiopharmaceutical/radiobiologic therapy] unsealed byproduct material for which a written directive is required is designed and used 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's or registrant's quality assurance manual.

(3) Each licensee shall audit the [radiopharmaceutical/radiobiologic] unsealed byproduct material for which a written directive is required quality assurance program at intervals not to exceed twelve (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.

[§175.07(e) *Records and reports of misadministrations* (1) *Diagnostic misadministrations.*

(i) Records of misadministrations as defined in §175.02(a)(129) of this Code which involve diagnostic procedures and the corrective actions taken pursuant to §175.07(b)(1)(ix) shall be retained for three (3) years; and

(ii) if such a misadministration results in a dose to the patient exceeding 50 millisieverts (5 rem) to the whole body or 500 millisieverts (50 rem) to any individual organ, or involves the administration of iodine-125 or iodine-131 in the form of iodide in a quantity greater than 1 megabecquerel (30 microcuries), the licensee or registrant shall notify the Department in writing within fifteen (15) days and make and retain a record pursuant to §175.07(e)(3).

(2) *Therapy misadministrations.* (i) When a misadministration described in §175.02(a) (129)(v), (vi) or (vii), in which the percentage of error is equal to or less than 20 percent is discovered, the licensee or registrant shall immediately investigate the cause and take corrective action; and

(A) the licensee or registrant shall make and retain a record of all therapy misadministrations described in §175.07(e)(2). The record shall contain all the information required by §175.07(e)(3) and shall be retained for six (6) years.

(ii) When a therapy misadministration described in 175.02(a)(129)(i), (ii), (iii) or (viii) is discovered, or when a misadministration described in §175.02(a)(129)(v), (vi) or (vii) is discovered in which the percentage of error is greater than 20 percent, the licensee or registrant shall notify the Department by telephone within 24 hours. The licensee or registrant shall also notify the referring physician of the affected patient and the patient of any therapy misadministration described herein, with the exception of the misadministration defined in §175.02(a)(129)(viii). 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 seven (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 required by §175.07(e)(3) and whether the licensee or registrant notified the patient or the patient's responsible relative or guardian. This reporting requirement may be satisfied by submitting to the Department a copy of the incident report filed with the New York State Department of Health pursuant to 10 NYCRR Part 405 provided, however, that such report contains all information required by this Code.

(3) Each licensee or registrant shall maintain a record of each reportable diagnostic misadministration and each therapy misadministration for six (6) years. The record shall 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 description of the event, the effect on the patient (including sequelae, prognosis and follow-up actions) and actions taken to prevent recurrence.

(4) Within seven (7) days after an initial therapy misadministration report made pursuant to §175.07(e)(2)(ii), 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 from 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. Such action shall be documented in the patient's treatment record.]

…

§175.53 **Prohibited uses and activities.**

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§175.55 **Compliance with federal standards and precedence thereof.**

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§175.64 **Therapeutic radiation machines.**

(a) *Purpose and scope.* (1) This section establishes requirements for the use of radiation machines used for therapeutic purposes in the healing arts to protect public health and safety and for which the registrant is responsible. The requirements of this section are in addition to, and not in substitution for, other applicable provisions of this Code. Except as specifically provided otherwise in this section, the requirements of this section are applicable to all therapeutic radiation machines used in the City of New York for the treatment of humans, regardless of the date of installation.

(b) *Certified registration for therapeutic radiation machines.* (1) *Certified registration required.*

(i) Section 175.64(b) applies only to therapeutic radiation machines subject to the requirements of §175.64(g) of this Code.

(ii) All new facilities with therapeutic radiation machines subject to the requirements of §175.64(g) of this Code, and all such existing

facilities not holding a certified registration on August 1, 1994, shall obtain a certified registration from the Department in accordance with the provisions of this section.

(2) *Certified registration application.* (i) If the application is for use sited in a medical institution, only the institution's management may apply; for use not sited in a medical institution, any professional practitioner may apply.

(ii) An application for a certified registration shall be filed in duplicate (original plus one copy) on, and shall contain completely and accurately all information called for by, a written form prescribed by the Department.

(iii) When a change affecting a radiation source or installation subject to the certified registration requirements of this section is considered by a registrant, including but not limited to changes ordered pursuant to this Code, so that the information on file with the Department, either in the initial certified registration application, or subsequent request for amendments, or in the initial certified registration or amendment previously granted, will no longer be accurate, the registrant shall so inform the Department in writing.

(A) For ministerial changes, such notification shall be within 10 days of effecting such change.

(B) For all other changes, an amendment must be requested and received pursuant to §175.64(b)(2)(xiv).

(C) Failure to notify the Department of a change of ownership or address of a radiation installation may result in revocation of the installation's certified registration under §175.64(b)(2)(xii).

(iv) At any time subsequent to the filing of an application for a certified registration and before the termination of a certified registration issued in response thereto, the Department may require the applicant to submit supplementary statements containing additional information to enable the Department to determine whether such application should be

approved or denied, or whether a previously issued certified registration should be amended, suspended or revoked.

(v) 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.

(vi) The Department will approve an application for, and issue in response thereto, a certified registration if the Department determines that the following requirements have been met:

(A) the applicant's proposed use, equipment, facilities and procedures will protect health and safety and will minimize danger to life and property from radiation hazards; and

(B) the applicant's instrumentation is appropriate for detecting and measuring the type(s) of radiation produced (either directly or indirectly) by the radiation source requested in the application; and

(C) the applicant, or the applicant's personnel, if the applicant is not an individual, is qualified by training and experience to use such radiation source for the purposes 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 §175.64(b)(2)(vi)(A), (B) and (C) are met.

(vii) Certified registrations issued by the Department shall be in the form of a written authorization permitting possession and use of radiation therapy machines capable of operating at 500 kV (photons) and/or 500 keV (electrons) or higher. Such possession and use provided for in the foregoing shall be subject to the requirements of:

(A) all applicable provisions of this Code; and

(B) all conditions as stated on the certified registration issued by the Department.

(viii) Except as otherwise provided in this Code, each certified registration shall expire on the expiration date stated on the certified registration. If any registrant duly files with the Department an application in proper form for renewal of such certified registration, or for a new and superseding certified registration, not less than 30 days prior to the stated expiration date, such certified registration shall not be deemed to have expired until the Department has finally determined such application.

(ix) The Department may terminate any certified registration upon the written request of the registrant.

(x) The Department may at any time set forth in any certified registration or incorporate by reference therein, additional conditions, restrictions or requirements applicable to the registrant's transfer, receipt, possession or use of any radiation source covered by such certified registration in order to protect the public health and safety and to minimize danger to life and property from radiation hazards.

(xi) Any certified registration may be amended or revoked by the Department by reason of amendment of this Code, or any other applicable law or regulation.

(xii) Any certified registration may be suspended or revoked by the Department 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's refusal to grant a certified registration on an original application; or

(C) any violation or failure to observe any condition of such certified registration, this Code, or any other applicable rule, regulation or law now or hereafter in effect.

(xiii) Any application by a registrant for the renewal of a certified registration, including amendments, shall be considered as an application for a certified registration and shall be filed on, and shall contain completely and accurately all information called for by, a written form or other manner prescribed by the Department. In considering any such application for renewal, the Department will apply the requirements set forth in §175.64(b)(2)(vi).

(xiv) A registrant shall apply for, and shall have received approval for, a certified registration amendment before:

(A) permitting anyone to work as an authorized user under the certified registration; (B) permanently changing the radiation safety officer or radiotherapy physicist;

(C) making any change in the treatment room shielding;

(D) making any change in the location of the therapeutic radiation machine within the treatment room;

(E) using the therapeutic radiation machine in a manner that could result in increased radiation levels in areas outside the treatment room;

(F) relocating the therapeutic radiation machine;

(G) allowing an individual not listed on the registrant's certified registration to perform the duties of the radiation therapy physicist, except during the temporary absence of the radiation therapy physicist when a person who is otherwise qualified to perform such duties may perform such duties. Such temporary absence shall not exceed sixty (60) days; or

(H) before changing non-ministerial statements, representations and/or procedures incorporated by reference into the certified registration.

Any application by a registrant for an amendment of a certified registration shall be filed in writing with the Department and shall set forth in detail the reasons for such requested amendment. In considering any such application for amendment, the Department will apply the requirements set forth in §175.64(b)(2)(vi).

(c) *Training requirements.* (1) The registrant of any therapeutic radiation machine shall require the authorized user to be a physician who:

(i) is certified in:

(A) Radiology, therapeutic radiology or radiation oncology by the American Board of Radiology; or

(B) Radiation oncology by the American Osteopathic Board of Radiology; or

(C) Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

(D) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

(ii) is in the active practice of therapeutic radiology, and has completed 200 hours of instruction in basic radiation techniques applicable to the use of an external beam radiation therapy unit, 500 hours of supervised work experience, and a minimum of three (3) years of supervised clinical experience.

(A) To satisfy the requirement for instruction, the classroom and laboratory training shall include:

(a) radiation physics and instrumentation;

(b) radiation protection;

(c) mathematics pertaining to the use and measurement of radiation; and

(d) radiation biology.

(B) To satisfy the requirement for supervised work experience, training shall be under the supervision of an authorized user at an institution and shall include:

(a) review of the full calibration measurements and periodic quality assurance checks;

(b) preparing treatment plans and calculating treatment times;

(c) using administrative controls to prevent misadministrations;

(d) implementing emergency procedures to be followed in the event of the abnormal operation of an external beam radiation therapy unit or its console; and

(e) checking and using survey meters.

(C) To satisfy the requirement for a period of supervised clinical experience, training shall include one (1) year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two (2) years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution. The supervised clinical experience shall include:

(a) examining individuals and reviewing their case histories to determine their suitability for external beam radiotherapy treatment, and any limitations or contraindications;

(b) selecting the proper dose and how it is to be administered;

(c) calculating the external beam radiotherapy doses and collaborating with the authorized user in the review of patients' progress and consideration of the need to modify originally prescribed doses as warranted by patients' reaction to radiation; and

(d) post-administration followup and review of case histories.

(2) The registrant of any therapeutic radiation machine shall require the [radiation therapy] authorized medical physicist to:

(i) be certified by the American Board of Radiology in:

(A) Therapeutic radiological physics; or

(B) Roentgen ray and gamma ray physics; or

(C) X-ray and radium physics; or

(D) Radiological physics; or

(ii) be certified by the American Board of Medical Physics in Radiation Oncology Physics; or

(iii) be certified by the Canadian College of Medical Physics; or

(iv) hold a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and have completed one (1) year of full time training in therapeutic radiological physics and an additional year of full time work experience under the supervision of a radiotherapy physicist at a medical institution. To meet this requirement, the individual shall have performed the tasks listed in §175.64(e)(1) and §175.64(g)(8) and (9) of this Code under the supervision of a [radiation therapy] authorized medical physicist during the year of work experience.

(v) Notwithstanding the provision of §175.64(c)(2)(iv), as of January 1, 2000, the [radiation therapy] authorized medical physicist shall be an individual who is certified as described in §175.64(c)(2)(i), (ii) or (iii).

(3) *Qualifications of operators.* (i) Any person, other than a qualified physician, who operates a therapeutic radiation machine for medical use shall be a licensed and registered radiation therapist, or a student currently enrolled in an approved program of study in radiation therapy technology and under the direct supervision of a qualified physician or licensed radiation therapist. Such direction or order to apply, or application of, radiation shall be in compliance with all applicable provisions of Title 10 of the New York Code of Rules and Regulations, Part 89, Subchapter L and Article 35 of the Public Health Law of the State of New York, or any successor laws or regulations.

(ii) The names and training of all personnel who currently operate any therapeutic radiation machine(s) shall be kept on file at the facility. Information on former operators shall be retained for a period of three (3) years beyond the last date such a person was authorized to operate a therapeutic radiation machine at the facility.

(4) The training and experience specified in §175.64(c)(1), (2) or (3) shall have been obtained within the 5 years preceding the date of application or the individual shall demonstrate continuing applicable experience since the required training and experience was completed.

(d) *General administrative requirements.* (1) The registrant shall be responsible for directing the operation of any therapeutic radiation machine and shall ensure that the requirements of this section are met in the operation of the therapeutic radiation machine(s).

(2) A therapeutic radiation machine which does not meet the requirements of this Code shall not be used for irradiation of patients.

(3) A physician shall not act as an authorized user for any therapeutic radiation machine which is subject to the provisions of §175.64(g) until such time as said physician's training has been reviewed and approved by the Department.

(4) *Written safety procedures and rules.* (i) Written safety procedures and rules, including any restrictions required for the safe operation of a particular therapeutic radiation machine, shall be developed by a radiation therapy physicist. At a minimum, these shall include:

(A) the procedure to be followed to ensure that, except for contact therapy machines, only the patient is in the treatment room before turning the primary beam of radiation on to begin a treatment or after a door interlock interruption; and

(B) the procedure to be followed if the operator is unable to turn the primary beam of radiation off with controls outside the treatment room or in the event that potential harm to the patient or personnel is imminent; and

(C) the names and telephone numbers of the authorized users, radiation safety officer and radiation therapy physicist to be contacted immediately if the therapeutic radiation machine or console operates abnormally.

(ii) Such procedures and rules shall be provided to each individual who operates a therapeutic radiation machine and shall be available at the control console of the therapeutic radiation machine.

(iii) The operator shall be able to demonstrate familiarity with these rules.

(iv) The registrant shall provide instruction in the written safety procedures and rules required by §175.64(d)(4)(i) to all individuals who operate a therapeutic radiation machine and shall provide appropriate refresher training to such individuals at intervals not to exceed one (1) year. Such instruction shall include "dry runs" of emergency procedures.

(v) The registrant shall retain for three (3) years a record of individuals receiving instruction required by §175.64(d)(4)(iv), a description of the instruction, the date of instruction, and the name of the individual who gave the instruction.

(5) All individuals associated with the operation of a therapeutic radiation machine shall be instructed in, and shall comply with, the provisions of the registrant's quality assurance program as required by §175.07 of this Code.

(6) Individuals shall not be exposed to the useful beam except for medical therapy purposes and unless such exposure has been ordered in writing by an authorized user who meets the training requirements of §175.64(c). This provision specifically prohibits deliberate exposure of an individual for training, demonstration or other non-healing arts purposes.

(7) For radiation therapy machines installed after August 1, 1994, the registrant shall maintain the following information for each therapeutic radiation machine for inspection by the Department:

(i) report of acceptance testing;

(ii) records of calibrations and periodic spot checks for the therapeutic radiation machine, as well as the name(s) of the person(s) who performed such activities;

(iii) records of major maintenance and modifications performed on the therapeutic radiation machine after August 1, 1994, as well as the name(s) of the person(s) who performed such services; and

(iv) copies of all correspondence with this Department regarding that therapeutic radiation machine.

(8) For each radiation therapy machine, the registrant shall retain records of all surveys for inspection by the Department.

(9) *Record retention.* (i) Unless specified otherwise, all records required by this section shall be retained until disposal is authorized by the Department. All required records shall be retained in an active file from at least the time of generation until the next Departmental inspection. Any required record generated prior to the last Departmental inspection may be microfilmed or otherwise archived providing a

complete copy of such record can be retrieved until such time as the Department authorizes final disposal.

(e) *General technical requirements.* (1) *Protection surveys.*

(i) The registrant shall ensure that radiation protection surveys of all new facilities, and existing facilities not previously surveyed, are performed with an operable radiation measurement survey instrument calibrated in accordance with §175.64(h). The radiation protection survey shall be performed by a radiation therapy physicist or by a physicist certified by the American Board of Health Physics or by the American Board of Radiology, the American Board of Medical Physics or the Canadian College of Medical Physics in the appropriate specialty and shall verify, with the therapeutic radiation machine in a "BEAM-ON" condition with the largest clinically available treatment field and with a scattering phantom in the useful beam of radiation, that:

(A) radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in §175.03(c); and

(B) radiation levels in unrestricted areas do not exceed the limits specified in §175.03(d).

(ii) In addition to the requirements of §175.64(e)(1)(i), a radiation protection survey also shall be performed prior to any subsequent medical use:

(A) after making any change in the treatment room shielding;

(B) after making any change in the location of the therapeutic radiation machine within the treatment room;

(C) after relocating the therapeutic radiation machine;

(D) before using the therapeutic radiation machine in a manner that could result in increased radiation levels in areas outside the external beam radiation therapy treatment room; or

(E) whenever there is reason to believe that radiation levels in unrestricted areas may have increased.

(iii) The survey record shall indicate all instances where the facility, in the opinion of the physicist performing the survey, is in violation of applicable regulations. The survey record also …

(iv) If the results of the surveys required by §175.64(e)(1)(i) or (ii) indicate any radiation levels in excess of the respective limits specified in §175.64(e)(1)(i), the registrant shall lock the control in the "OFF" position and not use the unit:

(A) except as may be necessary to repair, replace or test the therapeutic radiation machine, the therapeutic radiation machine shielding or the treatment room shielding; or

(B) until the registrant has applied for, and received, a specific exemption from the Department.

(2) If the survey required by §175.64(e)(1) indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by §175.03(d) of this Code, prior to the first medical use of the radiation therapy machine the registrant shall:

(i) equip the unit with beam direction interlocks or install additional radiation shielding to ensure compliance with §175.03(d) of this Code;

(ii) perform the survey required by §175.64(e)(1) again; and

(iii) include in the report required by §175.64(e)(3) the results of the initial survey, a description of the modification made to comply with §175.64(e)(2)(i), and the results of the second survey; or

(iv) request and receive an amendment to the certified registration that authorizes radiation levels in unrestricted areas greater than those permitted by §175.03(d) of this Code.

(3) *Reports of external beam radiation therapy surveys and measurements.* (i) The registrant for any therapeutic radiation machine subject to the requirements of §175.64(f) or §175.64(g) of this Code shall furnish a copy of the records required in §175.64(e)(1) and (2) to the Department within thirty (30) days following completion of the action that initiated the record requirement.

(4) A registrant shall control access to a therapeutic radiation machine treatment room by a door at each entrance.

(5) A registrant shall equip each entrance to a therapeutic radiation machine room with a beam condition indicator light.

(6) *Dosimetry equipment.* (i) The registrant shall have a calibrated dosimetry system available for use. …

(ii) The registrant shall have available …

(iii) The registrant shall maintain …

(f) *Therapeutic radiation machines incapable of operating at 500 kV or above.* (1) *Leakage radiation.*

…

(16) *Full calibration measurements.* (i) Full calibration of a therapeutic radiation machine subject to the requirements of §175.64(f) of this Code shall be performed by, or under the direct supervision of, [a radiation therapy] <u>an authorized medical</u> physicist:

(A) before the first medical use following installation or reinstallation of the therapeutic radiation machine;

…

(17) *Periodic quality assurance checks.* (i) Periodic quality assurance checks shall be performed on therapeutic radiation machines subject to

the requirements of §175.64(f) of this Code which are capable of operation at greater than 50 kV.

(ii) To satisfy the requirement of §175.64(f)(17)(i), quality assurance checks shall meet the following requirements:

(A) the registrant shall perform quality assurance checks in accordance with written procedures established by the [radiation therapy] authorized medical physicist;

…

(iii) The cause for a parameter exceeding a tolerance set by the radiation therapy physicist shall be investigated and corrected before the system is used for patient irradiation.

(iv) The registrant shall use the dosimetry system specified in §175.64(e)(6)(ii) to make the periodic quality assurance check required in §175.64(f)(17)(i).

(v) The registrant shall have the [radiation therapy] authorized medical physicist review and sign the results of each radiation output quality assurance check at intervals not to exceed one month.

(vii) To satisfy the requirements of §175.64(f)(17)(vii), safety quality assurance checks shall ensure proper operation of:

…

(18) *Operating procedures.* (i) The therapeutic radiation machine shall not be used for irradiation of patients unless the requirements of §175.64(f)(16) and §175.64(f)(17) have been met.

…

(19) *Possession of survey instrument(s).* (i) Each facility location authorized to use a therapeutic radiation machine in accordance with §175.64(f) of this Code shall possess appropriately calibrated portable

monitoring equipment. At a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range of 10 mSv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. The survey instruments shall be operable and calibrated in accordance with §175.64(h).

(g) *Therapeutic radiation machines: photon therapy systems capable of operating at 500 kV and above and/or electron therapy systems capable of operating at 500 keV and above.*

…

(6) [*Radiation therapy physicist.*] (i) The [radiation therapy] authorized medical physicist named on the registrant's certified registration shall be responsible for:

…

(F) performance of calculations or other assessments regarding [misadministrations] medical events.

(ii) If the [radiation therapy] authorized medical physicist named on the registrant's certified registration is not a full-time employee of the registrant, the operating procedures required by §175.64(g)(7) shall specifically address how the radiation therapy physicist is to be contacted for problems or emergencies, as well as the specific actions to be taken until the radiation therapy physicist can be contacted.

(7) *Operating procedures.* (i) No individual, other than the patient, shall be in the treatment room during treatment.

…

(8) *Full calibration measurements.* (i) Full calibration of a therapeutic radiation machine subject to the requirements of §175.64(g) of this Code shall be performed by, or under the direct supervision of, the [radiation therapy] authorized medical physicist named on the registrant's certified registration:

…

(9) *Periodic quality assurance checks.* (i) Periodic quality assurance checks shall be performed on each therapeutic radiation machine subject to the requirements of §175.64(g) of this Code.

(ii) To satisfy the requirement of §175.64(g)(9)(i), quality assurance checks shall include …

(iii) The registrant shall use a dosimetry system described in §175.64(e)(6)(ii) to make the periodic quality assurance checks required by §175.64(g)(9)(ii).

(iv) The registrant shall perform periodic quality assurance checks required by §175.64(g)(8)(i) in accordance with procedures established by the [radiation therapy] <u>authorized medical</u> physicist named on the registrant's certified registration.

(v) The registrant shall review the results of each periodic radiation output check according to the following procedures:

(A) the authorized user and [radiation therapy] <u>authorized medical</u> physicist shall be notified immediately if any parameter is not within its acceptable range as determined pursuant to §175.64(g)(9)(iv). The therapeutic radiation machine shall not be made available for subsequent medical use until the [radiation therapy] authorized medical physicist has determined that all parameters are within their acceptable ranges;

(B) if all quality assurance check parameters appear to be within their acceptable ranges, the quality assurance check shall be reviewed and signed by either the authorized user or the [radiation therapy] <u>authorized medical</u> physicist within ten (10) days; and

(C) the [radiation therapy] <u>authorized medical</u> physicist shall review and sign the results of each radiation output quality assurance check at intervals not to exceed one (1) month.

…

(10) *Reports of calibrations.* (i) The registrant shall furnish a copy of the initial full calibration report required by §175.64(g)(8)(i)(A) to the [Bureau] Office of Radiological Health within thirty (30) days following completion of the calibration.

(11) *Possession of survey instrument(s).* (i) Each facility location authorized to use a therapeutic radiation machine in accordance with §175.64(g) of this Code shall possess appropriately calibrated portable monitoring equipment. At a minimum, … The survey instruments shall be operable and calibrated in accordance with §175.64(h).

…

(h) *Calibration and check of survey instruments.* (1) The registrant shall ensure that the survey instruments used to show compliance with the requirements of this section and other applicable parts of this Code have been calibrated before first use, at intervals not to exceed twelve (12) months and following repair.

(2) To satisfy the requirements of §175.64(h)(1), the registrant shall:

(i) calibrate all required [scale] scales with readings up to 10 mSv [(100 mrem)] (1000 mrem) per hour with an appropriate radiation source[;], the intensity of which is determined to within 10 percent accuracy;

[(ii) calibrate at least two (2) points on each scale to be calibrated. These points should be at approximately $^1/_3$ and $^2/_3$ of the full scale.]

(ii) calibrate at least two separated readings at approximately one-third and two-thirds of the full scale reading on each scale or decade that will be used to show compliance; and

(iii) conspicuously note on the instrument the apparent exposure rate from a dedicated check source as determined at the time of calibration, and the date of calibration.

(3) To satisfy the requirements of §175.64(h)(2), the registrant shall:

(i) consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than ten (10) percent; or

(ii) consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than twenty (20) percent if a correction factor or graph is conspicuously attached to the instrument.

(4) The registrant shall retain a record of each calibration required in §175.64(h)(1) for three (3) years. [and which] The record shall include:

(i) a description of the calibration procedure;

(ii) the manufacturer, model and serial number of the instrument;

(iii) a description of the source used and the certified dose rates from the source (as evidenced by NIST traceability);

(iv) the rates indicated by the instrument being calibrated, the correction factors determined from the calibration data; and

(v) the signature of individual who performed the calibration and the date of calibration.

(5) Records of calibrations which contain information required by §175.64(h)(4) shall be maintained by the registrant at the facility.

TO HERE

§175.65 **Veterinary radiography and fluoroscopy.**

…

§175.66 **Miscellaneous and special types of radiation equipment.**

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Radioactive Materials

§175.101 **General requirements for radioactive materials licenses.**

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§175.102 **Requirements for specific types of radioactive materials**

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§175.103 **Medical use of radioactive materials.**

§175.103 **Medical use of radioactive materials.**

(a) *General information.*

(1) *Purpose and scope.*

This section establishes the requirements and provisions for the medical use of byproduct material and for issuance of specific licenses authorizing the medical use of this material. These requirements and provisions provide for the radiation safety of workers, the general public, patients, human research subjects, and for the protection of the public health and safety. The requirements and provisions of this section are in addition to, and not in substitution for, others in this Code. The requirements and provisions of this Code apply to applicants and licensees subject to this section unless specifically exempted.

(2) Provisions for the protection of human research subjects.

(a) A licensee may conduct research involving human research subjects only if it uses the byproduct materials specified on its license for the uses authorized on its license.

(b) If the research is conducted, funded, supported, or regulated by another Federal agency that has implemented the Federal Policy for the

Protection of Human Subjects (Federal Policy), the licensee shall, before conducting research--

(1) Obtain review and approval of the research from an "Institutional Review Board," as defined and described in the Federal Policy; and

(2) Obtain "informed consent," as defined and described in the Federal Policy, from the human research subject.

(c) If the research will not be conducted, funded, supported, or regulated by another Federal agency that has implemented the Federal Policy, the licensee shall, before conducting research, apply for and receive a specific amendment to its NRC medical use license. The amendment request must include a written commitment that the licensee will, before conducting research--

(1) Obtain review and approval of the research from an "Institutional Review Board," as defined and described in the Federal Policy; and

(2) Obtain "informed consent", as defined and described in the Federal Policy, from the human research subject.

(d) Nothing in this section relieves licensees from complying with the other requirements in this Code.

(3) FDA, other Federal, and State requirements.

Nothing in this Code relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs or devices.

(4) Implementation.

(a) A Government agency or a Federally recognized Indian Tribe that possesses and uses accelerator-produced radioactive material or discrete sources of radium-226 for which a specific medical use license is required by the Atomic Energy Act of 1954, as amended, must comply with the requirements of 10 CFR 35, including provisions that are

specific to licensees, on November 30, 2007. All other persons who possess and use accelerator-produced radioactive material or discrete sources of radium-226 for which a specific medical use license is required, must comply with the requirements of 10 CFR 35, including provisions that are specific to licensees, on August 8, 2009, or earlier as noticed by the NRC.

(b) Reserved

(c) Reserved

(d) If a license condition exempted a licensee from a provision of Part 35 on October 24, 2002, then the license condition continues to exempt the licensee from the requirements in the corresponding provision of §§ 35.1-35.4002.

(e) When a requirement in this Code differs from the requirement in an existing license condition, the requirement in this Code shall govern.

(f) A licensee shall continue to comply with any license condition that requires it to implement procedures required by §§ 175.103(h)(5), (h)(12), (h)(13) and (h)(14) until there is a license amendment or renewal that modifies the license condition.

(5) License required.

(a) A person may manufacture, produce, acquire, receive, possess, prepare, use, or transfer byproduct material for medical use only in accordance with a specific license issued by the Commission or an Agreement State, or as allowed in paragraph (b) or (c) of this section.

(b) An individual may --

(1) Receive, possess, use, or transfer byproduct material in accordance with the regulations in this Code under the supervision of an authorized user as provided in § 175.103(b)(3), unless prohibited by license condition; or

(2) Prepare unsealed byproduct material for medical use in accordance with the regulations in this Code under the supervision of an authorized nuclear pharmacist or authorized user as provided in § 175.103(b)(3), unless prohibited by license condition.

(c)(1) A Government agency or a Federally recognized Indian Tribe, that possesses and uses accelerator-produced radioactive material or discrete sources of radium-226 for which a specific medical use license is required in paragraph (a) of this section, may continue to use such materials for medical uses until the date of the NRC's final licensing determination, provided that the person submits a medical use license application on or before December 1, 2008.

(2) Except as provided in paragraph (c)(1) of this section, all other persons, who possess and use accelerator-produced radioactive material or discrete sources of radium-226 for which a specific medical use license is required in paragraph (a) of this section, may continue to use this type of material for medical uses permitted under 10 CFR 35 until the date of the NRC's final licensing determination, provided that the person submits a medical use license application within 12 months from the waiver expiration date of August 7, 2009 or within 12 months from the date of an earlier termination of the waiver as noticed by the NRC, whichever date is earlier.

If the application is for medical use sited in a medical institution, only the institution's management may apply. If the application is for medical use not sited in a medical institution, any professional practitioner may apply.

(6) Application for license, amendment, or renewal.

(a) If the application is for medical use sited in a medical institution, only the institution's management may apply. If the application is for medical use not sited in a medical institution, any professional practitioner may apply. An application must be signed by the applicant or licensee's management.

(b) An application for a license for medical use of byproduct material as described in §§ 175.103(d)(1), 175.103(d)(2), 175.103(e)(1), 175.103(f)(1), 175.103(g)(1), 175.103(h)(1), and 175.103(i)(1) must be made by--

(1) Filing an original and one copy of Form RAD-1, "Application for Radioactive Material License," that includes the facility diagram, equipment, and training and experience qualifications of the Radiation Safety Officer, authorized user(s), authorized medical physicist(s), and authorized nuclear pharmacist(s); and

(2) Submitting procedures required by §§ 175.103(h)(5), (h)(12), (h)(13) and (h)(14) as applicable.

(c) A request for a license renewal must be made by--

(1) Submitting an original and one copy of Form RAD-1, "Application for Radioactive Material License"; and

(2) Submitting procedures required by §§ 175.103(h)(5), (h)(12), (h)(13) and (h)(14), as applicable.

(d) A request for a license amendment must be made by--

(1) Submitting an original and one copy of either--

(i) Form RAD-1, "Application for Radioactive Material License"; or

(ii) A letter requesting the amendment; and

(2) Submitting procedures required by §§ 175.103(h)(5), (h)(12), (h)(13) and (h)(14), as applicable.

(e) In addition to the requirements in paragraphs (b) through (d) of this section, an application for a license or amendment for medical use of byproduct material as described in § 175.103(i)(1) must also include information regarding any radiation safety aspects of the medical use of the material that is not addressed in Subparts A through C of 10 CFR 35.

(1) The applicant shall also provide specific information on--

(i) Radiation safety precautions and instructions;

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

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

(2) The applicant or licensee shall also provide any other information requested by the Department in its review of the application.

(f) An applicant that satisfies the requirements specified in § 33.13 of this chapter may apply for a specific license of broad scope.

(7) License amendments.

A licensee shall apply for and must receive a license amendment--

(a) Before it receives, prepares, or uses byproduct material for a type of use that is permitted under this Code, but is not authorized on the licensee's current license issued under this Code; except that—

(1) A Government agency or a Federally recognized Indian Tribe licensee who possesses and uses accelerator-produced radioactive material or discrete sources of radium-226 may continue to use such material for medical uses permitted under 10 CFR 35 until the date of the NRC's final licensing determination, provided that the licensee submits an amendment application on or before June 2, 2008.

(2) Except as provided in paragraph (a)(1) of this section, all other licensees who possess and use accelerator-produced radioactive material or discrete sources of radium-226 may continue to use those materials for medical uses permitted under 10 CFR 35 until the date of the NRC's final licensing determination, provided that the person submits a medical use license amendment request within 6 months from the waiver expiration date of August 7, 2009 or within 6 months from the date of an

earlier termination of the waiver as noticed by the NRC, whichever date is earlier.

(b) Before it permits anyone except a visiting authorized user to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist under the license, except--

(1) For an authorized user, an individual who meets the requirements in §§ 175.103(j)(4)(a), 175.103(j)(5)(a), 175.103(j)(6)(a), 175.103(j)(7)(a), 175.103(j)(8)(a), 175.103(j)(10)(a), 175.103(j)(12)(a), and 175.103(j)(13)(a);

(2) For an authorized nuclear pharmacist, an individual who meets the requirements in §§ 175.103(j)(3)(a) and 175.103(j)(15);

(3) For an authorized medical physicist, an individual who meets the requirements in §§ 175.103(j)(2)(a) and (c) and 175.103(j)(15);

(4) An individual who is identified as an authorized user, an authorized nuclear pharmacist, or authorized medical physicist--

(i) On a Commission or Agreement State license or other equivalent permit or license recognized by NRC that authorizes the use of byproduct material in medical use or in the practice of nuclear pharmacy;

(ii) On a permit issued by a Commission or Agreement State specific license of broad scope that is authorized to permit the use of byproduct material in medical use or in the practice of nuclear pharmacy;

(iii) On a permit issued by a Commission master material licensee that is authorized to permit the use of byproduct material in medical use or in the practice of nuclear pharmacy; or

(iv) By a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists.

(5) A physician, podiatrist, or dentist who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses or a nuclear pharmacist who used only accelerator-produced radioactive materials in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, and for only those materials and uses performed before these dates.

(c) Before it changes Radiation Safety Officers, except as provided in § 175.103(b)(2)(c);

(d) Before it receives byproduct material in excess of the amount or in a different form, or receives a different radionuclide than is authorized on the license;

(e) Before it adds to or changes the areas of use identified in the application or on the license, including areas used in accordance with either § 175.103(d)(1) or § 175.103(d)(2) if the change includes addition or relocation of either an area where PET radionuclides are produced or a PET radioactive drug delivery line from the PET radionuclide/PET radioactive drug production area. Other areas of use where byproduct material is used only in accordance with either § 175.103(d)(1) or § 175.103(d)(2) are exempt;

(f) Before it changes the address(es) of use identified in the application or on the license; and

(g) Before it revises procedures required by §§ 175.103(h)(5), (h)(12), (h)(13) and (h)(14), as applicable, where such revision reduces radiation safety.

(h) Before changing statements, representations, and procedures which are incorporated by reference into the license.

(8) Notifications.

(a) A licensee shall provide the Department a copy of the board certification and the written attestation(s), signed by a preceptor, the Commission or Agreement State license, the permit issued by a Commission master material licensee, the permit issued by a Commission or Agreement State licensee of broad scope, the permit issued by a Commission master material license broad scope permittee, or documentation that only accelerator-produced radioactive materials, discrete sources of radium-226, or both, were used for medical use or in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, and for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user, an authorized nuclear pharmacist, or an authorized medical physicist, under § 175.103(a)(7)(b). For individuals permitted to work under § 175.103(a)(7)(b)(4), within the same 30-day time frame, the licensee shall also provide, as appropriate, verification of completion of;

(1) Any additional case experience required in § 175.103(j)(6)(b)(1)(ii)(G) for an authorized user under § 175.103(e)(1);

(2) Any additional training required in § 175.103(j)(13)(c) for an authorized user under § 175.103(h)(1); and

(3) Any additional training required in § 175.103(j)(2)(c) for an authorized medical physicist.

(b) A licensee shall notify the Department no later than 30 days after:

(1) An authorized user, an authorized nuclear pharmacist, a Radiation Safety Officer, or an authorized medical physicist permanently discontinues performance of duties under the license or has a name change. This requirement is not intended to relieve the licensee of the requirements of §175.103(a)(4).

(2) The licensee permits an authorized user or an individual qualified to be a Radiation Safety Officer, under §§ 175.103(j)(1) and 175.103(j)(15), to function as a temporary Radiation Safety Officer and

to perform the functions of a Radiation Safety Officer in accordance with § 175.103(b)(2)(c).

(3) The licensee's mailing address changes;

(4) The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in § 30.34(b) of this chapter; or

(5) The licensee has added to or changed the areas of use identified in the application or on the license where byproduct material is used in accordance with either § 175.103(d)(1) or § 175.103(d)(2) if the change does not include addition or relocation of either an area where PET radionuclides are produced or a PET radioactive drug delivery line from the PET radionuclide/PET radioactive drug production area.

(c) The licensee shall send the documents required in this section to the Department at the address identified in § l75.01 "Applicability and inapplicability, communications".

(9) Exemptions regarding specific licenses of broad scope.

A licensee possessing a specific license of broad scope for medical use, issued under 10 CFR 33, is exempt from--

(a) The provisions of § 175.103(a)(6)(e) regarding the need to file an amendment to the license for medical use of byproduct material, as described in § 175.103(i)(1);

(b) The provisions of § 175.103(a)(7)(b);

(c) The provisions of § 175.103(a)(7)(e) regarding additions to or changes in the areas of use at the addresses identified in the application or on the license;

(d) The provisions of § 175.103(a)(8)(a);

(e) The provisions of § 175.103(a)(8)(b)(1) for an authorized user, an authorized nuclear pharmacist, or an authorized medical physicist;

(f) The provisions of § 175.103(a)(8)(b)(5).

(g) The provisions of § 175.103(b)(6)(a).

(10) License issuance.

(a) The Department shall issue a license for the medical use of byproduct material if--

(1) The applicant has filed RAD-1, "Application for Radioactive Material License" in accordance with the instructions in § 175.103(a)(6);

(2) The applicant has paid any applicable fee;

(3) The Department finds the applicant equipped and committed to observe the safety standards established by the Department in this Code for the protection of the public health and safety; and

(4) The applicant meets the requirements of 10 CFR 30.

(b) The Commission shall issue a license for mobile medical service if the applicant:

(1) Meets the requirements in paragraph (a) of this section; and

(2) Assures that individuals or human research subjects to whom unsealed byproduct material or radiation from implants containing byproduct material will be administered may be released following treatment in accordance with § 175.103(c)(9).

(11) Specific exemptions

The Department may, upon application of any interested person or upon its own initiative, grant exemptions from the regulations in this Code that

it determines are authorized by law and will not endanger life or property and are otherwise in the public interest.

(b) *General administrative requirements.*

(1) *ALARA Program.*

(i) Each licensee shall develop and implement a written program to maintain radiation doses and releases of radioactive material in effluents to unrestricted areas as low as reasonably achievable in accordance with §175.03(b) of this Code.

(ii) To satisfy the requirement of §175.103(b)(1)(i):

(A) for licensees that are medical institutions, the management, radiation safety officer and all authorized users shall participate in the establishment, implementation, and operation of the program as required by this Code or required by the radiation safety committee; or

(B) for licensees that are not medical institutions, management and all authorized users shall participate in the program as requested by the radiation safety officer.

(iii) The ALARA program shall include notice to workers of the program's existence and workers' responsibility to help keep dose equivalents ALARA.

(iv) The ALARA program shall include an annual review by the radiation safety committee for licensees that are medical institutions, or management, all authorized users and the radiation safety officer for licensees that are not medical institutions, of summaries of the types and amounts of radioactive material used, occupational dose reports, and continuing education and training for all personnel who work with or in the vicinity of radioactive material.

(v) The purpose of the review required by §175.103(b)(1)(iv) is to ensure that individuals make every reasonable effort to maintain occupational doses, doses to the general public, and releases of

radioactive material to unrestricted areas as low as reasonably achievable, taking into account the state of technology, and the cost of improvements in relation to benefits.

(vi) The licensee shall retain a current written description of the ALARA program for the duration of the license. The written description must include:

(A) a commitment by management to keep occupational doses as low as reasonably achievable;

(B) a requirement that the radiation safety officer brief management once each year on the radiation safety program;

(C) personnel exposure investigational levels that, when exceeded, will initiate an investigation by the radiation safety officer of the cause of the exposure; and

(D) personnel exposure investigational levels that, when exceeded, will initiate a prompt investigation by the radiation safety officer of the cause of the exposure and a consideration of actions that might be taken to reduce the probability of recurrence.

(2) *Radiation safety officer.*

<u>(2) Authority and responsibilities for the radiation protection program.</u>

<u>(b)A licensee's management shall appoint a Radiation Safety Officer, who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements.</u>

(ii) The radiation safety officer shall:

(A) investigate overexposures, [misadministrations] <u>medical events</u>, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, and

disposals, and other deviations from approved radiation safety practice and implement corrective actions as necessary;

(B) establish, implement and maintain written policy and procedures for:

(a) authorizing the purchase of radioactive material;

(b) receiving and opening packages of radioactive material;

(c) storing radioactive material;

(d) keeping an inventory record of radioactive material;

(e) using radioactive material safely;

(f) taking emergency action if control of radioactive material is lost;

(g) performing periodic radiation surveys;

(h) performing checks of survey instruments and other safety equipment;

(i) disposing of radioactive material;

(j) training personnel who work in or frequent areas where radioactive material is used or stored; and

(k) keeping copies of this Code, all records and reports required by this Code, each licensing request and license and amendments, and the written policies and procedures required by this Code;

(C) brief management at least once each year on the radioactive materials program; and

(D) for medical use sited at a medical institution, assist the radiation safety committee in the performance of its duties; or

(E) for medical use not sited at a medical institution, approve or disapprove radiation safety program changes with the advice and consent of management prior to submittal to the Department for licensing action.

(3) *Radiation safety committee.*

(i) The committee shall meet the following administrative requirements:

(A) §175.103(b)(2)(f) Licensees that are authorized for two or more different types of uses of byproduct material under Subparts E, F, and H of 10 CFR 35, or two or more types of units under Subpart H of 10 CFR 35, shall establish a Radiation Safety Committee to oversee all uses of byproduct material permitted by the license. The Committee must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer. The Committee may include other members the licensee considers appropriate.

(B) The committee shall meet at least quarterly.

(C) To establish a quorum and to conduct business, at least one-half of the committee's membership shall be present, including the radiation safety officer and the management's representative.

(D) The minutes of each radiation safety committee meeting shall include:

(a) the date of the meeting;

(b) members present;

(c) members absent;

(d) summary of deliberations and discussions;

(e) recommended actions and the numerical results of all ballots; and

(f) document any reviews required in §175.103(b)(1)(iv) and (b)(3)(ii).

(E) The committee shall provide each member with a copy of the meeting minutes, and retain one copy for the duration of the license.

(ii) To oversee the use of licensed material, the committee shall:

(A) be responsible for monitoring the institutional program to maintain individual and collective doses as low as reasonably achievable;

(B) review, on the basis of safety and with regard to the training and experience standards of this Code, and approve or disapprove any individual who is to be listed as an authorized user, the radiation safety officer, or authorized medical physicist before submitting a license application or request for amendment or renewal;

(C) review on the basis of safety and approve or disapprove each proposed method of use of radioactive material;

(D) review on the basis of safety, and approve or disapprove with the advice and consent of the radiation safety officer and the management representative, minor changes in radiation safety procedures that are not potentially important to safety and are permitted under §175.103(b)(3)(iii);

(E) review on the basis of safety, and approve or disapprove with the advice and consent of the radiation safety officer and the management representative, procedures and radiation safety program changes prior to submittal to the [Bureau] Office of Radiological Health for licensing action;

(F) review quarterly, with the assistance of the radiation safety officer, occupational radiation exposure records of all personnel working with radioactive material;

(G) review quarterly, with the assistance of the radiation safety officer, all incidents involving radioactive material with respect to cause and subsequent actions taken;

(H) review annually, with the assistance of the radiation safety officer, the radioactive materials program; and

(I) establish a table of investigational levels for occupational dose that, when exceeded, will initiate investigations and considerations of action by the radiation safety officer.

(iii) A licensee may make minor changes in radiation safety procedures that are not potentially important to safety (*e.g.* editing of procedures for clarity, updating names or telephone numbers, replacement of equipment or assignment of service contracts), except for changes in §175.103(a)(4) or §175.103(i)(3). A licensee is responsible for assuring that any change made is in compliance with the requirements of this Code and the license.

(iv) A licensee shall retain a record of each change made pursuant to §175.103 (b)(3)(iii) until the license has been renewed or terminated. The record must include the effective date of the change, a copy of the old and new radiation safety procedures, the reason for the change, a summary of radiation safety matters that were considered before making the change, the signature of the radiation safety officer, and the signatures of the affected authorized user and of management or, in a medical institution, the radiation safety committee's chairman and the management representative.

(4) *Statement of authorities and responsibilities.* (i) A licensee shall provide the radiation safety officer, and at a medical institution the radiation safety committee, sufficient authority and organizational freedom to:

(A) identify radiation safety problems;

(B) initiate, recommend, or provide corrective actions; and

(C) verify implementation of corrective actions.

(ii) A licensee shall establish in writing the authorities, duties, responsibilities, and radiation safety activities of the radiation safety officer, and at a medical institution the radiation safety committee, and retain the current edition of these statements for the duration of the license

(3) Supervision.(a) A licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user, as allowed by § 175.103(a)(5)(b)(1), shall--

(1) In addition to the requirements in § 10 CFR 19.12, instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, regulations of this Code, and license conditions with respect to the use of byproduct material; and

(2) Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of byproduct material, written radiation protection procedures established by the licensee, written directive procedures, regulations of this Code, and license conditions with respect to the medical use of byproduct material.

(b) A licensee that permits the preparation of byproduct material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by § 175.103(a)(5)(b)(2), shall--

(1) In addition to the requirements in § 10 CFR 19.12, instruct the supervised individual in the preparation of byproduct material for medical use, as appropriate to that individual's involvement with byproduct material; and

(2) Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of byproduct material for medical use, written radiation protection procedures established by the licensee, the regulations of this Code, and license conditions.

[(iii)](c)(i) Personnel, other than physicians or registered professional nurses, at [institutional] licensees involved in the performance of diagnostic procedures utilizing radioactive material which includes performing parenteral administration of radioactive material by intravenous, intramuscular or subcutaneous methods shall:

(A) have satisfactorily completed an educational program in nuclear medicine technology accredited by the Committee on Allied Health Education and Accreditation or the accrediting agency of the state in which the program was completed, provided such state accreditation

requires education and training in the above methods of parenteral administration; or

(B) possess certification as a nuclear medicine technologist by the American Registry of Radiologic Technologists or certification by the Nuclear Medicine Technology Board; and

[(iv)] (ii) prior to permitting parenteral administration by a nuclear medicine technologist, the medical board of a hospital, a physician, or the radiation safety committee of an institution who have no medical board, shall adopt with governing authority approval:

(A) procedures to assure that the nuclear medicine technologist possesses the education and training or certification set forth in §175.103(b)(5)(iii) and is proficient in the competent performance of parenteral administration; and

(B) requirements for authorized user physician which at a minimum shall require supervision by such a physician [on the premises] when parenteral administration of radioactive material for diagnostic testing is performed by a qualified nuclear medicine technologist.

[(c)] (d) A licensee that permits supervised activities under paragraphs (a) and (b) of this section is responsible for the acts and omissions of the supervised individual.

(4) Written directives.

(a) A written directive must be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 1.11 megabecquerels (MBq) (30 microcuries (μCi)), any therapeutic dosage of unsealed byproduct material or any therapeutic dose of radiation from byproduct material.

(1) If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive must be documented as soon as possible in writing in the

patient's record. A written directive must be prepared within 48 hours of the oral directive.

(b) The written directive must contain the patient or human research subject's name and the following information--

(1) For any administration of quantities greater than 1.11 MBq (30 µCi) of sodium iodide I-131: the dosage;

(2) For an administration of a therapeutic dosage of unsealed byproduct material other than sodium iodide I-131: the radioactive drug, dosage, and route of administration;

(3) For gamma stereotactic radiosurgery: the total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site;

(4) For teletherapy: the total dose, dose per fraction, number of fractions, and treatment site;

(5) For high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or

(6) For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders:

(i) Before implantation: treatment site, the radionuclide, and dose; and

(ii) After implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose).

(c) A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed byproduct material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

(1) If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision must be documented as soon as possible in the patient's record. A revised written directive must be signed by the authorized user within 48 hours of the oral revision.

(d) The licensee shall retain a copy of the written directive in accordance with § 175.03(k)(12).

(5) Procedures for administrations requiring a written directive.

(a) For any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that:

(1) The patient's or human research subject's identity is verified before each administration; and

(2) Each administration is in accordance with the written directive.

(b) At a minimum, the procedures required by paragraph (a) of this section must address the following items that are applicable to the licensee's use of byproduct material--

(1) Verifying the identity of the patient or human research subject;

(2) Verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive;

(3) Checking both manual and computer-generated dose calculations; and

(4) Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by §§ 175.103(h)(1) or 175.103(i)(1).

(c) A licensee shall retain a copy of the procedures required under paragraph (a) in accordance with § 175.03(k)(13).

(6)*Suppliers.*

For medical use, a licensee may only use--

(a) Sealed sources or devices manufactured, labeled, packaged, and distributed in accordance with a license issued under 10 CFR Part 30 and 10 CFR 32.74 or equivalent requirements of an Agreement State;

(b) Sealed sources or devices non-commercially transferred from a Part 35 licensee or an Agreement State medical use licensee.

(c) Teletherapy sources manufactured and distributed in accordance with a license issued under 10 CFR Part 30 or the equivalent requirements of an Agreement State.

(d) Radioactive material manufactured, labeled, packaged, and distributed in accordance with a license issued for such activities by an Agreement State or the U.S. Nuclear Regulatory Commission; and

(e) Reagent kits that have been manufactured, labeled, packaged, and distributed in accordance with an approval issued by the U.S. Department of Health and Human Services, Food and Drug Administration ("FDA").

(c) *General technical requirements.* (1) *Possession, use, calibration, and check of dose calibrators.*

(i) A medical use licensee authorized to administer radioactive materials shall possess a dose calibrator and use it to measure the amount of activity administered to each patient.

(ii) A licensee shall:

(A) check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use. To satisfy this requirement,

the check must be done on a frequently used setting with a sealed source of not less than 370 kBq (10 mCi) of radium-226 or 1.85 MBq (50 mCi) of any other photon-emitting radionuclide with a half-life greater than 90 days; and

(B) test each dose calibrator for accuracy upon installation and at intervals not to exceed 12 months thereafter by assaying at least 2 sealed sources containing different radionuclides, the activity of which the manufacturer has determined by traceability to a national standard to be within 5 percent of the stated activity, with minimum activity of 370 kBq (10 mCi) for radium-226 and 1.85 MBq (50 mCi) for any other photon-emitting radionuclide, and at least one of which has a principal photon energy between 100 keV and 500 keV; and

(C) test each dose calibrator for linearity upon installation and at intervals not to exceed three months thereafter over the range of use between 370 kBq (10 mCi) and the highest dosage that will be administered; and

(D) test each dose calibrator for geometry dependence upon installation over the range of volumes and volume configurations for which it will be used. The licensee shall keep a record of this test for the duration of the use of the dose calibrator.

(iii) Notwithstanding the provisions of §175.103(c)(1)(ii), a licensee that must use a dose calibrator to measure the activity of beta-emitting radioactive materials to be administered to a patient shall perform additional checks specified in §175.103(c)(1)(ii)(A) and (B) using the same radionuclide to be administered and having an activity of at least 50 percent, but not more than 200 percent, of the prescribed activity or by equivalent procedures approved by the Department. Records shall be kept pursuant to §175.103(c)(1)(vi).

(iv) A licensee shall mathematically correct dosage readings for any geometry or linearity error that exceeds ± 10 percent if the dosage is greater than 370 kBq (10 mCi) and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds ± 10 percent.

(v) A licensee shall also perform checks and tests required by §175.103(c)(1)(ii) following adjustment or repair of the dose calibrator.

(vi) A licensee shall retain a record of each check and test required by §175.103(c)(1)(ii), (iii), and (v) for 3 years. Such records shall include:

(A) for §175.103(c)(1)(ii)(A), the models and serial numbers of the dose calibrator and check source, the identity and calibrated activity of the radionuclide contained in the check source, the date of the check, the activity measured, the instrument settings, and the name of the individual who performed the check;

(B) for §175.103(c)(1)(ii)(B), the model and serial number of the dose calibrator, the model and serial number of each source used and the identity of the radionuclide contained in the source and its activity, proof of traceability to a national standard, the date of the test, the results of the test, the instrument settings, and the signature of the radiation safety officer;

(C) for §175.103(c)(1)(ii)(C), the model and serial number of the dose calibrator, the calculated activities, the measured activities, the date of the test, and the signature of the radiation safety officer; and

(D) for §175.103(c)(1)(ii)(D), the model and serial number of the dose calibrator, the configuration and calibrated activity of the source measured, the activity of the source, the activity measured and the instrument setting for each volume measured, the date of the test, and the signature of the radiation safety officer.

<u>(2) Possession, use, and calibration of instruments used to measure the activity of unsealed byproduct material</u>

<u>(a) For direct measurements performed in accordance with § 175.103(3)(4), a licensee shall possess and use instrumentation to measure the activity of unsealed byproduct material before it is administered to each patient or human research subject.</u>

(b) A licensee shall calibrate the instrumentation required in paragraph (a) of this section in accordance with nationally recognized standards or the manufacturer's instructions.

(c) A licensee shall retain a record of each instrument calibration required by this section in accordance with § 175.03(k)(14).

(3) Calibration of survey instruments.

(i) A licensee shall calibrate the survey instruments used to show compliance with this Code and § 175.03 before first use, annually, and following a repair that affects the calibration.

(ii) To satisfy the requirements of §175.103(c)(3)(i) the licensee shall:

(A) Calibrate all scales with readings up to 10 mSv (1000 mrem) per hour with a radiation source, the intensity of which is determined to within 10 percent accuracy;

(B) Calibrate two separated readings at approximately one-third and two-thirds of the full scale reading on each scale or decade that will be used to show compliance; and

(C) Conspicuously note on the instrument the apparent exposure rate from a dedicated check source as determined at the time of calibration, and the date of calibration.

(iii) To satisfy the requirements of §175.103(c)(2)(ii) the licensee shall:

(A) consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 10 percent; and

(B) consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 20 percent and if a correction chart or graph is conspicuously attached to the instrument.

(C) A licensee may not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is more than 20 percent.

(iv) To meet the requirements of §175.103(c)(3)(i), (ii) and (iii), the licensee shall perform such calibrations as authorized by specific license condition or shall obtain the services of persons licensed by the U.S. Nuclear Regulatory Commission or an agreement state to perform calibrations of survey instruments.

(v) A licensee shall check each survey instrument for proper operation with the dedicated check source before each use. The licensee shall not be not required to keep records of these checks.

(vi) A licensee shall retain a record of each survey instrument calibration in accordance with § 175.03(k)(15).

(4) Determination of dosages of unsealed byproduct material for medical use.

(a) A licensee shall determine and record the activity of each dosage before medical use.

(b) For a unit dosage, this determination must be made by--

(1) Direct measurement of radioactivity; or

(2) A decay correction, based on the activity or activity concentration determined by--

(i) A manufacturer or preparer licensed under § 10 CFR 32.72 or equivalent Agreement State requirements; or

(ii) An NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

(iii) A PET radioactive drug producer licensed under § 10 CFR 30.32(j) or equivalent Agreement State requirements.

(c) For other than unit dosages, this determination must be made by--

(1) Direct measurement of radioactivity;

(2) Combination of measurement of radioactivity and mathematical calculations; or

(3) Combination of volumetric measurements and mathematical calculations, based on the measurement made by:

(i) A manufacturer or preparer licensed under § 10 CFR 32.72 or equivalent Agreement State requirements; or

(ii) A PET radioactive drug producer licensed under § 10 CFR 30.32(j) or equivalent Agreement State requirements.

(d) Unless otherwise directed by the authorized user, a licensee may not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent.

(e) A licensee shall retain a record of the dosage determination required by this section in accordance with § 175.03(k)(16).

(5) Authorization for calibration, transmission, and reference sources.

Any person authorized by § 175.103(a)(5) for medical use of byproduct material may receive, possess, and use any of the following byproduct material for check, calibration, transmission, and reference use.

(a) Sealed sources, not exceeding 1.11 GBq (30 mCi) each, manufactured and distributed by a person licensed under § 10 CFR 32.74 or equivalent Agreement State regulations.

(b) Sealed sources, not exceeding 1.11 GBq (30 mCi) each, redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed under § 10 CFR 32.74 or equivalent Agreement State regulations, providing the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions.

(c) Any byproduct material with a half-life not longer than 120 days in individual amounts not to exceed 0.56 GBq (15 mCi).

(d) Any byproduct material with a half-life longer than 120 days in individual amounts not to exceed the smaller of 7.4 MBq (200 µCi) or 1000 times the quantities in Appendix B of 10 CFR Part 30.

(e) Technetium-99m in amounts as needed.

(6) Requirements for possession of sealed sources and brachytherapy sources.

(a) A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer.

(b) A licensee in possession of a sealed source shall--

(1) Test the source for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within 6 months before transfer to the licensee; and

(2) Test the source for leakage at intervals not to exceed 6 months or at other intervals approved by the Commission or an Agreement State in the Sealed Source and Device Registry.

(c) To satisfy the leak test requirements of this section, the licensee shall measure the sample so that the leak test can detect the presence of 185 Bq (0.005 µCi) of radioactive material in the sample.

(d) A licensee shall retain leak test records in accordance with § 175.03(k)(17)(a).

(e) If the leak test reveals the presence of 185 Bq (0.005 µCi) or more of removable contamination, the licensee shall--

(1) Immediately withdraw the sealed source from use and store, dispose, or cause it to be repaired in accordance with the requirements in parts 20 and 30 of 10 CFR; and

(2) File a report within 5 days of the leak test in accordance with § 175.03(l)(10).

(f) A licensee need not perform a leak test on the following sources:

(1) Sources containing only byproduct material with a half-life of less than 30 days;

(2) Sources containing only byproduct material as a gas;

(3) Sources containing 3.7 MBq (100 µCi) or less of beta or gamma-emitting material or 0.37 MBq (10 µCi) or less of alpha-emitting material;

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

(5) Sources stored and not being used. However, the licensee shall test each such source for leakage before any use or transfer unless it has been leak tested within 6 months before the date of use or transfer.

(g) A licensee in possession of sealed sources or brachytherapy sources, except for gamma stereotactic radiosurgery sources, shall conduct a physical inventory of all such sources in its possession at intervals not to exceed three months. The licensee shall retain each inventory record in accordance with § 175.03(k)(17)(b).

(iii) A licensee in possession of a sealed source or brachytherapy source shall survey with a radiation survey instrument at intervals not to exceed

3 months all areas where such sources are stored. This shall not apply to teletherapy sources in teletherapy units or sealed sources in diagnostic devices.

(iv) A licensee shall retain a record of each survey required in §175.103(c)(5)(iii) for 3 years. The record must include the date of the survey, a sketch of each area that was surveyed, the measured dose rate at several points in each area expressed in microsieverts (mrem) per hour, the model number and serial number of the survey instrument used to make the survey, and the signature of the radiation safety officer.

(7) Labeling of vials and syringes.

Each syringe and vial that contains unsealed byproduct material must be labeled to identify the radioactive drug. Each syringe shield and vial shield must also be labeled unless the label on the syringe or vial is visible when shielded.

(8) Surveys for contamination and ambient radiation exposure rate.

(a) In addition to the surveys required by §175.03 of this Article, a licensee shall survey with a radiation detection survey instrument at the end of each day of use. A licensee shall survey all areas where unsealed byproduct material requiring a written directive was prepared for use or administered.

(b) A licensee does not need to perform the surveys required by paragraph (a) of this section in an area(s) where patients or human research subjects are confined when they cannot be released under § 175.103(c)(9).

(ii) A licensee shall survey with a radiation detection survey instrument at least once each week all areas where unsealed byproduct materials or radioactive wastes are stored.

(iii) A licensee shall conduct the surveys required by §175.103(c)(8)(i) and (ii) so as to be able to detect and measure dose rates as low as 1 mSv (0.1 mrem) per hour.

(iv) A licensee shall establish dose rate action levels for the surveys required by §175.103(c)(8)(i) and (ii) and shall require that the individual performing the survey immediately notify the radiation safety officer if a dose rate exceeds an action level.

(v) A licensee shall perform wipe tests for removable contamination once each week on all areas where radioactive materials are routinely prepared for use or administered and where unsealed sources of radioactive materials are stored.

(vi) A licensee shall perform the wipe tests required by §175.103(c)(8)(v) so as to be able to detect contamination on each wipe sample of 35 Bq (2000 disintegrations or transformations per minute).

(vii) A licensee shall establish removable contamination action levels for the surveys required by §175.103(c)(8)(v) and shall require that the individual performing the survey immediately notify the radiation safety officer if contamination exceeds action levels.

(viii) A licensee shall retain a record of each survey or wipe test required by §175.103(c)(8)(i), (ii) and (v) of this section for 3 years. The record must include the date of the survey, a sketch of each area surveyed, action levels established for each area, the measured dose rate at several points in each area expressed in mSv (mrem) per hour or the removable contamination in each area expressed in becquerels (disintegrations or transformations per minute) per 100 square centimeters, the serial number and the model number of the instrument used to make the survey or analyze the samples, and the initials of the individual who performed the survey.

(c) A licensee shall retain a record of each survey in accordance with § 175.03(k)(18).

(9) Release of individuals containing unsealed byproduct material or implants containing byproduct material.

(a) A licensee may authorize the release from its control of any individual who has been administered unsealed byproduct material or

implants containing byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem). (note 1)

(b) A licensee shall provide the released individual, or the individual's parent or guardian, with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem). If the total effective dose equivalent to a nursing infant or child could exceed 1 mSv (0.1 rem) assuming there were no interruption of breast-feeding, the instructions must also include--

(1) Guidance on the interruption or discontinuation of breast-feeding; and

(2) Information on the potential consequences, if any, of failure to follow the guidance.

(c) A licensee shall maintain a record of the basis authorizing the release of an individual in accordance with § 175.03(k)(19)(a).

(d) The licensee shall maintain a record of instructions provided to a breast-feeding female in accordance with § 175.03(k)(19)(b).

(note 1) The current revision of NUREG–1556, Vol. 9, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Licenses" describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 5 mSv (0.5 rem).

(iv) *Radioactive cadavers.* (A) If any patient containing radioactive material administered/implanted for therapeutic purposes dies, it shall be the responsibility of the physician who pronounces such patient as dead to notify immediately the physician in charge of the case or such physician's designated representative.

(B) No person shall commence any autopsy on any cadaver that contains more than 185 MBq (5 mCi) of radioactive material

administered/implanted for therapeutic purposes without first having consulted with, and having been advised by, the radiation safety officer of the hospital or the physician responsible for the administration/implantation of the radioactive material. If neither is available, a designated representative may serve.

(C) A radioactivity report on every cadaver containing more than 185 MBq (5 mCi) of radioactive material administered/implanted 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 representative. The report must include the name, address and radioactive materials license number 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 date of the report and the physical form; the location(s) of the radioactive materials within the body and the external dose 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, by telephone, by mailgram or by facsimile within 24 hours of the death and a copy of the radioactivity report shall be sent to the Department within fifteen (15) days of the date of death.

(10) *Storage of volatiles and gases.* (i) A licensee shall store volatile radiopharmaceuticals and radioactive gases in the shippers' radiation shield and container.

(ii) After drawing the first dosage, a licensee shall store and use a multidose container in a properly functioning fume hood.

<u>(11) Decay-in-storage.</u>

(a) A licensee may hold byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if it—

(1) Monitors byproduct material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and

(2) Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee.

(b) A licensee shall retain a record of each disposal permitted under paragraph (a) of this section in accordance with § 175.03(k)(21).

(12) Provision of mobile medical service.

(a) A licensee providing mobile medical service shall--

(1) Obtain a letter signed by the management of each client for which services are rendered that permits the use of byproduct material at the client's address and clearly delineates the authority and responsibility of the licensee and the client;

(2) Check instruments used to measure the activity of unsealed byproduct material for proper function before medical use at each client's address or on each day of use, whichever is more frequent. At a minimum, the check for proper function required by this paragraph must include a constancy check;

(3) Check survey instruments for proper operation with a dedicated check source before use at each client's address; and

(4) Before leaving a client's address, survey all areas of use to ensure compliance with the requirements in 175.03 of this Article.

(b) A mobile medical service may not have byproduct material delivered from the manufacturer or the distributor to the client unless the client has a license allowing possession of the byproduct material. Byproduct material delivered to the client must be received and handled in conformance with the client's license.

(c) A licensee providing mobile medical services shall retain the letter required in paragraph (a)(1) and the record of each survey required in paragraph (a)(4) of this section in accordance with § 175.03(k)(20)(a) and (b), respectively.

(d)Unsealed Byproduct Material--Written Directive Not Required

(1) Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required.

Except for quantities that require a written directive under § 175.103(b)(4)(b), a licensee may use any unsealed byproduct material prepared for medical use for uptake, dilution, or excretion studies that is—

(a) Obtained from:

(1) A manufacturer or preparer licensed under § 10 CFR 32.72 or equivalent Agreement State requirements; or

(2) A PET radioactive drug producer licensed under § 10 CFR 30.32(j) or equivalent Agreement State requirements; or

(b) Excluding production of PET radionuclides, prepared by:

(1) An authorized nuclear pharmacist;

(2) A physician who is an authorized user and who meets the requirements specified in §§ 175.103(j)(5), or 175.103(j)(6) and 175.103(j)(5)(c)(1)(ii)(G); or

(3) An individual under the supervision, as specified in § 175.103(b)(3), of the authorized nuclear pharmacist in paragraph (b)(1) of this section or the physician who is an authorized user in paragraph (b)(2) of this section; or

(c) Obtained from and prepared by an NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

(d) Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

(2) Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.

Except for quantities that require a written directive under § 175.103(b)(4)(b), a licensee may use any unsealed byproduct material prepared for medical use for imaging and localization studies that is—

(a) Obtained from:

(1) A manufacturer or preparer licensed under § 10 CFR 32.72 or equivalent Agreement State requirements; or

(2) A PET radioactive drug producer licensed under § 10 CFR 30.32(j) or equivalent Agreement State requirements; or

(b) Excluding production of PET radionuclides, prepared by:

(1) An authorized nuclear pharmacist;

(2) A physician who is an authorized user and who meets the requirements specified in § 175.103(j)(5), or 175.103(j)(6) and 175.103(j)(5)(c)(1)(ii)(G); or

(3) An individual under the supervision, as specified in § 175.103(b)(3), of the authorized nuclear pharmacist in paragraph (b)(1) of this section or the physician who is an authorized user in paragraph (b)(2) of this section;

(c) Obtained from and prepared by an NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

(d) Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

(ii) A licensee may use generators upon approval of the Department. OUT?

(iii) Provided the conditions of §175.103(e)(3) are met, a licensee shall use radioactive aerosols or gases only if specific application is made to and approved by the Department.

(3) Permissible molybdenum-99, strontium-82, and strontium-85 concentrations.

(a) A licensee may not administer to humans a radiopharmaceutical that contains:

(1) More than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m); or

(2) More than 0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 chloride injection (0.02 microcurie of strontium-82 per millicurie of rubidium-82 chloride); or more than 0.2 kilobecquerel of strontium-85 per megabecquerel of rubidium-82 chloride injection (0.2 microcurie of strontium-85 per millicurie of rubidium-82).

(b) A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration of the first eluate after receipt of a generator to demonstrate compliance with paragraph (a) of this section.

(c) A licensee that uses a strontium-82/rubidium-82 generator for preparing a rubidium-82 radiopharmaceutical shall, before the first patient use of the day, measure the concentration of radionuclides strontium-82 and strontium-85 to demonstrate compliance with paragraph (a) of this section.

(d) If a licensee is required to measure the molybdenum-99 concentration or strontium-82 and strontium-85 concentrations, the licensee shall retain a record of each measurement in accordance with § 175.03(k)(22).

(iv) A licensee shall report immediately to the [Bureau] Office of Radiological Health each occurrence of molybdenum-99 concentration exceeding the limits specified in §175.103(e)(2)(1).

(4) *Control of aerosols and gases.* (i) A licensee who administers radioactive aerosols or gases shall do so with a system that will keep airborne concentrations within the limits prescribed by §175.03 of this Code.

(ii) The system shall provide for collection and decay or disposal of the aerosol or gas in a shielded container.

(iii) Before receiving, producing, using, or storing a radioactive gas, the licensee shall calculate the amount of time needed after a release to reduce the concentration in the area of use to the ALI listed in Table 1 of Appendix A of §175.03 of this Code. The calculation shall be based on the highest activity of gas handled in a single container and the measured available air exhaust rate.

(iv) A licensee shall post the time calculated in §175.103(e)(3)(iii) at the area of use, as well as safety measures to be instituted in case of a spill at the area of use.

(v) A licensee shall check the operation of collection systems monthly and measure the ventilation rates in areas of use at intervals not to exceed 6 months. Records of these checks and measurements shall be maintained for 3 years.

(vi) A copy of the calculations, including assumptions, measurements and calculations made, required in §175.103(e)(3)(iii) shall be recorded and retained for the duration of the license.

(5) *Possession of survey instruments.* A licensee authorized to use unsealed byproduct material-written directive not required, shall have in its possession a portable, radiation detection survey instrument capable of detecting dose rates over the range of 1.0 mSv (0.1 mrem) per hour to 1000 mSv (100 mrem) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 mSv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. The instruments shall be operable and calibrated in accordance with §175.103(c)(2).

(e)Unsealed Byproduct Material--Written Directive Required

(1) *Use of unsealed byproduct material for which a written directive is required.*

(i) A licensee may use any unsealed byproduct material prepared for medical use and for which a written directive is required that is—

(a) Obtained from:

(1) A manufacturer or preparer licensed under §10 CFR 32.72 or equivalent Agreement State requirements; or

(2) A PET radioactive drug producer licensed under §10 CFR 30.32(j) or equivalent Agreement State requirements; or

(b) Excluding production of PET radionuclides, prepared by:

(1) An authorized nuclear pharmacist;

(2) A physician who is an authorized user and who meets the requirements specified in §§175.103(j)(5), 175.103(j)(6), or

(3) An individual under the supervision, as specified in §175.103(b)(3), of the authorized nuclear pharmacist in paragraph (b)(1) of this section or the physician who is an authorized user in paragraph (b)(2) of this section; or

(c) Obtained from and prepared by an NRC or Agreement State licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA; or

(d) Prepared by the licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA.

(2) Safety instruction.

In addition to the requirements of § 10 CFR 19.12,

(a) A licensee shall provide oral and written radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who cannot be released under § 175.103(c)(9). To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include—

(1) Patient or human research subject control;

(2) Visitor control, including—

(i) Routine visitation to hospitalized individuals in accordance with § 10 CFR 20.1301(a)(1); and

(ii) Visitation authorized in accordance with § 10 CFR 20.1301(c);

(3) Contamination control;

(4) Waste control; and

(5) Notification of the Radiation Safety Officer, or his or her designee, and an authorized user if the patient or the human research subject has a medical emergency or dies.

(b) A licensee shall retain a record of individuals receiving instruction in accordance with § 175.03(k)(23).

(3) Safety precautions.

(a) For each patient or human research subject who cannot be released under § 175.103(c)(9), a licensee shall—

(1) Quarter the patient or the human research subject either in—

(i) A private room with a private sanitary facility; or

(ii) A room, with a private sanitary facility, with another individual who also has received therapy with unsealed byproduct material and who also cannot be released under § 175.103(c)(9);

(2) Visibly post the patient's or the human research subject's room with a "Radioactive Materials" sign.

(3) Note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or the human research subject's room and authorize visits by individuals under age 18 only on a patient-by-patient basis with the approval of the authorized user after consultation with the radiation safety officer; and

(4) Either monitor material and items removed from the patient's or the human research subject's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle the material and items as radioactive waste; and

(5) Promptly after administration of the dosage, measure the dose rates in contiguous restricted and unrestricted areas with a radiation

measurement survey instrument to demonstrate compliance with the requirements of §175.03 of this Code and retain for 3 years a record of each survey that includes the time and date of the survey, a plan of the area or list of points surveyed, the measured dose rate at several points expressed in mSv (mrem) per hour, the instrument used to make the survey, and the initials of the individual who made the survey.

(6) Survey the patient's room and private sanitary facility for removable contamination with a radiation detection survey instrument before assigning another patient to the room. The room must not be reassigned until removable contamination is less than 5 Bq (l200 disintegrations per minute) per 100 square centimeters.

(7) Measure the thyroid burden of each individual who helped prepare or administer a dosage of iodine-131 within 3 days after administering the dosage, and retain for the period required by §175.03(k) a record of each thyroid burden measurement, date of measurement, the name of the individual whose thyroid burden was measured, and the initials of the individual who made the measurements.

(b) A licensee shall notify the Radiation Safety Officer, or his or her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

(4) *Possession of survey instruments.* A licensee authorized to use unsealed byproduct material for which a written directive is required shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range 1.0 mSv (0.1 mrem) per hour to 1000 mSv (100 mrem) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 mSv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. The instruments shall be operable and calibrated in accordance with §175.103(c)(2).

(f) ManualBrachytherapy

(1) Use of sources for manual brachytherapy.

A licensee shall use only brachytherapy sources for therapeutic medical uses:

(a) As approved in the Sealed Source and Device Registry; or

(b) In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of § 175.103(b)(6)(a) are met.

(2) Surveys after source implant and removal.

(a) Immediately after implanting sources in a patient or a human research subject, the licensee shall make a survey to locate and account for all sources that have not been implanted.

(b) Immediately after removing the last temporary implant source from a patient or a human research subject, the licensee shall make a survey of the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed.

(c) A licensee shall retain a record of the surveys required by paragraphs (a) and (b) of this section in accordance with § 175.03(k)(24).

(3) Brachytherapy sources accountability.

(a) A licensee shall maintain accountability at all times for all brachytherapy sources in storage or use.

(b) As soon as possible after removing sources from a patient or a human research subject, a licensee shall return brachytherapy sources to a secure storage area.

(c) A licensee shall maintain a record of the brachytherapy source accountability in accordance with § 175.03(k)(25).

(4) Safety instruction.

In addition to the requirements of § 10 CFR 19.12,

(a) The licensee shall provide oral and written radiation safety instruction, initially and at least annually, to all personnel caring for patients or human research subjects who are receiving brachytherapy and cannot be released under § 175.103(c)(9). To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include the--

(1) Size and appearance of the brachytherapy sources;

(2) Safe handling and shielding instructions;

(3) Procedures for patient or human research subject control;

(4) Procedures for visitor control, including both:

(i) Routine visitation of hospitalized individuals in accordance with § 10 CFR 20.1301(a)(1); and

(ii) Visitation authorized in accordance with §10 CFR 20.1301(c); and

(5) Procedures for notification of the Radiation Safety Officer, or his or her designee, and an authorized user if the patient or the human research subject has a medical emergency or dies.

(b) A licensee shall retain a record of individuals receiving instruction in accordance with § 175.03(k)(23).

(5) Safety precautions.

(a) For each patient or human research subject who is receiving brachytherapy and cannot be released under § 175.103(c)(9), a licensee shall--

(1) Not quarter the patient or the human research subject in the same room as an individual who is not receiving brachytherapy;

(2) Visibly post the patient's or human research subject's room with a "Radioactive Materials" sign; and

(3) Note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room, and authorize visits by individuals under age 18 only on a case-by-case basis with the approval of the authorized user after consultation with the radiation safety officer.

(4) Promptly after implanting the sources, survey the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with §175.03 of this Code and retain for 3 years a record of each survey that includes the time and date of the survey, a sketch of the area or list of points surveyed, the measured dose rate at several points expressed in mSv (mrem) per hour, the instrument used to make the survey, and the initials of the individual who made the survey; and

(5) Provide the patient with radiation safety guidance that will help to keep the radiation dose to household members and the public as low as reasonably achievable before releasing the patient if the patient was administered a permanent implant.

(b) A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source--

(1) Dislodged from the patient; and

(2) Lodged within the patient following removal of the source applicators.

(c) A licensee shall notify the Radiation Safety Officer, or his or her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

(6) *Possession of survey instruments.* A licensee authorized to use sources for manual brachytherapy shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range 1.0 mSv (0.1 mrem) per hour to 1000 mSv (100 mrem) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 mSv (1 mrem) per

hour to 10 mSv (1000 mrem) per hour. The instruments shall be operable and calibrated in accordance with §175.103(c)(2).

(7) Calibration measurements of brachytherapy sources.

(a) Before the first medical use of a brachytherapy source on or after October 24, 2002, a licensee shall have—

(1) Determined the source output or activity using a dosimetry system that meets the requirements of § 175.103(h)(8)(a);

(2) Determined source positioning accuracy within applicators; and

(3) Used published protocols currently accepted by nationally recognized bodies to meet the requirements of paragraphs (a)(1) and (a)(2) of this section.

(b) Instead of a licensee making its own measurements as required in paragraph (a) of this section, the licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine that are made in accordance with paragraph (a) of this section.

(c) A licensee shall mathematically correct the outputs or activities determined in paragraph (a) of this section for physical decay at intervals consistent with 1 percent physical decay.

(d) A licensee shall retain a record of each calibration in accordance with § 175.03(k)(26).

(8) Decay of strontium-90 sources for ophthalmic treatments.

(a) Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under § 175.103(f)(7).

(b) A licensee shall retain a record of the activity of each strontium-90 source in accordance with § 175.03(k)(27).

(9) Therapy-related computer systems.

The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

(a) The source-specific input parameters required by the dose calculation algorithm;

(b) The accuracy of dose, dwell time, and treatment time calculations at representative points;

(c) The accuracy of isodose plots and graphic displays; and

(d) The accuracy of the software used to determine sealed source positions from radiographic images.

(g) Sealed sources for diagnosis

(1) Use of sealed sources for diagnosis.

A licensee shall use only sealed sources for diagnostic medical uses as approved in the Sealed Source and Device Registry.

(2) *Availability of survey instrument.* A licensee authorized to use sealed sources for diagnosis shall have available for use a portable radiation detection survey instrument capable of detecting dose rates over the range 1.0 mSv (0.1 mrem) per hour to 1000 mSv (100 mrem) per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 mSv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. The instrument shall be operable and calibrated in accordance with §175.103(c)(2).

(h) Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

(1) Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit.

A licensee shall use sealed sources in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units for therapeutic medical uses:

(a) As approved in the Sealed Source and Device Registry; or

(b) In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of § 175.103(b)(6)(a) are met.

(2) Surveys of patients and human research subjects treated with a remote afterloader unit.

[Release of patients treated with temporary implants. (i) Immediately after removing the last temporary implant source from a patient, the licensee shall make a radiation survey of the patient with a radiation detection survey instrument to confirm that all sources have been removed.]

(a) Immediately after removing the last temporary implant source from a patient or a human research subject, a licensee shall survey the patient or the human research subject and the remote afterloader unit with a portable radiation detection survey instrument to confirm that the source(s) has been removed from the patient or human research subject and returned to the safe shielded position.

The licensee shall not release from confinement for medical care a patient or a human research subject treated by temporary implant until all sources have been removed.

(b) A licensee shall retain a record of these surveys in accordance with § 175.03(k)(24).

[(ii) A licensee shall retain a record of patient surveys which demonstrate compliance with §175.103(h)(2)(a) for 3 years. Each record must include the date of the survey, the name of the patient, the dose rate from the patient expressed as mSv (mrem) per hour and measured within 1 meter from the patient, and the initials of the individual who made the survey.]

(3) Installation, maintenance, adjustment, and repair.

(a) Only a person specifically licensed by the Commission or an Agreement State shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source(s), reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

(b) Except for low dose-rate remote afterloader units, only a person specifically licensed by the Commission or an Agreement State shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units.

(c) For a low dose-rate remote afterloader unit, only a person specifically licensed by the Commission or an Agreement State or an authorized medical physicist shall install, replace, relocate, or remove a sealed source(s) contained in the unit.

(d) A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units in accordance with § 175.03(k)(28).

(4) *Amendments.* In addition to the requirements specified in §175.103(a)(5), a licensee shall apply for and shall have received a license amendment before:

(i) making any change in the treatment room shielding;

(ii) making any change in the location of the teletherapy unit within the treatment room;

(iii) using the teletherapy unit in a manner that could result in increased radiation levels in areas outside the teletherapy treatment room;

(iv) relocating the teletherapy unit; or

(v) allowing an individual not listed on the licensee's license to perform the duties of the authorized medical physicist.

(5) Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

(a) A licensee shall--

(1) Secure the unit, the console, the console keys, and the treatment room when not in use or unattended;

(2) Permit only individuals approved by the authorized user, Radiation Safety Officer, or authorized medical physicist to be present in the treatment room during treatment with the source(s);

(3) Prevent dual operation of more than one radiation producing device in a treatment room if applicable; and

(4) Develop, implement, and maintain written procedures for ensuring that only approved individuals are present in the treatment room during treatment with the source(s); for responding to an abnormal situation when the operator is unable to place the source(s) in the shielded position; or removing the patient or human research subject from the radiation field with controls from outside the treatment room. These procedures must include--

(i) Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;

(ii) The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

(iii) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

(b) A copy of the procedures required by paragraph (a)(4) of this section must be physically located at the unit console.

(c) A licensee shall post instructions at the unit console to inform the operator of--

(1) The location of the procedures required by paragraph (a)(4) of this section; and

(2) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

(d) A licensee shall provide instruction, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties, in--

(1) The procedures identified in paragraph (a)(4) of this section; and

(2) The operating procedures for the unit.

(e) A licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

(f) A licensee shall retain a record of individuals receiving instruction required by paragraph (d) of this section, in accordance with § 175.03(k)(23).

(g) A licensee shall retain a copy of the procedures required by §§ 175.103(h)(5)(a)(4) and (d)(2) in accordance with § 175.03(k)(29).

(6) Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

(a) A licensee shall control access to the treatment room by a door at each entrance.

(b) A licensee shall equip each entrance to the treatment room with an electrical interlock system that will--

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

(2) Cause the source(s) to be shielded when an entrance door is opened; and

(3) Prevent the source(s) from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source(s) on-off control is reset at the console.

(c) A licensee shall equip each entrance to the teletherapy room with a beam condition indicator light.

(d) A licensee shall have in each teletherapy room a permanent radiation monitor capable of continuously monitoring beam status.

(1) Each radiation monitor shall be capable of providing visible notice of a teletherapy unit malfunction that results in an exposed or partially exposed source. The visible indicator of high radiation levels must be observable by an individual entering the teletherapy room.

(2) A licensee shall require any individual entering the treatment room to assure, through the use of the radiation monitors, that radiation levels have returned to ambient levels.

(3) Each radiation monitor shall be equipped with a backup power supply separate from the power supply to the teletherapy unit. This backup power supply may be a battery system.

(4) A radiation monitor must be checked with a dedicated check source for proper operation each day before the teletherapy unit is used for treatment of patients.

(5) A licensee shall maintain a record of the check required by §175.103(i)(7)(iv) for 3 years. The record shall include the date of the check, notation that the monitor indicates when the source is exposed, and the initials of the individual who performed the check.

(6) If a radiation monitor is inoperable, the licensee shall require any individual entering the teletherapy room to use a survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the source exposure mechanism that may result in an exposed or partially exposed source. The instrument or dosimeter shall be checked with a dedicated check source for proper operation at the beginning of each day of use. The licensee shall keep a record as described in §175.103(i)(7)(v).

(7) A licensee shall promptly repair or replace the radiation monitor if it is inoperable.

(e) Except for low-dose remote afterloader units, a licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation.

(f) For licensed activities where sources are placed within the patient's or human research subject's body, a licensee shall only conduct treatments which allow for expeditious removal of a decoupled or jammed source.

(g) In addition to the requirements specified in paragraphs (a) through (f) of this section, a licensee shall--

(1) For medium dose-rate and pulsed dose-rate remote afterloader units, require--

(i) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit to be physically present during the initiation of all patient treatments involving the unit; and

(ii) An authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who has been trained to remove the source applicator(s) in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit.

(2) For high dose-rate remote afterloader units, require—

(i) An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and

(ii) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, to be physically present during continuation of all patient treatments involving the unit.

(3) For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit.

(4) Notify the Radiation Safety Officer, or his/her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

(g) A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source--

(1) Remaining in the unshielded position; or

(2) Lodged within the patient following completion of the treatment.

(7) *Possession of survey instruments.* A licensee authorized to use a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit shall have in its possession a portable radiation detection survey instrument capable of detecting rates over the range 1.0 mSv (0.1 mrem) per hour to 1000 mSv (100 mrem) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 mSv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. The instruments shall be operable and calibrated in accordance with §175.103(c)(2).

(8) Dosimetry equipment.

(a) Except for low dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer, a licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions must be met.

(1) The system must have been calibrated using a system or source traceable to the National Institute of Standards and Technology (NIST) and published protocols accepted by nationally recognized bodies; or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration must have been performed within the previous 2 years and after any servicing that may have affected system calibration; or

(2) The system must have been calibrated within the previous 4 years. Eighteen to thirty months after that calibration, the system must have been intercompared with another dosimetry system that was calibrated within the past 24 months by NIST or by a calibration laboratory accredited by the AAPM. The results of the intercomparison must indicate that the calibration factor of the licensee's system had not changed by more than 2 percent. The licensee may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee shall use a comparable unit with beam attenuators or collimators, as

applicable, and sources of the same radionuclide as the source used at the licensee's facility.

(b) The licensee shall have a dosimetry system available for use for spot-check output measurements, if applicable. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with paragraph (a) of this section. This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in paragraph (a) of this section.

(c) The licensee shall retain a record of each calibration, intercomparison, and comparison in accordance with § 175.03(k)(30).

(9) Full calibration measurements on teletherapy units.

(a) A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit--

(1) Before the first medical use of the unit; and

(2) Before medical use under the following conditions:

(i) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(ii) Following replacement of the source or following reinstallation of the teletherapy unit in a new location;

(iii) Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(3) At intervals not exceeding 1 year.

(b) To satisfy the requirement of paragraph (a) of this section, full calibration measurements must include determination of--

(1) The output within +/-3 percent for the range of field sizes and for the distance or range of distances used for medical use;

(2) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(3) The uniformity of the radiation field and its dependence on the orientation of the useful beam;

(4) Timer accuracy and linearity over the range of use;

(5) On-off error; and

(6) The accuracy of all distance measuring and localization devices in medical use.

(c) A licensee shall use the dosimetry system described in § 175.103(h)(8)(a) to measure the output for one set of exposure conditions. The remaining radiation measurements required in paragraph (b)(1) of this section may be made using a dosimetry system that indicates relative dose rates.

(d) A licensee shall make full calibration measurements required by paragraph (a) of this section in accordance with published protocols accepted by nationally recognized bodies.

(e) A licensee shall mathematically correct the outputs determined in paragraph (b)(1) of this section for physical decay for intervals not exceeding 1 month for cobalt-60, 6 months for cesium-137, or at intervals consistent with 1 percent decay for all other nuclides.

(f) Full calibration measurements required by paragraph (a) of this section and physical decay corrections required by paragraph (e) of this section must be performed by the authorized medical physicist named on the license.

(g) A licensee shall retain a record of each calibration in accordance with § 175.03(k)(31).

(10) Full calibration measurements on remote afterloader units.

(a) A licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit--

(1) Before the first medical use of the unit;

(2) Before medical use under the following conditions:

(i) Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and

(ii) Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(3) At intervals not exceeding 1 quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds 75 days; and

(4) At intervals not exceeding 1 year for low dose-rate remote afterloader units.

(b) To satisfy the requirement of paragraph (a) of this section, full calibration measurements must include, as applicable, determination of:

(1) The output within ± 5 percent;

(2) Source positioning accuracy to within ±1 millimeter;

(3) Source retraction with backup battery upon power failure;

(4) Length of the source transfer tubes;

(5) Timer accuracy and linearity over the typical range of use;

(6) Length of the applicators; and

(7) Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

(c) A licensee shall use the dosimetry system described in § 175.103(h)(8)(a) to measure the output.

(d) A licensee shall make full calibration measurements required by paragraph (a) of this section in accordance with published protocols accepted by nationally recognized bodies.

(e) In addition to the requirements for full calibrations for low dose-rate remote afterloader units in paragraph (b) of this section, a licensee shall perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding 1 quarter.

(f) For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with paragraphs (a) through (e) of this section.

(g) A licensee shall mathematically correct the outputs determined in paragraph (b)(1) of this section for physical decay at intervals consistent with 1 percent physical decay.

(h) Full calibration measurements required by paragraph (a) of this section and physical decay corrections required by paragraph (g) of this section must be performed by the authorized medical physicist.

(i) A licensee shall retain a record of each calibration in accordance with § 175.03(k)(31).

(11) Full calibration measurements on gamma stereotactic radiosurgery units.

(a) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each unit--

(1) Before the first medical use of the unit;

(2) Before medical use under the following conditions--

(i) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(ii) Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and

(iii) Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and

(3) At intervals not exceeding 1 year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.

(b) To satisfy the requirement of paragraph (a) of this section, full calibration measurements must include determination of--

(1) The output within ±3 percent;

(2) Relative helmet factors;

(3) Isocenter coincidence;

(4) Timer accuracy and linearity over the range of use;

(5) On-off error;

(6) Trunnion centricity;

(7) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

(8) Helmet microswitches;

(9) Emergency timing circuits; and

(10) Stereotactic frames and localizing devices (trunnions).

(c) A licensee shall use the dosimetry system described in § 175.103(h)(8)(a) to measure the output for one set of exposure conditions. The remaining radiation measurements required in paragraph (b)(1) of this section may be made using a dosimetry system that indicates relative dose rates.

(d) A licensee shall make full calibration measurements required by paragraph (a) of this section in accordance with published protocols accepted by nationally recognized bodies.

(e) A licensee shall mathematically correct the outputs determined in paragraph (b)(1) of this section at intervals not exceeding 1 month for cobalt-60 and at intervals consistent with 1 percent physical decay for all other radionuclides.

(f) Full calibration measurements required by paragraph (a) of this section and physical decay corrections required by paragraph (e) of this section must be performed by the authorized medical physicist.

(g) A licensee shall retain a record of each calibration in accordance with § 175.03(k)(31).

(12) Periodic spot-checks for teletherapy units.

(a) A licensee authorized to use teletherapy units for medical use shall perform output spot-checks on each teletherapy unit once in each calendar month and after making any change for which an amendment is required by §175.103(i)(3) that include determination of--

(1) Timer accuracy, and timer linearity over the range of use;

(2) On-off error;

(3) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(4) The accuracy of all distance measuring and localization devices used for medical use;

(5) The output for one typical set of operating conditions measured with the dosimetry system described in § 175.103(h)(8)(b); and

(6) The difference between the measurement made in paragraph (a)(5) of this section and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

( ) A licensee shall use the dosimetry system described in § 175.103(i)(9) to measurements required in § 175.103(i)(11)(ii)(E).

(b) A licensee shall perform measurements required by paragraph (a) of this section in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot-check measurements.

(c) A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check. The licensee shall retain a copy of each such notification for three years.

(d) A licensee authorized to use a teletherapy unit for medical use shall perform safety spot-checks of each teletherapy facility once in each calendar month and after each source installation to assure proper operation of--

(1) Electrical interlocks at each teletherapy room entrance;

(2) Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);

(3) Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;

(4) Viewing and intercom systems;

(5) Treatment room doors from inside and outside the treatment room; and

(6) Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

(e) If the results of the checks required in paragraph (d) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(f) A licensee shall retain a record of each spot-check required by paragraphs (a) and (d) of this section, and a copy of the procedures required by paragraph (b), in accordance with § 175.03(k)(32).

(13) Periodic spot-checks for remote afterloader units.

(a) A licensee authorized to use a remote afterloader unit for medical use shall perform spot-checks of each remote afterloader facility and on each unit--

(1) Before the first use of a high dose-rate, medium dose-rate, or pulsed dose-rate remote afterloader unit on a given day;

(2) Before each patient treatment with a low dose-rate remote afterloader unit; and

(3) After each source installation.

(b) A licensee shall perform the measurements required by paragraph (a) of this section in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

(c) A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

(d) To satisfy the requirements of paragraph (a) of this section, spot-checks must, at a minimum, assure proper operation of--

(1) Electrical interlocks at each remote afterloader unit room entrance;

(2) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(3) Viewing and intercom systems in each high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader facility;

(4) Emergency response equipment;

(5) Radiation monitors used to indicate the source position;

(6) Timer accuracy;

(7) Clock (date and time) in the unit's computer; and

(8) Decayed source(s) activity in the unit's computer.

(e) If the results of the checks required in paragraph (d) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as

may be necessary to repair, replace, or check the malfunctioning system.

(f) A licensee shall retain a record of each check required by paragraph (d) of this section and a copy of the procedures required by paragraph (b) of this section in accordance with § 175.03(k)(33).

(14) Periodic spot-checks for gamma stereotactic radiosurgery units.

(a) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform spot-checks of each gamma stereotactic radiosurgery facility and on each unit--

(1) Monthly;

(2) Before the first use of the unit on a given day; and

(3) After each source installation.

(b) A licensee shall--

(1) Perform the measurements required by paragraph (a) of this section in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

(2) Have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

(c) To satisfy the requirements of paragraph (a)(1) of this section, spot-checks must, at a minimum--

(1) Assure proper operation of--

(i) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

(ii) Helmet microswitches;

(iii) Emergency timing circuits; and

(iv) Stereotactic frames and localizing devices (trunnions).

(2) Determine--

(i) The output for one typical set of operating conditions measured with the dosimetry system described in § 175.103(h)(8)(b);

(ii) The difference between the measurement made in paragraph (c)(2)(i) of this section and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay);

(iii) Source output against computer calculation;

(iv) Timer accuracy and linearity over the range of use;

(v) On-off error; and

(vi) Trunnion centricity.

(d) To satisfy the requirements of paragraphs (a)(2) and (a)(3) of this section, spot-checks must assure proper operation of--

(1) Electrical interlocks at each gamma stereotactic radiosurgery room entrance;

(2) Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;

(3) Viewing and intercom systems;

(4) Timer termination;

(5) Radiation monitors used to indicate room exposures; and

(6) Emergency off buttons.

(e) A licensee shall arrange for the repair of any system identified in paragraph (c) of this section that is not operating properly as soon as possible.

(f) If the results of the checks required in paragraph (d) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(g) A licensee shall retain a record of each check required by paragraphs (c) and (d) and a copy of the procedures required by paragraph (b) of this section in accordance with § 175.03(k)(34).

(15) Additional technical requirements for mobile remote afterloader units.

(a) A licensee providing mobile remote afterloader service shall--

(1) Check survey instruments before medical use at each address of use or on each day of use, whichever is more frequent; and

(2) Account for all sources before departure from a client's address of use.

(b) In addition to the periodic spot-checks required by § 175.103(h)(13), a licensee authorized to use mobile afterloaders for medical use shall perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks must be made to verify the operation of--

(1) Electrical interlocks on treatment area access points;

(2) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(3) Viewing and intercom systems;

(4) Applicators, source transfer tubes, and transfer tube-applicator interfaces;

(5) Radiation monitors used to indicate room exposures;

(6) Source positioning (accuracy); and

(7) Radiation monitors used to indicate whether the source has returned to a safe shielded position.

(c) In addition to the requirements for checks in paragraph (b) of this section, a licensee shall ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.

(d) If the results of the checks required in paragraph (b) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(e) A licensee shall retain a record of each check required by paragraph (b) of this section in accordance with § 175.03(k)(35).

(16) Radiation surveys.

(a) In addition to the survey requirement in §175.03, a person licensed under this section shall make surveys to ensure that:

(A) the maximum and average radiation levels at 1 meter from the teletherapy source with the source in the off position and the collimators set for a normal treatment field do not exceed 100 mSv (10 mrem) per hour and 20 mSv (2 mrem) per hour, respectively; and

(B) with the teletherapy source in the on position with the largest clinically available treatment field and with a scattering phantom in the primary beam of radiation, that:

(a) radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in §175.03; and

(b) radiation levels in unrestricted areas do not exceed the limits specified in §175.03.

(ii) If the results of the surveys required in §175.103(h)(16)(a) indicate any radiation levels in excess of the respective limit specified in §175.103(h(16)(a)(A) or (B), the licensee shall lock the control in the "off" position and not use the unit:

(A) except as may be necessary to repair, replace, or test the teletherapy unit, the teletherapy unit shielding or the treatment room shielding; or

(B) until the licensee has received a specific exemption from the Department.

<u>(b) The licensee shall make the survey required by paragraph (a) of this section at installation of a new source and following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).</u>

<u>(c) A licensee shall retain a record of the radiation surveys required by paragraph (a) of this section in accordance with § 175.03(k)(36).</u>

(17) *Reports of teletherapy <u>and gamma stereotactic radiosurgery</u> surveys, checks, tests, and measurements.* A licensee shall furnish a copy of the records required in 175.103(h)(9) and (11) and the output from the teletherapy source expressed as Sv (rem) per hour at one meter from the source determined during the surveys required in §175.103(i)(16) to the

[Bureau] Office of Radiological Health within 30 days following completion of the action that initiated the record requirement.

(18) *Modification of a teletherapy unit or room before beginning a treatment program.* (i) If the survey required by §175.103(i)(16) indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by §175.03, before beginning the treatment program the licensee shall:

(A) either equip the unit with stops or add additional radiation shielding to ensure compliance with §175.03;

(B) perform the survey required by §175.103(i)(16) again; and

(C) include in the report required by §175.103(i)(15) the results of the initial survey, a description of the modification made to comply with §175.103(i)(16)(i) and the results of the second survey; or

(D) request and receive a license amendment that authorizes radiation levels in unrestricted areas greater than those permitted by §175.03.

(19) Five-year inspection for teletherapy and gamma stereotactic radiosurgery units.

(a) A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement or at intervals not to exceed 5 years, whichever comes first, to assure proper functioning of the source exposure mechanism.

(b) This inspection and servicing may only be performed by persons specifically licensed to do so by the Commission or an Agreement State.

(c) A licensee shall keep a record of the inspection and servicing in accordance with § 175.03(k)(37).

(20) Therapy-related computer systems.

The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

(a) The source-specific input parameters required by the dose calculation algorithm;

(b) The accuracy of dose, dwell time, and treatment time calculations at representative points;

(c) The accuracy of isodose plots and graphic displays;

(d) The accuracy of the software used to determine sealed source positions from radiographic images; and

(e) The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

(i) Other Medical Uses of Byproduct Material or Radiation From Byproduct Material

(1) 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 §175.103(d) through (h) if--

(a) The applicant or licensee has submitted the information required by § 175.103(a)(6)(b) through (d); and

(b) The applicant or licensee has received written approval from the Commission in a license or license amendment and uses the material in accordance with the regulations and specific conditions the Commission considers necessary for the medical use of the material.

§175.103(j) *Training and experience requirements.*

(1) *Radiation safety officer.* Except as provided in § 175.103(j)(14), the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in § 175.103(b)(2) to be an individual who--

(i) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraphs (iv) and (v) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(A)(a) Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;

(b) Have 5 or more years of professional experience in health physics (graduate training may be substituted for no more than 2 years of the required experience) including at least 3 years in applied health physics; and

(c) Pass an examination administered by diplomates of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or

(B)(a) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

(b) Have 2 years of full-time practical training and/or supervised experience in medical physics—

(I) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Commission or an Agreement State; or

(II) In clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of physicians who meet the requirements for authorized users in §§ 175.103(j)(14), 175.103(j)(5), or 175.103(j)(6);

(c) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or

(ii)(A) Has completed a structured educational program consisting of both:

(a) 200 hours of classroom and laboratory training in the following areas--

(I) Radiation physics and instrumentation;

(II) Radiation protection;

(III) Mathematics pertaining to the use and measurement of radioactivity;

(IV) Radiation biology; and

(V) Radiation dosimetry; and

(a) One year of full-time radiation safety experience under the supervision of the individual identified as the Radiation Safety Officer on a Commission or Agreement State license or permit issued by a Commission master material licensee that authorizes similar type(s) of use(s) of byproduct material involving the following--

(I) Shipping, receiving, and performing related radiation surveys;

(II) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;

(III) Securing and controlling byproduct material;

(IV) Using administrative controls to avoid mistakes in the administration of byproduct material;

(V) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

(VI) Using emergency procedures to control byproduct material; and

(VI) Disposing of byproduct material; or

(B) [Reserved]

(iii)(A) Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State under § 175.103(j)(2)(a) and has experience in radiation safety for similar types of use of byproduct material for which the licensee is seeking the approval of the individual as Radiation Safety Officer and who meets the requirements in paragraphs (d) and (e) of this section; or

(B) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual has Radiation Safety Officer responsibilities; and,

(iv) Has obtained written attestation, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in paragraph (v) and in paragraphs (i)(A)(a) and (i)(A)(b) or (i)(B)(a) and (i)(B)(b) or (ii)(A) or (iii)(A) or (iii)(B) of this section, and has achieved a level of radiation safety knowledge sufficient to

function independently as a Radiation Safety Officer for a medical use licensee; and

(v) Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a Radiation Safety Officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

(2) Training for an authorized medical physicist.

Except as provided in § 175.103(j)(14), the licensee shall require the authorized medical physicist to be an individual who—

(i) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraphs (ii)(B) and (iii) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(A) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

(B) Have 2 years of full-time practical training and/or supervised experience in medical physics—

(*a*) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Commission or an Agreement State; or

(*b*) In clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of

physicians who meet the requirements in § 175.103(j)(14), 175.103(j)(10), or 175.103(j)(13); and

(C) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery; or

(ii)(A) Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and has completed 1 year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type(s) of use for which the individual is seeking authorization. This training and work experience must be conducted in clinical radiation facilities that provide high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services and must include:

(*a*) Performing sealed source leak tests and inventories;

(*b*) Performing decay corrections;

(*c*) Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(*d*) Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(B) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (iii) and (i)(A) and (i)(B), or (ii)(A) and (iii) of this section, and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is

requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in §§ 175.103(j)(2), 175.103(j)(14), or equivalent Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; and

(iii) Has training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the type(s) of use for which the individual is seeking authorization.

(3) Training for authorized nuclear pharmacist.

Except as provided in § 175.103(j)(14), the licensee shall require the authorized nuclear pharmacist to be a pharmacist who--

(a) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraph (b)(2) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Have graduated from a pharmacy program accredited by the American Council on Pharmaceutical Education (ACPE) or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;

(2) Hold a current, active license to practice pharmacy;

(3) Provide evidence of having acquired at least 4000 hours of training/experience in nuclear pharmacy practice. Academic training

may be substituted for no more than 2000 hours of the required training and experience; and

(4) Pass an examination in nuclear pharmacy administered by diplomates of the specialty board, that assesses knowledge and competency in procurement, compounding, quality assurance, dispensing, distribution, health and safety, radiation safety, provision of information and consultation, monitoring patient outcomes, research and development; or

(b)(1) Has completed 700 hours in a structured educational program consisting of both:

(i) 200 hours of classroom and laboratory training in the following areas—

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(ii) Supervised practical experience in a nuclear pharmacy involving--

(A) Shipping, receiving, and performing related radiation surveys;

(B) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;

(C) Calculating, assaying, and safely preparing dosages for patients or human research subjects;

(D) Using administrative controls to avoid medical events in the administration of byproduct material; and

(E) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

(2) Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in paragraphs (a)(1), (a)(2), and (a)(3) or (b)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

(4) *Training for uptake, dilution, or excretion studies.*

Except as provided in § 175.103(j)(14), the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under § 175.103(d)(1) to be a physician who—

(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraph (c)(2) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies as described in paragraphs (c)(1)(i) through (c)(1)(ii)(F) of this section; and

(2) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

(b) Is an authorized user under §§ 175.103(j)(5), 175.103(j)(6), or equivalent Agreement State requirements; or (c)(1)*

(c)(1) Has completed 60 hours of training and experience, including a minimum of 8 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies. The training and experience must include—

(i) Classroom and laboratory training in the following areas—

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in §§ 175.103(j)(14), 175.103(j)(4), 175.103(j)(5), 175.103(j)(6), or equivalent Agreement State requirements, involving—

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(C) Calculating, measuring, and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(F) Administering dosages of radioactive drugs to patients or human research subjects; and

(2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 175.103(j)(14), 175.103(j)(4), 175.103(j)(5), or 175.103(j)(6), or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (a)(1) or (c)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 175.103(d)(1).

(5) *Training for imaging and localization studies.*

Except as provided in § 175.103(j)(14), the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under § 175.103(d)(2) to be a physician who—

(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraph (c)(2) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for imaging and localization studies as described in paragraphs (c)(1)(i) through (c)(1)(ii)(G) of this section; and

(2) Pass an examination, administered by diplomates of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

(b) Is an authorized user under § 175.103(j)(6) and meets the requirements in § 175.103(j)(5)(c)(1)(ii)(G), or equivalent Agreement State requirements; or

(c)(1) Has completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for imaging and localization studies. The training and experience must include, at a minimum—

(i) Classroom and laboratory training in the following areas—

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use;

(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in §§ 175.103(j)(14), 175.103(j)(5), 175.103(j)(5)(c)(1)(ii)(G), and 175.103(j)(6) or equivalent Agreement State requirements, involving—

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(C) Calculating, measuring, and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(E) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;

(F) Administering dosages of radioactive drugs to patients or human research subjects; and

(G) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

(2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 175.103(j)(14), 175.103(j)(5), or 175.103(j)(6) and 175.103(j)(5)(c)(1)(ii)(G), or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (a)(1) or (c)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under §§ 175.103(d)(1) and 175.103(d)(2).

(6) Training for use of unsealed byproduct material for which a written directive is required.

Except as provided in § 175.103(j)(14), the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under § 175.103(e)(1) to be a physician who—

(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraphs (b)(1)(ii)(G) and (b)(2) of this section. (Specialty boards whose certification processes have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To be recognized, a specialty board shall require all candidates for certification to:

(1) Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must include 700 hours of training and experience as described in paragraphs (b)(1)(i) through (b)(1)(ii)(E) of this section. Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for

Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(2) Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed byproduct material for which a written directive is required; or

(b)(1) Has completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material requiring a written directive. The training and experience must include—

(i) Classroom and laboratory training in the following areas—

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in §§ 175.103(j)(14), 175.103(j)(6), or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in § 175.103(j)(6)(b), must also have experience in administering dosages in the same dosage category or categories (*i.e.*, § 175.103(j)(6)(b)(1)(ii)(G)) as the individual requesting authorized user status. The work experience must involve—

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

(C) Calculating, measuring, and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures;

(F) [Reserved]

(G) Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status—

(*1*) Oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I–131, for which a written directive is required;

(*2*) Oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-1312;

(*3*) Parenteral administration of any beta emitter, or a photon- emitting radionuclide with a photon energy less than 150 keV, for which a written directive is required; and/or

(4) Parenteral administration of any other radionuclide, for which a written directive is required; and

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (a)(1) and (b)(1)(ii)(G) or (b)(1) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses

authorized under § 175.103(e)(1). The written attestation must be signed by a preceptor authorized user who meets the requirements in §§ 175.103(j)(14), 175.103(j)(6), or equivalent Agreement State requirements. The preceptor authorized user, who meets the requirements in § 175.103(j)(6)(b) must have experience in administering dosages in the same dosage category or categories (i.e., § 175.103(j)(6)(b)(1)(ii)(G)) as the individual requesting authorized user status

(7) Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries).

Except as provided in § 175.103(j)(14), the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries), to be a physician who—

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraphs (c)(1) and (c)(2) of this section and whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraph (c)(3) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.); or

(b) Is an authorized user under § 175.103(j)(6) for uses listed in §175.103(j)(6)(b)(1)(ii)(G)(1) or (2), § 175.103(j)(8), or equivalent Agreement State requirements; or

(c)(1) Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include—

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of byproduct material for medical use; and

(v) Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in §§ 175.103(j)(14), 175.103(j)(6), 175.103(j)(7), 175.103(j)(8), or equivalent Agreement State requirements. A supervising authorized user who meets the requirements in § 175.103(j)(6)(b) must also have experience in administering dosages as specified in §§ 175.103(j)(6)(b)(1)(ii)(G)(1) or 175.103(j)(6)(b)(1)(ii)(G)(2). The work experience must involve—

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent a medical event involving the use of byproduct material;

(v) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(vi) Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under §

175.103(e)(1). The written attestation must be signed by a preceptor authorized user who meets the requirements in §§ 175.103(j)(14), 175.103(j)(6), 175.103(j)(7), 175.103(j)(8), or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirement in § 175.103(j)(6)(b), must also have experience in administering dosages as specified in §§ 175.103(j)(6)(b)(1)(ii)(G)(1) or 175.103(j)(6)(b)(1)(ii)(G)(2).

(8) Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries).

Except as provided in 175.103(j)(14), the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries), to be a physician who—

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraphs (c)(1) and (c)(2) of this section, and whose certification has been recognized by the Commission or an Agreement State, and who meets the requirements in paragraph (c)(3) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.); or

(b) Is an authorized user under § 175.103(j)(6) for uses listed in § 175.103(j)(6)(b)(1)(ii)(G)(2) or equivalent Agreement State requirements; or

(c)(1) Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include—

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of byproduct material for medical use; and

(v) Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in §§ 175.103(j)(14), 175.103(j)(6), 175.103(j)(8), or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in § 175.103(j)(6)(b), must also have experience in administering dosages as specified in § 175.103(j)(6)(b)(1)(ii)(G)(2). The work experience must involve—

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent a medical event involving the use of byproduct material;

(v) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(vi) Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under § 175.103(e)(1). The written attestation must be signed by a preceptor authorized user who meets the requirements in §§ 175.103(j)(14), 175.103(j)(6), 175.103(j)(8), or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in § 175.103(j)(6)(b), must also have experience in administering dosages as specified in § 175.103(j)(6)(b)(1)(ii)(G)(*2*).

(9) Training for the parenteral administration of unsealed byproduct material requiring a written directive.

Except as provided in § 175.103(j)(14), the licensee shall require an authorized user for the parenteral administration requiring a written directive, to be a physician who--

(a) Is an authorized user under § 175.103(j)(6) for uses listed in §§ 175.103(j)(6)(b)(1)(ii)(G)(3) or 175.103(j)(6)(b)(1)(ii)(G)(4), or equivalent Agreement State requirements; or

(b) Is an authorized user under §§ 175.103(j)(10), 175.103(j)(13), or equivalent Agreement State requirements and who meets the requirements in paragraph (d) of this section; or

c) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State under §§ 175.103(j)(10) or 175.103(j)(13), and who meets the requirements in paragraph (d) of this section.

(d)(1) Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. The training must include--

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of byproduct material for medical use; and

(v) Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in §§ 175.103(j)(14), 175.103(j)(6), 175.103(j)(9), or equivalent Agreement State requirements, in the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized user who meets the requirements in § 175.103(j)(6) must

have experience in administering dosages as specified in §§ 175.103(j)(6)(b)(1)(ii)(G)(3) and/or 175.103(j)(6)(b)(1)(ii)(G)(4). The work experience must involve—

(i) Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;

(ii) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(v) Using procedures to contain spilled byproduct material safely, and using proper decontamination procedures; and

(vi) Administering dosages to patients or human research subjects, that include at least 3 cases involving the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV and/or at least 3 cases involving the parenteral administration of any other radionuclide, for which a written directive is required; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph (b) or (c) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed byproduct material requiring a written directive. The written attestation must be signed by a preceptor authorized user who meets the requirements in §§ 175.103(j)(14), 175.103(j)(6), 175.103(j)(9), or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in § 175.103(j)(6), must have experience in administering dosages as specified in §§ 175.103(j)(6)(b)(1)(ii)(G)(3) and/or 175.103(j)(6)(b)(1)(ii)(G)(*4*).

(10) Training for use of manual brachytherapy sources.

Except as provided in § 175.103(j)(14), the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under § 175.103(f)(1) to be a physician who—

(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State, and who meets the requirements in paragraph (b)(3) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Successfully complete a minimum of 3 years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(2) Pass an examination, administered by diplomates of the specialty board, that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy; or

(b)(1) Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes—

(i) 200 hours of classroom and laboratory training in the following areas—

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity; and

(D) Radiation biology; and

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in §§ 175.103(j)(14), 175.103(j)(10), or equivalent Agreement State requirements at a medical institution, involving—

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Checking survey meters for proper operation;

(C) Preparing, implanting, and removing brachytherapy sources;

(D) Maintaining running inventories of material on hand;

(E) Using administrative controls to prevent a medical event involving the use of byproduct material;

(F) Using emergency procedures to control byproduct material; and

(2) Has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in §§ 175.103(j)(14), 175.103(j)(10), or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (b)(1)(ii) of this section; and

(3) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 175.103(j)(14), 175.103(j)(10), or equivalent Agreement State requirements, that the individual has

satisfactorily completed the requirements in paragraph (a)(1), or paragraphs (b)(1) and (b)(2), of this section and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under § 175.103(f)(1).

(11) Training for ophthalmic use of strontium-90.

Except as provided in § 175.103(j)(14), the licensee shall require the authorized user of strontium-90 for ophthalmic radiotherapy to be a physician who—

(a) Is an authorized user under § 175.103(j)(10) or equivalent Agreement State requirements; or

(b)(1) Has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training must include—

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity; and

(iv) Radiation biology; and

(2) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution, clinic, or private practice that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training must involve—

(i) Examination of each individual to be treated;

(ii) Calculation of the dose to be administered;

(iii) Administration of the dose; and

(iv) Follow up and review of each individual's case history; and

(3) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 175.103(j)(14), 175.103(j)(10), 175.103(j)(11), or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs (a) and (b) of this section and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

(12) Training for use of sealed sources for diagnosis.

Except as provided in § 175.103(j)(14), the licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized under § 175.103(g)(1) to be a physician, dentist, or podiatrist who—

(a) Is certified by a specialty board whose certification process includes all of the requirements in paragraphs (b) and (c) of this section and whose certification has been recognized by the Commission or an Agreement State. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.); or

(b) Has completed 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include—

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity; and

(4) Radiation biology; and

(c) Has completed training in the use of the device for the uses requested.

(13) Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

Except as provided in § 175.103(j)(14), the licensee shall require an authorized user of a sealed source for a use authorized under § 175.103(h)(1) to be a physician who—

(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraphs (b)(3) and (c) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Successfully complete a minimum of 3 years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(2) Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders and external beam therapy; or

(b)(1) Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes—

(i) 200 hours of classroom and laboratory training in the following areas—

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity; and

(D) Radiation biology; and

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in §§ 175.103(j)(14), 175.103(j)(13), or equivalent Agreement State requirements at a medical institution, involving—

(A) Reviewing full calibration measurements and periodic spot-checks;

(B) Preparing treatment plans and calculating treatment doses and times;

(C) Using administrative controls to prevent a medical event involving the use of byproduct material;

(D) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;

(E) Checking and using survey meters; and

(F) Selecting the proper dose and how it is to be administered; and

(2) Has completed 3 years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in §§ 175.103(j)(14), 175.103(j)(13), or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (b)(1)(ii) of this section; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph (a)(1) or paragraphs (b)(1) and (b)(2), and paragraph (c), of this section, and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation must be signed by a preceptor authorized user who meets the requirements in §§ 175.103(j)(14), 175.103(j)(13), or equivalent Agreement State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; and

(c) Has received training in device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought. This

training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type(s) of use for which the individual is seeking authorization.

(14) Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist.

(a)(1) An individual identified as a Radiation Safety Officer, a teletherapy or medical physicist, or a nuclear pharmacist on a Commission or Agreement State license or a permit issued by a Commission or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope before October 24, 2002, need not comply with the training requirements of §§ 175.103(j)(1), 175.103(j)(2), or 175.103(j)(3), respectively.

(2) An individual identified as a Radiation Safety Officer, an authorized medical physicist, or an authorized nuclear pharmacist on a Commission or Agreement State license or a permit issued by a Commission or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope between October 24, 2002 and April 29, 2005 need not comply with the training requirements of §§ 175.103(j)(1), 175.103(j)(2), or 175.103(j)(3), respectively.

(3) A Radiation Safety Officer, a medical physicist, or a nuclear pharmacist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses or in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of § 175.103(j)(1), § 175.103(j)(2) or § 175.103(j)(3), respectively, when performing the same uses. A nuclear pharmacist, who prepared only radioactive drugs containing accelerator-produced radioactive materials,

or a medical physicist, who used only accelerator-produced radioactive materials, at the locations and time period identified in this paragraph, qualifies as an authorized nuclear pharmacist or an authorized medical physicist, respectively, for those materials and uses performed before these dates, for purposes of this chapter.

(b)(1) Physicians, dentists, or podiatrists identified as authorized users for the medical use of byproduct material on a license issued by the Commission or Agreement State, a permit issued by a Commission master material licensee, a permit issued by a Commission or Agreement State broad scope licensee, or a permit issued by a Commission master material license broad scope permittee before October 24, 2002, who perform only those medical uses for which they were authorized on that date need not comply with the training requirements of Subparts D through H of 10 CFR 35.

(2) Physicians, dentists, or podiatrists identified as authorized users for the medical use of byproduct material on a license issued by the Commission or Agreement State, a permit issued by a Commission master material licensee, a permit issued by a Commission or Agreement State broad scope licensee, or a permit issued by a Commission master material license broad scope permittee who perform only those medical uses for which they were authorized between October 24, 2002 and April 29, 2005, need not comply with the training requirements of Subparts D through H of 10 CFR 35.

(3) Physicians, dentists, or podiatrists who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses performed at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of subparts D through H of this 10 CFR 35 when performing the same medical uses. A physician, dentist, or podiatrist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses at the locations and time period identified in this paragraph,

qualifies as an authorized user for those materials and uses performed before these dates, for purposes of this chapter.

(c) Individuals who need not comply with training requirements as described in this section may serve as preceptors for, and supervisors of, applicants seeking authorization on NRC licenses for the same uses for which these individuals are authorized.

(15) Recentness of training.

The training and experience specified in §175.103(j)(1) through (14) must have been obtained within the 7 years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.