§175.101 General requirements for radioactive materials licenses.

(a) *License required.* (1) (i) Except for the removal of source material from its place of deposit in nature or as otherwise provided in this Code, no person shall transfer, receive, produce, possess or use any radioactive material except pursuant to a license issued by the Department.

(ii) Except as provided in 10 CFR §§30.3(b)(2), (b)(3), (c)(2), and (c)(3), and for persons exempt as provided in 10 CFR §30.3 and 10 CRF Part 150, no person shall manufacture, produce, transfer, receive, acquire, own, possess, or use byproduct material unless authorized in a specific or general license issued in accordance with this Code.

(2) Fees for each license shall be paid pursuant to §5.07 of this Code.

(3) The requirements of this section are in addition to, and not in substitution for, other requirements of this Code. In any conflict between the requirements of this section and a specific requirement in another part of this Code, the specific requirement governs.

(b) *Exempt source material.* (1) Any person is exempt from the provisions of this code to the extent that such person receives, possesses, uses or transfers unrefined and unprocessed ore containing source material; provided that, except as authorized in a specific license issued by the Department, the U.S. Nuclear Regulatory Commission or an agreement state, such person shall not refine or process such ore.

(2) Any person is exempt from the provisions of this Code to the extent that such person receives, possesses, uses or transfers source material in any chemical mixture, compound, solution or alloy in which the source material is by weight less than 1/20 of 1 percent (0.05%) of the mixture, compound, solution or alloy.

(3) Any person is exempt from the provisions of this Code to the extent that such person receives, possesses, uses or transfers:

(i) any quantities of thorium contained in:

(A) incandescent gas mantles;

(B) vacuum tubes;

(C) welding rods;

(D) electric lamps for illuminating purposes provided that each lamp does not contain more than 50 milligrams of thorium;

(E) germicidal lamps, sunlamps, and lamps for outdoor or industrial lighting provided that each lamp does not contain more than 2 grams of thorium;

(F) rare earth metals and compounds, mixtures, and products containing not more than 0.25 percent, by weight of thorium, uranium, or any combination of these; or

(G) personnel neutron dosimeters, provided that each dosimeter does not contain more than 50 milligrams of thorium;

(ii) any source material contained in the following products:

(A) glazed ceramic tableware, provided that the glaze contains not more than 20 percent by weight source material;

(B) glassware, containing not more than 10 percent by weight source material, but not including commercially manufactured glass brick, pane glass, ceramic tile or other glass, glass enamel or ceramic used in construction;

(C) glass enamel or glass enamel frit containing not more than 10 percent by weight of source material imported or ordered for importation into the United States, or initially distributed by manufacturers in the United States, before July 25, 1983; or

(D) piezoelectric ceramic, containing not more than 2 percent by weight source material;

(iii) photographic film, negatives, and prints containing uranium or thorium;

(iv) any finished or partly fabricated product of, or containing, tungsten- thorium or magnesium-thorium alloys, provided that the thorium content of the alloy does not exceed 4 percent by weight and that this exemption shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such product or part;

(v) uranium contained in counterweights installed in aircraft, rockets, projectiles, and missiles, or stored or handled in connection with installation or removal of such counterweights, provided that:

(A) each counterweight is manufactured in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, authorizing distribution by the licensee pursuant to 10 CFR Part 40;

(B) each counterweight has been impressed with the following legend clearly legible through any plating or other covering: "DEPLETED URANIUM";

(C) each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: "UNAUTHORIZED ALTERATIONS PROHIBITED"; and

(D) this exemption shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such counterweights other than repair or restoration of any plating or other covering;

(vi) natural or depleted uranium metal used as shielding constituting part of any shipping container, provided that:

(A) the shipping container is conspicuously and legibly impressed with the legend "Caution—Radioactive Shielding—Uranium"; and

(B) the uranium metal is encased in mild steel or equally fire resistant metal or minimum wall thickness of one-eighth inch (3.2 mm);

(vii) thorium contained in finished optical lenses, provided that each lens does not contain more than 30 percent by weight of thorium, and that this exemption shall not be deemed to authorize either:

(A) the shaping, grinding, or polishing of such lens or manufacturing processes other than the assembly of such lens into optical systems and devices without any alteration of the lens; or

(B) the receipt, possession, use, or transfer of thorium contained in contact lenses, or in spectacles, or in eyepieces in binoculars or other optical instruments;

(viii) uranium contained in detector heads for use in fire detection units, provided that each detector head contains not more than 0.005 microcurie of uranium;

(ix) thorium contained in any finished aircraft engine part containing nickel-thoria alloy, provided that:

(A) the thorium is dispersed in the nickel-thoria alloy in the form of finely divided thoria (thorium dioxide); and

(B) the thorium content in the nickel-thoria alloy does not exceed 4 percent by weight.

(x) The exemptions contained in §175.101(b)(2) and (3)(i) through (ix) shall not authorize the manufacturer of any of the products described.

(c) *Exempt radioactive material other than source material.* (1) *Exempt concentrations.*

(i) Except as provided in §175.101(c)(1)(ii), any person is exempt from the provisions of this Code to the extent that such person receives, possesses, uses, transfers, owns or acquires products containing radioactive material introduced in concentrations not in excess of those listed in Schedule A of this section.

(ii) No person may introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under §175.101(c)(1)(i) or equivalent regulations of the U.S. Nuclear Regulatory Commission or an agreement state, except in accordance

with a specific license issued pursuant to this Code or a general license provided for in this Code.

(2) *Exempt quantities.* (i) Except as provided in §175.101(c)(2)(ii) and (iii), any person is exempt from the provisions of this Code to the extent that such person receives, possesses, uses, transfers, owns or acquires radioactive material in individual quantities, each of which does not exceed the applicable quantity set forth in Schedule B of this section.

(ii) Section 175.101(c)(2)(i) does not authorize the production, packaging or repackaging of radioactive material for purposes of commercial distribution, or the incorporation of radioactive material into products intended for commercial distribution.

(iii) No person shall, for purposes of commercial distribution, transfer radioactive material in the individual quantities set forth in Schedule B of this section, knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt under §175.101(c)(2)(i) or equivalent regulations of the U.S. Nuclear Regulatory Commission or an agreement state, except in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to §32.18 of 10 CFR Part 32, or by the Department, which license states that the radioactive material may be transferred by the licensee to persons exempt under §175.101(c)(2)(i) or the equivalent regulations of the U.S. Nuclear Regulatory Commission or any agreement state.

(iv) Pursuant to 10 CFR §30.18(b), any person who possesses byproduct material received or acquired before September 25, 1971, under the general license then provided in 10 CFR §31.4 or similar general license of a state, is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in 10 CFR Parts 30 through 34, 36 and 39 to the extent that this person possess, uses , transfers or owns byproduct material.

(3) *Exempt items.* Except for persons who apply radioactive material to, or persons who incorporate radioactive material into the following products, or persons who initially transfer such products for sale or distribution, any person is exempt from the provisions of this Code to the extent that such person receives, possesses, uses, transfers, owns or acquires the following products:

(i) Timepieces or timepiece hands or dials containing radium which were manufactured under a specific license issued by the Department or an agreement state and which meet the following or equivalent conditions:

(A) The timepiece or timepiece hands or dials contain no more than the following specified quantities of radium:

(a) 5.55 kBq (0.15 mCi) per watch;

(b) 1.11 kBq (0.03 mCi) per watch hand;

(c) 3.33 kBq (0.09 mCi) per watch dial;

(d) 7.4 kBq (0.2 mCi) per clock;

(e) 1.48 kBq (0.04 mCi) per clock hand;

(f) 4.44 kBq (0.12 mCi) per clock dial; or

(g) 37 kBq (1 mCi) of radium-226 per timepiece in intact timepieces manufactured prior to November 30, 2007.

(B) The timepiece is not a pocket watch.

(C) The timepiece is marked or coded to identify the date of manufacture and that it contains radium.

(D) The timepiece emits sufficient luminosity, omitting photoactivation, that its dial can be read in the dark during its entire design lifetime.

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

(A) 925 MBq (25 mCi) of hydrogen-3 per timepiece.

(B) 185 MBq (5 mCi) of hydrogen-3 per hand.

(C) 555 MBq (15 mCi) of hydrogen-3 per dial (bezels when used shall be considered as part of the dial).

(D) 3.7 MBq (100 mCi) of promethium-147 per watch or 7.4 MBq (200 mCi) of promethium-147 per any other timepiece.

(E) 0.74 MBq (20 mCi) of promethium-147 per watch hand or 1.48 MBq (40 mCi) of promethium-147 per other timepiece hand.

(F) 2.22 MBq (60 mCi) of promethium-147 per watch dial or 4.44 MBq (120 mCi) of promethium-147 per other timepiece dial (bezels when used shall be considered as part of the dial).

(G) The radiation dose rate from hands and dials containing promethium-147 will not exceed, when measured through 50 milligrams per square centimeter of absorber:

(a) for wristwatches, 1 mGy (0.1 millirad) per hour at 10 centimeters from any surface; *(b)* for pocket watches, 1 mGy (0.1 millirad) per hour at 1 centimeter from any surface; *(c)* for any other timepiece, 2 mGy (0.2 millirad) per hour at 10 centimeters from any surface.

(H) 37 kBq (1 mCi) of radium-226 per timepiece in timepieces manufactured prior to November 30, 2007.

(iii) Lock illuminators containing not more than 555 MBq (15 millicuries) of hydrogen-3 or not more than 74 MBq (2 millicuries) of promethium-147 installed in automobile locks. The radiation dose rate from each lock illuminator containing promethium-147 will not exceed 10 mGy (1 millirad) per hour at one centimeter from any surface when measured through 50 milligrams per square centimeter of absorber.

(iv) Precision balances containing not more than 37 MBq (1 millicurie) of hydrogen-3 per balance or not more than 18.5 MBq (0.5 millicurie) of hydrogen-3 per balance part.

(v) Automobile shift quadrants containing not more than 925 MBq (25 millicuries) of hydrogen-3.

(vi) Marine compasses containing not more than 27.8 GBq (750 millicuries) of hydrogen-3 gas and other marine navigational instruments containing not more than 9.25 GBq (250 millicuries) of hydrogen-3 gas.

(vii) Reserved.

(viii) Reserved.

(ix) Electron tubes, provided, that each tube does not contain more than one of the following specified qualities of radioactive material:

(A) 5.55 GBq (150 millicuries) of hydrogen-3 per microwave receiver detector tube or 370 MBq (10 millicuries) of hydrogen-3 per any other electron tube;

(B) 37 kBq (1 mCi) of cobalt-60;

(C) 185 kBq (5 mCi) of nickel-63;

(D) 1.11 MBq (30 mCi) of krypton-85;

(E) 185 kBq (5 mCi) of cesium-137;

(F) 1.11 MBq (30 mCi) of promethium-147;

and, provided further, that the radiation dose rate due to radioactive material contained in each electron tube does not exceed 10 mGy (1 millirad) per hour at one centimeter from any surface when measured through 7 milligrams per square centimeter of absorber.

(x) Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, one or more sources of radioactive material, provided that:

(A) each source contains no more than one exempt quantity set forth in Schedule B of this section, and

(B) each instrument contains no more than 10 exempt quantities. For purposes of this requirement, an instrument's source(s) may contain either one or different types of radioactive materials and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in Schedule B of this section, provided that the sum of such fractions shall not exceed unity; and

(C) for the purposes of §175.101(c)(3)(x), 1.85 kBq (0.05 mCi) of americium-241 shall be considered one exempt quantity.

(xi) Reserved.

(xii) The exemptions contained in §175.101(c)(3)(i) through (xi) shall not authorize the application or incorporation of radioactive materials into the listed devices.

(4) Any person, except those who manufacture, process, or produce self-luminous products containing hydrogen-3, krypton-85, or promethium-147, is exempt from the provisions of this Code to the extent that such person receives, possesses, uses, transfers, owns, or acquires hydrogen-3, krypton-85 or promethium-147 in self-luminous products manufactured, processed, produced, imported, or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR §32.22, which license authorizes the transfer of the product to persons who are exempt from regulatory requirements. This exemption does not apply to hydrogen-3, krypton-85, or promethium-147 used in products for frivolous purposes or in toys or adorn- ments.

(5) Any person is exempt from the provisions of this Code to the extent that such person receives, possesses, uses, transfers, or owns articles containing less than 3.7 kBq (0.1 mCi) of radium-226 which were acquired prior to October 30, 1986.

(6) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution gas and aerosol detectors containing byproduct material, pursuant to 10 CRF §30.20(a), any person is exempt from the requirements for a license set forth in section 81 of the act and from the regulations in 10 CRF Part 19. 20, and 30 through 36, and 39 to the extent that the person receives, possesses, uses, transfers, owns, or acquires byproduct material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued under 10 CRF §32.26, which license authorizes the initial transfer of the product for use under this section. This exemption also covers gas and aerosol detectors manufactured or distributed before November 30, 2007 in accordance with a specific license issued by a state
under comparable provisions to 10 CFR §32.26 authorizing distribution to persons exempt from regulatory requirements.

(i) Gas and aerosol detectors previously manufactured and distributed to general licensees in accordance with a specific license issued by an agreement state shall be considered exempt, provided that the device is labeled in accordance with the specific license authorizing distribution of the generally licensed device, and provided further that they meet requirements equivalent to 10 CFR §32.26.

(d) *Licensees and contractors of the U.S. Department of Energy and U.S. Nuclear Regulatory Commission.* (1) The owner or the person in charge of any radiation installation licensed by the U.S. Department of Energy and/or the U.S. Nuclear Regulatory Commission is exempt from the requirements of this Code provided that such owner or person in charge shall:

(i) afford the Department access to all records which such person is required to maintain pursuant to the U.S. Department of Energy or U.S. Nuclear Regulatory Commission license or contract issued to such person;

(ii) afford the Department opportunity to sample effluents, and to conduct such surveys of

levels of radiation and radioactive contamination, as will not substantially interfere with or interrupt for any substantial period of time any activity licensed by or contracted for by the U.S. Department of Energy or U.S. Nuclear Regulatory Commission; and

(iii) afford inspectors or officers of the Department access to any installation in which such radioactive materials are present to accomplish the foregoing review of records, sampling of effluents, and conduct of surveys.

(2) Any U.S. Department of Energy or U.S. Nuclear Regulatory Commission contractor or subcontractor of the following categories operating within the City is exempt from the requirements of this Code to the extent that such contractor, or subcontractor under such contractor, transfers, receives, possesses, uses or acquires sources of radiation:

(i) prime contractors performing work for the U.S. Department of Energy at United States government-owned or controlled sites including the transportation of sources of radiation to or from such sites and the performance of contract services during temporary interruptions of such transportation;

(ii) prime contractors of the U.S. Department of Energy performing research in, or development, manufacture, storage, testing, or transportation of, atomic weapons or components thereof;

(iii) prime contractors of the U.S. Department of Energy using or operating nuclear reactors or other nuclear devices in a United States-owned vehicle or vessel; and

(iv) any other prime contractor or subcontractor of the U.S. Department of Energy or of the U.S. Nuclear Regulatory Commission when the City and the U.S. Nuclear Regulatory Commission jointly determine:

(A) that the exemption of the prime contractor or subcontractor is authorized by law; and

(B) that under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety.

(e) *General requirements for issuing specific licenses.* (1) The Department will approve an application for, and issue in response thereto, a specific license to receive, produce, possess, use and transfer any radioactive material, if the Department determines that the following requirements have been met:

(i) 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

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

(iii) the applicant, or the applicant's personnel, if the applicant is not an individual, is qualified by training and experience to use such radioactive material for 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

(iv) the applicant submits sufficient information to support a determination that the requirements of §175.101(e)(1)(i) through (iii) are satisfied.

(f) *Applications for specific licenses.* (1) A license application shall be made in writing on forms prescribed by the Department and shall contain completely and accurately the information required thereon. Such application shall be filed in duplicate (original plus one copy) and may incorporate, by clear specific reference, information contained in any previous application, supplementary statement, notification or report filed with the Department.

(2) 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.

(3) An application for a specific license to use byproduct material in the form of a sealed source

in a device that contains a sealed source must:

(i) Identify the source or device by manufacturer and model number as registered with the U.S. Nuclear Regulatory Commission under 10 CFR §32.210, with an agreement state, or for a source or device containing radium-226 or accelerator-produced radioactive material with a state under provisions comparable to 10 CFR §32.210;

(ii) Contain information identified in 10 CFR §32.210(c); or

(iii) For sources or devices containing naturally occurring or accelerator-produced radioactive material manufactured prior to November 30, 2007 that are not registered with the U.S. Nuclear Regulatory Commission under 10 CFR §32.210 or with an agreement state, and for which the applicant is unable to provide all categories of information specified in 10 CFR §32.210(c), the applicant must provide:

(A) All available information identified in 10 CFR §32.210(c) concerning the source, and, if applicable, the device; and

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

(4) An application from a medical facility, educational institution, or federal facility to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to licensees in its consortium authorized for medical use under 10 CFR Part 35 or equivalent agreement state requirements, shall include:

(i) A request for authorization for the production of PET radionuclides or evidence of an existing license issued under 10 CFR Part 30 or agreement state requirements for a PET radionuclide production facility within its consortium from which it receives PET radionuclides;

(ii) Evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in 10 CFR §32.72(a)(2);

(iii) Identification of any individual authorized to prepare the PET radioactive drugs if the applicant is a pharmacy, and documentation that any such individual meets the requirements of an authorized nuclear pharmacist as specified in 10 CFR § 32.72(b)(2); and

(iv) Information identified in 10 CFR § 32.72(a)(3) on the PET drugs to be noncommercially transferred to members of its consortium..

(5) A single application may apply for a license covering more than one radioactive material.

(6) Specific licenses issued by the Department shall be in the form of a written authorization permitting possession of certain specific radioactive materials in not more than certain specific quantities, and certain specific uses of these radioactive materials. Such possession and use of radioactive materials provided for in the foregoing shall be subject to the requirements of:

(i) all applicable provisions of this Code; and

(ii) all conditions as stated on the license issued by the Department.

(g) *Amendments.* (1) When a change affecting the licensed operation or facility is considered by a licensee, including but not limited to changes ordered pursuant to this Code, so that the information on file with the Department, either in the initial license application or subsequent requests for amendments, or in the initial license or amendment previously granted, will no longer be accurate, the licensee shall request and receive an amendment for such change prior to causing such change.

(2) Any application by a licensee for a license amendment to conform with the provisions of

§175.101(g)(1) 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 shall apply the requirements set forth in §175.101(e).

(3) A corrective amendment of any license may be issued by the Department at any time upon its initiative.

(4) Any license may be amended or revoked by the Department by reason of the amendment of this Code, or any other applicable law.

(h) *Expiration, renewal and termination of licenses.* (1) Except as otherwise provided in this Code, each license shall expire at the end of the day on the expiration date stated in the license. If, not less than 30 days prior to such expiration date, a licensee duly files with the Department an application in proper form for license renewal, or for a new and superseding license, the existing license shall not be deemed to have expired until the Department has finally determined such application.

(2) Any application by a licensee for the renewal of such license, including amendments, shall be considered as an application for a license 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 shall apply the requirements set forth in §175.101(e).

(3) Each licensee shall notify the Department in writing and request termination of the license when the licensee decides to terminate all activities authorized under the license. This notification and request for termination shall include the reports and information specified in §175.101(h)(4)(v) and a plan for completion of decommissioning.

(4) If a licensee does not submit an application for renewal pursuant to §175.101(h)(1), the licensee shall on or before the expiration date stated in the license:

(i) terminate use of radioactive material;

(ii) dispose of all radioactive material in accordance with all applicable regulations in effect at the time of disposal;

(iii) submit a written certification of the disposition of all radioactive materials authorized by the license on forms prescribed by the Department;

(iv) remove radioactive contamination to the extent practicable; and

(v) conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey to the Department. Such survey shall be subject to confirmation by the Department and shall include:

(A) levels of radiation in units (or multiples) of Gy-hr^{-1} (millirads-hr^{-1}) at one (1) cm for beta-gamma radiation or at one (1) m for gamma radiation;

(B) levels of removable and fixed contamination, including alpha, in units of disintegrations (transformations) per min (becquerels) per 100 cm^2 for surfaces;

(C) becquerels-ml^{-1} (mCi-ml^{-1}) for water;

(D) becquerels-g^{-1} (pCi-ml^{-1}) for solids such as soil or concrete; and

(E) a description of the survey or other measuring instrument(s) used, including manufacturer(s) and model number(s) and date of most recent calibration.

(vi) If the information submitted pursuant to §175.101(h)(4)(v) does not adequately demonstrate that the premises are suitable for unrestricted use, the Department shall inform the licensee of the appropriate further actions required for the termination of the license, including, but not limited to, decontamination of the licensed premises to such levels and within such time frames as the Department may prescribe.

(vii) Each specific license shall continue in effect, beyond the expiration date if necessary,

with respect to possession of residual radioactive materials present as contamination until the Department issues an amendment terminating the license. During this time the licensee shall:

(A) limit activities involving radioactive material to those related to decommissioning; and

(B) continue to control entry to restricted areas until the Department determines they are suitable for release for unrestricted use and the Department issues an amendment terminating the license.

(viii) The Department will approve a request for termination of a specific license, and issue an amendment terminating such license, when the Department determines that:

(A) radioactive material has been properly disposed; and

(B) premises have been decontaminated to such levels that the total effective dose equivalent (TEDE) from residual radioactivity distinguishable from background radiation, to an average member of the public will not exceed 25 mrem (0.25 mSv) per year;

(C) a radiation survey has been performed which describes all radiation levels and levels of fixed and removable contamination; and

(D) the licensee submits sufficient information to support a determination that the requirements of §175.101(h)(4)(viii)(A) through (C) have been met.

(i) *Amendment, suspension or revocation of licenses.* (1) Specific and general licenses shall be subject to amendment, suspension or revocation by reason of amendment of the New York State Public Health Law, enactment or amendment of any other applicable law, amendment of the New York State Sanitary Code, amendment of this Code, or amendment or promulgation of any other applicable rule, regulation or order.

(2) In addition to the provisions of §5.17 of this Code, the Department may amend, revoke or suspend any license, in whole or in part, for:

(i) Any material misstatement in the application therefor or in any supplementary statement thereto.

(ii) Any condition revealed by such application, supplementary statement, report, record, inspection or other means, which would warrant the Department's refusal to grant a license on an original application.

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

(iv) Failure to notify the Department of a change in ownership or address of a radiation installation.

(j) *Emergency response plan.* (1) Each application for a license to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass and in excess of the quantities specified in Schedule C of this section shall include either:

(i) an evaluation showing that the maximum dose to a person offsite due to a release of radioactive materials would not exceed 10 mSv (1 rem) effective dose equivalent or 50 mSv (5 rem) to the thyroid; or

(ii) an emergency plan for responding to a release of radioactive material.

(2) One or more of the following factors may be used to support an evaluation submitted pursuant to §175.101(j)(1)(i):

(i) The radioactive material is physically separated so that only a portion could be involved in an accident.

(ii) All or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged.

(iii) The release fraction in the respirable size range would be lower than the release fraction shown in Schedule C of this section due to the chemical or physical form of the material.

(iv) The solubility of the radioactive material would reduce the dose received.

(v) Facility design or engineered safety features in the facility would cause the release fraction to be lower than that shown in Schedule C of this section.

(vi) Operating restrictions or procedures would prevent a release fraction as large as that shown in Schedule C of this section.

(vii) Other factors appropriate for the specific facility.

(3) An emergency plan for responding to a release of radioactive material submitted pursuant to §175.101(j)(1)(ii) shall include the following information:

(i) A brief description of the licensee's facility and area near the site.

(ii) An identification of each type of radioactive materials accident for which protective actions may be needed.

(iii) A classification system for classifying accidents as alerts or site area emergencies.

(iv) Identification of the means of detecting each type of accident in a timely manner.

(v) A brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers onsite, and a description of the program for maintaining the equipment.

(vi) A brief description of the methods and equipment to assess releases of radioactive materials.

(vii) A brief description of the responsibilities of licensee personnel should an accident occur, including identification of personnel responsible for promptly notifying offsite response organizations and the Department.

(viii) A brief description of the responsibilities for developing, maintaining and updating the plan.

(ix) A commitment to, and brief description of, the means to promptly notify offsite response organizations and to request offsite assistance, including medical assistance for the treatment of contaminated injured onsite workers when appropriate. A control point must be established. The notification and coordination must be planned so that unavailability of some personnel, parts of the facility, and some equipment will not prevent the notification and coordination. The licensee shall also commit to notify the Department immediately after notification of the appropriate offsite response organizations and not later than one (1) hour after the licensee declares an emergency.

(x) A brief description of the types of information on facility status, radioactive releases, and recommended protective actions, if necessary, to be given to offsite response organizations and the Department.

(xi) A brief description of the frequency, performance objectives and plans for the training that the licensee will provide workers on how to respond to an emergency including any special instructions and orientation tours the licensee would offer to fire, police, medical and other emergency personnel. The training shall familiarize personnel with site-specific emergency procedures. The training shall thoroughly prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site, including the use of team training for such scenarios.

(xii) A brief description of the means of restoring the facility to a safe condition after an accident.

(xiii) Provisions for conducting quarterly communications checks with offsite response organizations and biennial onsite exercises to test response to simulated emergencies. Quarterly communications checks with offsite response organizations must include the check and update of all necessary telephone numbers. The licensee shall invite offsite response organizations to participate in the biennial exercises. Participation of offsite response organizations is

recommended, but not required. Exercises must use accident scenarios postulated as most probable for the specific site and the scenarios shall not be known to most exercise participants. The licensee shall critique each exercise using individuals not having direct implementation responsibility for the plan. Critiques of exercises must evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel and overall effectiveness of the response. Plan deficiencies identified in the critiques shall be corrected.

(xiv) A certification that the applicant has met its responsibilities under the Emergency Planning and Community Right-to-Know Act of 1986 codified at 42 USCA 11001 *et seq.,* if applicable to the applicant's activities at the proposed place of use of the radioactive materials.

(4) The licensee shall allow the offsite response organizations expected to respond in case of an accident sixty (60) days to comment on the licensee's emergency response plan before submitting it to the Department. The licensee shall provide any comments received within the sixty (60) days to the Department with the plan.

(k) *Conditions of specific licenses.* (1) Each of the following is hereby made a condition of each specific license:

(i) The licensee thereunder shall comply with all applicable provisions of the New York State Public Health Law, all applicable provisions of this Code, all other laws now or hereafter in effect, and with all applicable rules, regulations, codes and orders now or hereafter in effect of the Department and of all appropriate regulatory agencies.

(ii) Neither such license, nor any right, title or interest in, of or to such license, shall be disposed of by assignment, transfer or otherwise, either voluntarily or involuntarily, either directly or indirectly, unless the Department shall, after securing complete and accurate pertinent information, have approved in writing of such disposal.

(iii) The licensee shall confine the possession and use of radioactive material to such location or locations and for such purpose or purposes as the license may authorize; provided, however, that except as otherwise provided in such license or this Code, such license shall be deemed to authorize the licensee to transfer the material covered by such license to any other person authorized to receive it by the Department, the U.S. Nuclear Regulatory Commission or an agreement state.

(iv) No person, in any advertisement, expressly or by implication, shall refer to the fact that an installation is licensed by the Department, and no person shall state or imply that an installation or its activities have been approved by the Board of Health, the Department or the Commissioner.

(v) The licensee shall notify the Department, in writing, within thirty (30) days if an authorized user, radiation safety officer or radiation therapy physicist permanently discontinues performance of duties under the license.

(vi) Each licensee shall notify the Department, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of Title 11 (Bankruptcy) of the United States Code by or against:

(A) the licensee;

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

(C) an affiliate (as that term is defined in 11 U.S.C. §101(2)) of the licensee.

This notification must indicate:

(A) the bankruptcy court in which the petition for bankruptcy was filed; and

(B) the date of the filing of the petition.

(vii) Any license covering the use of special nuclear material, in the course of which licensed use additional special nuclear material is produced, shall be deemed to cover any such special

nuclear material so produced, provided however, that the total quantity of special nuclear material possessed by the licensee is not sufficient to form a critical mass.

(viii) A licensee, employee of a licensee, contractor, subcontractor, or employee of a contractor or subcontractor shall not:

(A) engage in a deliberate misconduct that causes or would have caused if not detected, a licensee or applicant to be in violation of any provision of this Code or license condition issued by the Department; or

(B) deliberately submit to the Department information that the person submitting the information knows to be incomplete or inaccurate in some respect to the Department.

(ix) (A) Authorization under 10 CFR §30.32(j) to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, Federal, and State requirements governing radioactive drugs.

(B) Each licensee authorized under 10 CFR §30.32(j) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:

(a) atisfy the labeling requirements in 10 CFR § 32.72(a)(4) for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium; and

(b) ossess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in 10 CFR § 32.72(c).

(C) A licensee that is a pharmacy authorized under 10 CFR §30.32(j) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radioactive drugs : (*a*) an authorized nuclear pharmacist who meets the requirements in 10 CFR § 32.72(b)(2); or (*b*) an individual under the supervision of an authorized nuclear pharmacist as specified in 10 CFR § 35.27.

(D) pharmacy, authorized under 10 CFR §30.32(j) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirements of 10 CFR § 32.72(b)(5). All reports and notifications required by 10 CFR § 32.72(b)(5) shall be provided to the Department.

(x) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with 10 CFR § 35.204. The licensee shall record the results of each test and retain each record for 3 years after the record is made.

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

(3) All licensees subject to the criteria to implement Increased Controls pursuant to the U.S. Nuclear Regulatory Commission (NRC) Order EA 05-090, 70 FR 72128, dated December 1, 2005, shall have as part of their Increased Control Program, a Fingerprinting and Criminal History Records Check procedure established for all individuals whom the licensee wishes to allow unescorted access to radioactive material quantities of concern. Such Fingerprinting and Criminal History Records Check procedures shall adhere to the requirements in NRC Order EA-

07-305, 72 FR 70901, or any successor order, law or regulation. The requirements of this provision shall apply to all affected licensees upon its effective date.

(l) *Transfer of radioactive materials.* (1) No licensee shall transfer radioactive material except as authorized pursuant to this subsection.

(2) Except as provided otherwise by the license, and subject to the provisions of §175.101(l)(3) and (4), a licensee may transfer radioactive material:

(i) to the Department, after receiving prior written approval of the Department;

(ii) to the U.S. Nuclear Regulatory Commission;

(iii) to any person exempt from the provisions of this Code to the extent permitted under such exemption;

(iv) to any person authorized to receive radioactive material under the terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the Department, the U.S. Nuclear Regulatory Commission, or an agreement state, or to any person otherwise authorized to receive radioactive material by the federal government or any agency thereof, the department, or an agreement state; or

(v) as otherwise authorized by the Department in writing.

(3) Before transferring radioactive material to a specific licensee of the Department, the U.S. Nuclear Regulatory Commission or an agreement state, or to a general licensee who is required to register with the Department, the U.S. Nuclear Regulatory Commission or an agreement state prior to the receipt of the radioactive materials, the licensee transferring the radioactive material shall verify that the transferee's license or registration certificate authorizes the receipt of the type, form and quantity of radioactive material to be transferred.

(4) The following methods for the verification required by §175.101(l)(3) are acceptable:

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

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

(iii) for emergency shipments the transferor may accept oral certification by the transferee that he is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency and expiration date, provided that the oral certification is confirmed in writing within 10 days; or

(iv) the transferor may obtain other sources of information compiled by a reporting service from official records of the Department, the U.S. Nuclear Regulatory Commission or an agreement state as to the identity of licensees and the scope and expiration dates of licenses and registrations; or

(v) when none of the methods of verification described in §175.101(l)(4)(i) through (iv) are readily available, or when a transferor desires to verify that information received by one of such methods is correct or up-to-date, the transferor may obtain and record confirmation from the Department, the U.S. Nuclear Regulatory Commission, or an agreement state that the transferee is licensed to receive the radioactive material.

(5) Preparation for shipment and transport of radioactive material shall be in accordance with the provisions of §175.105 of this Code.

(m) *Reciprocity.* (1) The holder of a license issued by the New York State Department of Labor, the New York State Department of Health, the U.S. Nuclear Regulatory Commission or

any agreement state, may bring, possess or use radioactive material covered by such license within the Department's jurisdiction for a period not in excess of 30 days in any twelve consecutive months without obtaining a license from the Department, provided that:

(i) such license does not limit the holder's possession or use of such material to a specific installation or installations;

(ii) such holder, prior to bringing such material into the city, files with the Department a notice indicating the period, type and location of proposed possession and use within the Department's jurisdiction, and a copy of the license;

(iii) such holder supplies such additional information as the Department may reasonably request;

(iv) such holder, during the period of this possession and use of such material within the city, complies with all applicable sections of this Code except §175.101(a)(1); and

(v) such holder, during such period, complies with all the terms and conditions of his license, except such terms or conditions which may be inconsistent with this Code.

(2) The holder of a license issued by the New York State Department of Labor, the New York State Department of Health, the New York City Department of Health and Mental Hygiene or an Agreement State must obtain reciprocity approval from the U.S. Nuclear Regulatory Commission to conduct licensed activity in areas of exclusive federal jurisdiction within New York City. At least three days before engaging in each activity for the first time in a calendar year, the licensee will provide the U.S. Nuclear Regulatory Commission with advanced notice of its proposed activity in areas under exclusive federal jurisdiction within New York City.

(n) *Financial assurance and recordkeeping for decommissioning.*

(1)(a) Each applicant for a specific license authorizing the possession and use of unsealed radioactive material of half-life greater than 120 days and in quantities exceeding 10^5 times the applicable quantities set forth in Appendix B to this section shall submit a decommissioning funding plan as described in §175.101(n)(5). The decommissioning funding plan must also be submitted when a combination of isotopes is involved if R divided by 10^5 is greater than one (1) (unity rule), where R is defined here as the sum of the ratios of the quantity of each isotope to the applicable value in Appendix B to this section.

(b) Each holder of, or applicant for, any specific license authorizing the possession and use of sealed sources or plated foils of half-life greater than 120 days and in quantities exceeding 10 times the applicable quantities set forth in Appendix B to this section shall submit a decommissioning funding plan as described in §175.101(n)(5). The decommissioning funding plan must also be submitted when a combination of isotopes is involved if R, as defined in §175.101(n)(1)(a), divided by 10^{12} is greater than one (1) (unity rule). The decommissioning funding plan must be submitted to the Department within 2 years of the effective date of this provision.

(c) Each applicant for a specific license authorizing the possession and use of more than 100 mCi of source material in a readily dispersible form shall submit a decommissioning funding plan as described in §175.101(n)(5).

(d) Each applicant for a specific license authorizing possession and use of quantities of source material greater than 10 mCi but less than or equal to 100 mCi in a readily dispersible form shall either:

(i) submit a decommissioning funding plan as described in §175.101(n)(5); or

(ii) submit a certification that financial assurance for decommissioning has been provided in the amount of $225,000 within eighteen months of the effective date of this provision using one of the methods described in §175.101(n)(6). For an applicant, this certification may state that the

appropriate assurance will be obtained after the application has been approved and the license issued but before the receipt of licensed material. If the applicant defers execution of the financial instrument until after the license has been issued, a signed original of the financial instrument obtained to satisfy the requirements of paragraph §175.101(n)(6) of this section must be submitted to the Department prior to receipt of licensed material. If the applicant does not defer execution of the financial instrument, the applicant shall submit to the Department as part of the certification, a signed original of the financial instrument obtained to satisfy the requirements of paragraph §175.101(n)(6) of this section.

(e) Each applicant for a specific license authorizing the possession and use of unsealed special nuclear material in quantities exceeding 10^5 times the applicable quantities set forth in Appendix B to this section shall submit a decommissioning funding plan as described in §175.101(n)(5). A decommissioning funding plan must also be submitted when a combination of isotopes is involved if R, as defined in §175.101(n)(1)(a), divided by 10^5 is greater than one (1) (unity rule).

(2) Each applicant for a specific license authorizing possession and use of radioactive material of half-life greater than 120 days and in quantities specified in §175.101(n)(4) shall either:

(i) submit a decommissioning funding plan as described in §175.101(n)(4); or

(ii) submit a certification that financial assurance for decommissioning has been provided in the amount prescribed by §175.101(n)(4) using one of the methods described in §175.101(n)(6). For an applicant, this certification may state that the appropriate assurance will be obtained after the application has been approved and the license issued but before the receipt of licensed material. If the applicant defers execution of the financial instrument until after the license has been issued, a signed original of the financial instrument obtained to satisfy the requirements of paragraph §175.101(n)(6) of this section must be submitted to the Department prior to receipt of licensed material. If the applicant does not defer execution of the financial instrument, the applicant shall submit to the Department as part of the certification, a signed original of the financial instrument obtained to satisfy the requirements of paragraph §175.101(n)(6) of this section.

(3) (i) Each holder of a specific license issued on or after July 27, 1990, which is of a type described in §175.101(n)(1) or (2), shall provide financial assurance for decommissioning in accordance with the criteria set forth in this section.

(ii) Each holder of a specific license issued before July 27, 1990, and of a type described in §175.101(n)(1) or (2), shall submit a decommissioning funding plan as described in §175.101(n)(5) or a certification of financial assurance for decommissioning in an amount at least equal to $1,125,000 in accordance with the criteria set forth in this section. If the licensee submits the certification of financial assurance rather than a decommissioning funding plan, the licensee shall include a decommissioning funding plan in any application for license renewal.

(iii) Each holder of a specific license issued before July 27, 1990, and of a type described in §175.101(n)(2), shall submit a certification of financial assurance for decommissioning or a decommissioning funding plan in accordance with the criteria set forth in this section.

(4) Table of required amounts of financial assurance for decommissioning by quantity of material. Licensees required to submit the $1,125,000 amount must do so within 1 year of the effective date of this provision. Licensees required to submit the $113,000 or $225,000 amount must do so within 18 months of the effective date of this provision. Licensees having possession limits exceeding the upper bounds of this table must base financial assurance on a decommissioning funding plan.

(i) Greater than 10^4 but less than or equal to 10^5 times the applicable quantities of Appendix B to this section in unsealed form (for a combination of isotopes, if R, as defined in

§175.101(n)(1)(a), divided by 10^4 is greater than 1, but R divided by 10^5 is less than or equal to 1)—$1,125,000.

(ii) Greater than 10^3 but less than or equal to 10^4 times the applicable quantities of Appendix B to this section in unsealed form (for a combination of isotopes, if R, as defined in §175.101(n)(1)(a), divided by 10^3 is greater than 1, but R divided by 10^4 is less than or equal to 1)—$225,000.

(iii) Greater than 10^{10} but less than or equal to 10^{12} times the applicable quantities of Appendix B to this section in sealed sources or plated foils (for a combination of isotopes, if R, as defined in §175.101(n)(1)(a), divided by 10^{10} is greater than 1, but R divided by 10^{12} is less than or equal to 1)—$113.000.

(5) Each decommissioning funding plan must contain a cost estimate for decommissioning and a description of the method of assuring funds for decommissioning from §175.101(n)(6), including means of adjusting cost estimates and associated funding levels periodically over the life of the facility. Cost estimates must be adjusted at intervals not to exceed 3 years. The decommissioning funding plan must also contain a certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning and a signed original of the financial instrument obtained to satisfy the requirements of §175.101(n)(6).

(6) Financial assurance for decommissioning must be provided by one or more of the following methods:

(i) *Prepayment.* Prepayment is the deposit prior to the start of operation into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets such that the amount of funds would be sufficient to pay decommissioning costs. Prepayment may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities.

(ii) *A surety method, insurance, or other guarantee method.* These methods guarantee that decommissioning costs will be paid. A surety method may be in the form of a surety bond, letter of credit, or line of credit. A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in Appendix D. A parent company guarantee may not be used in combination with other financial methods to satisfy the requirements of this section. A guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in Appendix E. A guarantee by the applicant or licensee may not be used in combination with any other financial methods to satisfy the requirements of this section or in any situation where the applicant or licensee has a parent company holding majority control of the voting stock of the company. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

(A) the surety method or insurance must be open-ended or, if written for a specified term, such as five years, must be renewed automatically unless 90 days or more prior to the renewal date, the issuer notifies the Department, the beneficiary, and the licensee of its intention not to renew. The surety method or insurance must also provide that the full face amount be paid to the beneficiary automatically prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the Department within 30 days after receipt of notification of cancellation.

(B) The surety method or insurance must be payable to a trust established for decommissioning costs. The trustee and trust must be acceptable to the Department. An acceptable

trustee includes an appropriate state or federal government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a federal or state agency.

(C) The surety method or insurance must remain in effect until the Department has terminated the license.

(iii) An external sinking fund in which deposits are made at least annually, coupled with a surety method or insurance, the value of which may decrease by the amount being accumulated in the sinking fund. An external sinking fund is a fund established and maintained by setting aside funds periodically in an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of funds would be sufficient to pay decommissioning costs at the time termination of operation is expected. An external sinking fund may be in the form of a trust, escrow account, government fund, certificate of deposit, or depost of government securities. The surety or insurance provisions must be as stated in §175.101(n)(6)(ii).

(iv) In the case of federal, state or local government licensees, a statement of intent containing a cost estimate for decommissioning or an amount based on the Table in §175.101(n)(4), and indicating that funds for decommissioning will be obtained when necessary.

(7) Each licensed person shall keep records of information important to the safe and effective decommissioning of the facility in an identified location until the license is terminated by the Department and the site is released for unrestricted use. If records of relevant information are kept for other purposes, reference to these records and their location may be used. Information the Department considers important to decom- missioning consists of:

(i) Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment or site. These records may be limited to instances when contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas as in the case of possible seepage into porous materials such as concrete. These records must include any known information on identification of involved nuclides, quantities, forms and concentrations.

(ii) As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored, and of locations of possible inaccessible contamination such as buried pipes which may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations.

(iii) Except for areas containing only sealed sources (provided the sources have not leaked or no contamination remains after any leak) or radioactive materials having only half-lives of less than 65 days, a list contained in a single document and updated every two (2) years, of the following:

(A) All areas designated and formerly designated restricted areas as defined in §175.02(a)(194);

(B) all areas outside of restricted areas that require documentation under §175.101(n)(7)(i);

(C) all areas where current and/or previous wastes have been buried; and

(D) all areas outside of restricted areas which contain material such that, if the license expired, the licensee would be required to decontaminate the area to unrestricted release levels or to apply for approval for disposal under §175.104(b).

(iv) Records of the cost estimate performed for the decommissioning funding plan or of the

amount certified for decommissioning, and records of the funding method used for assuring funds if either a funding plan or certification is used.

SCHEDULE A

Element (atomic number)	Isotope	Col. I	Col. II
		Gas Concentration µCi/ml[1] –	Liquid and Solid Concentration µCi/ml[2] –
Antimony (51)	Sb 122		3×10^{-4}
	Sb 124		2×10^{-4}
	Sb 125		1×10^{-3}
Argon (18)	A 37	1×10^{-3}	
	A 41	4×10^{-7}	
Arsenic (33)	As 73		5×10^{-3}
	As 74		5×10^{-4}
	As 76		2×10^{-4}
	As 77		8×10^{-4}
Barium (56)	Ba 131		2×10^{-3}
	Ba 140		3×10^{-4}
Beryllium (4)	Be 7		2×10^{-2}
Bismuth (83)	Bi 206		4×10^{-4}
Bromine (35)	Br 82	4×10^{-7}	3×10^{-3}
Cadmium (48)	Cd 109		2×10^{-3}
	Cd 115M		3×10^{-4}
	Cd 115		3×10^{-4}
Calcium (20)	Ca 45		9×10^{-5}
	Ca 47		5×10^{-4}
Carbon (6)	C 14	1×10^{-6}	8×10^{-3}
Cerium (58)	Ce 141		9×10^{-4}
	Ce 143		4×10^{-4}
	Ce 144		1×10^{-4}
Cesium (55)	Cs 131		2×10^{-2}
	Cs 134m		6×10^{-2}

	Cs 134		9×10^{-5}
Chlorine (17)	Cl 38	9×10^{-7}	4×10^{-3}
Chromium (24)	Cr 51		2×10^{-2}
Cobalt (27)	Co 57		5×10^{-3}
	Co 58		1×10^{-3}
	Co 60		5×10^{-4}
Copper (29)	Cu 64		3×10^{-3}
Dysprosium (66)	Dy 165		4×10^{-3}
	Dy 166		4×10^{-4}
Erbium (68)	Er 169		9×10^{-4}
	Er 171		1×10^{-3}
Europium (63)	Eu 152 (T/2=9.2 hrs)		6×10^{-4}
	Eu 155		2×10^{-3}
Fluorine (9)	F 18	2×10^{-6}	8×10^{-3}
Gadolinium (64)	Gd 153		2×10^{-3}
	Gd 159		8 x `0^{-4}
Gallium (31)	Ga 72		4×10^{-4}
Germanium (32)	Ge 71		2×10^{-2}
Gold (79)	Au 196		2×10^{-3}
	Au 198		5×10^{-4}
	Au 199		2×10^{-3}
Hafnium (72)	Hf 181		7×10^{-4}
Hydrogen (1)	H 3	5×10^{-6}	3×10^{-2}
Indium (49)	In 113M		1×10^{-2}
	In 114M		2×10^{-4}
Iodine (53)	I 126	3×10^{-9}	2×10^{-5}
	I 131	3×10^{-9}	2×10^{-5}
	I 132	8×10^{-8}	6×10^{-4}
	I 133	1×10^{-8}	7×10^{-5}
	I 134	2×10^{-7}	1×10^{-3}
Iridium (77)	Ir 190		2×10^{-3}

	Ir 192		4×10^{-4}
	Ir 194		3×10^{-4}
Iron (26)	Fe 55		8×10^{-3}
	Fe 59		6×10^{-4}
Krypton (36)	Kr 85M	1×10^{-6}	
	Kr 85	3×10^{-6}	
Lanthanum (57)	La 140		2×10^{-4}
Lead (82)	Pb 203		4×10^{-3}
Lutetium (71)	Lu 177		1×10^{-3}
Manganese (25)	Mn 52		3×10^{-4}
	Mn 54		1×10^{-3}
	Mn 56		1×10^{-3}
Mercury (80)	Hg 197M		2×10^{-3}
	Hg 197		3×10^{-3}
	Hg 203		2×10^{-4}
Molybdenum (42)	Mo 99		2×10^{-3}
Neodymium (60)	Nd 147		6×10^{-4}
	Nd 149		3×10^{-3}
Nickel (28)	Ni 65		1×10^{-3}
Niobium (Columbium) (41)	Nb 95		1×10^{-3}
	Nb 97		9×10^{-3}
Osmium (76)	Os 185		7×10^{-4}
	Os 191M		3×10^{-2}
	Os 191		2×10^{-3}
	Os 193		6×10^{-4}
Palladium (46)	Pd 103		3×10^{-3}
	Pd 109		9×10^{-4}
Phosphorus (15)	P 32		2×10^{-4}
Platinum (78)	Pt 191		1×10^{-3}
	Pt 193M		1×10^{-2}
	Pt 197M		1×10^{-2}
	Pt 197		1×10^{-3}

Potassium (19)	K 42		3×10^{-3}
Praseodymium (59)	Pr 142		3×10^{-4}
	Pr 143		5×10^{-4}
Promethium (61)	Pm 147		2×10^{-3}
	Pm 149		4×10^{-4}
Rhenium (75)	Re 183		6×10^{-3}
	Re 186		9×10^{-4}
	Re 188		6×10^{-4}
Rhodium (45)	Rh 103M		1×10^{-1}
	Rh 105		1×10^{-3}
Rubidium (37)	Rb 86		7×10^{-4}
Ruthenium (44)	Ru 97		4×10^{-4}
	Ru 103		8×10^{-4}
	Ru 105		1×10^{-3}
	Ru 106		1×10^{-4}
Samarium (62)	Sm 153		8×10^{-4}
Scandium (21)	Sc 46		4×10^{-4}
	Sc 47		9×10^{-4}
	Sc 48		3×10^{-4}
Selenium (34)	Se 75		3×10^{-3}
Silicon (14)	Si 31		9×10^{-3}
Silver (47)	Ag 105		1×10^{-3}
	Ag 110M		3×10^{-4}
	Ag 111		4×10^{-4}
Sodium (11)	Na 24		2×10^{-3}
Strontium (38)	Sr 85		1×10^{-4}
	Sr 89		1×10^{-4}
	Sr 91		7×10^{-4}
	Sr 92		7×10^{-4}
Sulfur (16)	S 35	9 x 10 -8	6×10^{-4}
Tantalum (73)	Ta 182		4×10^{-4}
Technetium (43)	Tc 96M		1×10^{-1}

	Tc 96		1×10^{-3}
Tellurium (52)	Te 125M		2×10^{-3}
	Te 127M		6×10^{-4}
	Te 127		3×10^{-3}
	Te 129M		3×10^{-4}
	Te 131M		6×10^{-4}
	Te 132		3×10^{-4}
Terbium (65)	Tb 160		4×10^{-4}
Thallium (81)	Tl 200 Tl 201 Tl 202 Tl 204		4×10^{-3} 3×10^{-3} 1×10^{-3} 1×10^{-3}
Thulium (69)	Tm 170 Tm 171		5×10^{-4} 5×10^{-3}
Tin (50)	Sn 113 Sn 125		9×10^{-4} 2×10^{-4}
Tungsten (Wolfram) (74)	W 181 W 187		4×10^{-3} 7×10^{-4}
Vanadium (23)	V 48		3×10^{-4}
Xenon (54)	Xe 131M	4×10^{-6}	
	Xe 133	3×10^{-6}	
	Xe 135	1×10^{-6}	
Ytterbium (70)	Yb 175		1×10^{-3}
Yttrium (39)	Y 90		2×10^{-4}
	Y 91M		3×10^{-2}
	Y 91		3×10^{-4}
	Y 92		6×10^{-4}
	Y 93		3×10^{-4}
Zinc (30)	Zn 65		1×10^{-3}
	Zn 69M		7×10^{-4}
	Zn 69		2×10^{-2}
Zirconium (40)	Zr 95		6×10^{-4}
	Zr 97		2×10^{-4}
Beta and/or gamma emitting		1×10^{-10}	1×10^{-6}

byproduct not listed above with half-life less than three years			

Footnotes to Schedule A

1. Values are given only for those materials normally used as gases.
2. μCi/gm for solids.

NOTE 1: Many radioisotopes disintegrate into isotopes which are also radioactive. In expressing the concentrations in Schedule A, the activity stated is that of the parent isotope and takes into account the daughters.

NOTE 2: For purposes of 30.14 where there is involved a combination of isotopes, the limit for the combination should be derived as follows: Determine for each isotope in the product the ratio between the concentration present in the product and the exempt concentration established in Schedule A for the specific isotope when not in combination. The sum of such ratios may not exceed "1" (i.e., unity).

Example:

$$\frac{\text{Concentration of Isotope A in product}}{\text{Exempt concentration of Isotope A}} + \frac{\text{Concentration of Isotope B in product}}{\text{Exempt concentration of Isotope B}} \leq 1$$

SCHEDULE B EXEMPT QUANTITIES

Byproduct material	Microcuries
Antimony 122 (Sb 122)	100
Antimony 124 (Sb 124)	10
Antimony 125 (Sb 125)	10
Arsenic 73 (As 73)	100
Arsenic 74 (As 74)	10
Arsenic 76 (As 76)	10
Arsenic 77 (as 77)	100
Barium 131 (Ba 131)	10
Barium 133 (Ba 133)	10
Barium 140 (Ba 140)	10

Bismuth 210 (Bi 210)	1
Bromine 82 (Br 82)	10
Cadmium 109 (Cd 109)	10
Cadmium 115m (Cd 115m)	10
Cadmium 115 (Cd 115)	100
Calcium 45 (Ca 45)	10
Calcium 47 (Ca 47)	10
Carbon 14 (C 14)	100
Cerium 141 (Ce 141)	100
Cerium 143 (Ce 143)	100
Cerium 144 (Ce 144)	1
Cesium 129 (Cs 129)	100
Cesium 131 (Cs 131)	1,000
Cesium 134m (Cs 134m)	100
Cesium 134 (Cs 134)	1
Cesium 135 (Cs 135)	10
Cesium 136 (Cs 136)	10
Cesium 137 (Cs 137)	10
Chlorine 36 (Cl 36)	10
Chlorine 38 (Cl 38)	10
Chromium 51 (Cr 51)	1,000
Cobalt 57 (Co 57)	100
Cobalt 58m (Co 58m)	10
Cobalt 58 (Co 58)	10
Cobalt 60 (Co 60)	1
Copper 64 (Cu 64)	100

Dysprosium 165 (Dy 165)	10
Dysprosium 166 (Dy 166)	100
Erbium 169 (Er 169)	100
Erbium 171 (Er 171)	100
Europium 152 9.2 h (Eu 152 9.2 h)	100
Europium 152 13 yr (Eu 152 13 yr)	1
Europium 154 (Eu 154)	1
Europium 155 (Eu 155)	10
Fluorine 18 (F 18)	1,000
Gadolinium 153 (Gd 153)	10
Gadolinium 159 (Gd 159)	100
Gallium 67 (Ga 67)	100
Gallium 72 (Ga 72)	10
Germanium 68 (Ge 68)	10
Germanium 71 (Ge 71)	100
Gold 195 (Au 195)	10
Gold 198 (Au 198)	100
Gold 199 (Au 199)	100
Hafnium 181 (Hf 181)	10
Holmium 166 (Ho 166)	100
Hydrogen 3 (H3)	1,000
Indium 111 (In 111)	100
Indium 113m (In 113m)	100
Indium 114m (In 114m)	10
Indium 115m (In 115m)	100
Indium 115 (In 115)	10

Iodine 123 (I 123)	100
Iodine 125 (I 125)	1
Iodine 126 (I 126)	1
Iodine 129 (I 129)	0.1
Iodine 131 (I 131)	1
Iodine 132 (I 132)	10
Iodine 133 (I 133)	1
Iodine 134 (I 134)	10
Iodine 135 (I 135)	10
Iridium 192 (Ir 192)	10
Iridium 194 (Ir 194)	100
Iron 52 (Fe 52)	10
Iron 55 (Fe 55)	100
Iron 59 (Fe 59)	10
Krypton 85 (Kr 85)	100
Krypton 87 (Kr 87)	10
Lanthanum 140 (La 140)	10
Lutetium 177 (Lu 177)	100
Manganese 52 (Mn 52)	10
Manganese 54 (Mn 54)	10
Manganese 56 (Mn 56)	10
Mercury 197m (Hg 197m)	100
Mercury 197 (Hg 197)	100
Mercury 203 (Hg 203)	10
Molybdenum 99 (Mo 99)	100
Neodymium 147 (Nd 147)	100

Neodymium 149 (Nd 149)	100
Nickel 59 (Ni 59)	100
Nickel 63 (Ni 63)	10
Nickel 65 (Ni 65)	100
Niobium 93m (Nb 93m)	10
Niobium 95 (Nb 95)`	10
Niobium 97 (Nb 97)	10
Osmium 185 (Os 185)	10
Osmium 191m (Os 191)	100
Osmium 191 (Os 191)	100
Osmium 193 (Os 193)	100
Palladium 103 (Pd 103)	100
Palladium 109 (Pd 109)	100
Phosphorus 32 (P 32)	10
Platinum 191 (Pt 191)	100
Platinum 193m (Pt 193m)	100
Platinum 193 (Pt 193)	100
Platinum 197m (Pt 197m)	100
Platinum 197 (Pt 197)	100
Polonium 210 (Po 210)	0.1
Potassium 42 (K 42)	10
Potassium 43 (K 43)	10
Praseodymium 142 (Pr 142)	100
Praseodymium 143 (Pr 143)	100
Promethium 147 (Pm 147)	10
Promethium 149 (Pm 149)	10

Rhenium 186 (Re 186)	100
Rhenium 188 (Re 188)	100
Rhodium 103m (Rh 103m)	100
Rhodium 105 (Rh 105)	100
Rubidium 81 (Rb 81)	10
Rubidium 86 (Rb 86)	10
Rubidium 87 (Rb 87)	10
Ruthenium 97 (Ru 97)	100
Ruthenium 103 (Ru 103)	10
Ruthenium 105 (Ru 105)	10
Ruthenium 106 (Ru 106)	1
Samarium 151 (Sm 151)	10
Samarium 153 (Sm 153)	100
Scandium 46 (Sc 46)	10
Scandium 47 (Sc 47)	100
Scandium 48 (Sc 48)	10
Selenium 75 (Se 75)	10
Silicon 31 (Si 31)	100
Silver 105 (Ag 105)	10
Silver 110m (Ag 110m)	1
Silver 111 (Ag 111)	100
Sodium 22 (Na 22)	10
Sodium 24 (Na 24)	10
Strontium 85 (Sr 85)	10
Strontium 89 (Sr 89)	1
Strontium 90 (Sr 90)	0.1

Strontium 91 (Sr 91)	10
Strontium 92 (Sr 92)	10
Sulphur 35 (S 35)	100
Tantalum 182 (Ta 182)	10
Technetium 96 (Tc 96)	10
Technetium 97m (Tc 97m)	100
Technetium 97 (Tc 97)	100
Technetium 99m (Tc 99m)	100
Technetium 99 (Tc 99)	10
Tellurium 125 m (Te 125 m)	10
Tellurium 127m (Te 127m)	10
Tellurium 127 (Te 127)	100
Tellurium 129m (Te 129m)	10
Tellurium 129 (Te 129)	100
Tellurium 131m (Te 131m)	10
Tellurium 132 (Te 132)	10
Terbium 160 (Tb 160)	10
Thallium 200 (Tl 200)	100
Thallium 201 (Tl 201)	100
Thallium 202 (Tl 202)	100
Thallium 204 (Tl 204)	10
Thulium 170 (Tm 170)	10
Thulium 171 (Tm 171)	10
Tin 113 (Sn 113)	10
Tin 125 (Sn 125)	10
Tungsten 181 (W 181)	10

Tungsten 185 (W 185)	10
Tungsten 187 (W 187)	100
Vanadium 48 (V 48)	10
Xenon 131m (Xe 131m)	1,000
Xenon 133 (Xe 133)	100
Xenon 135 (Xe 135)	100
Ytterbium 175 (Yb 175)	100
Yttrium 87 (Y 87)	10
Yttrium 88 (Y 88)	10
Yttrium 90 (Y 90)	10
Yttrium 91 (Y91)	10
Yttrium 92 (Y92)	100
Yttrium 93 (Y93)	100
Zinc 65 (Zn 65)	10
Zinc 69m (Zn 69m)	100
Zinc 69 (Zn 69)	1,000
Zirconium 93 (Zr 93)	10
Zirconium 95 (Zr 95)	10
Zirconium 97 (Zr 97)	10
Any byproduct material not listed above other than alpha emitting byproduct materials	0.1

SCHEDULE C

QUANTITIES OF RADIOACTIVE MATERIALS REQUIRING CONSIDERATION OF THE NEED FOR AN EMERGENCY PLAN FOR RESPONDING TO A RELEASE.

Radioactive material[1]	Release fraction	Quantity (curies)

Actinium-228	0.001	4,000
Americium 241	.001	2
Americium-242	.001	2
Americium-243	.001	2
Antimony-124	.01	4,000
Antimony-126	.01	6,000
Barium-133	.01	10,000
Barium-140	.01	30,000
Bismuth-207	.01	5,000
Bismuth-210	.01	600
Cadmium-109	.01	1,000
Cadmium-113	.01	80
Calcium-45	.01	20,000
Californium-252	.001	9 (20 mg)
Carbon-14 (non-carbon dioxide)	.01	50,000
Cerium-141	.01	10,000
Cerium-144	.01	300
Cesium-134	.01	2,000
Cesium-137	.01	3,000
Chlorine-36	.5	100
Chromium-51	.01	300,000
Cobalt-60	.001	5,000
Copper-64	.01	200,000
Curium-242	.001	60
Curium-243	.001	3
Curium-244	.001	4
Curium-245	.001	2
Europium-152	.01	500
Europium-154	.01	400
Europium-155	.01	3,000
Germanium-68	.01	2,000
Gadolinium-153	.01	5,000

Gold-198	.01	30,000
Hafnium-172	.01	400
Hafnium-181	.01	7,000
Holmium-166m	.01	100
Hydrogen-3	.5	20,000
Iodine-125	.5	10
Iodine-131	.5	10
Indium-114m	.01	1,000
Iridium-192	.001	40,000
Iron-55	.01	40,000
Iron-59	.01	7,000
Krypton-85	1.0	6,000,000
Lead-210	.01	8
Manganese-56	.01	60,000
Mercury-203	.01	10,000
Molybdenum-99	.01	30,000
Neptunium-237	.001	2
Nickel-63	.01	20,000
Niobium-94	.01	300
Phosphorus-32	.5	100
Phosphorus-33	.5	1,000
Polonium-210	.01	10
Potassium-42	.01	9,000
Promethium-145	.01	4,000
Promethium-147	.01	4,000
Radium-226	0.001	100
Ruthenium-106	.01	200
Samarium-151	.01	4,000
Scandium-46	.01	3,000
Selenium-75	.01	10,000
Silver-110m	.01	1,000
Sodium-22	.01	9,000

Sodium-24	.01	10,000
Strontium-89	.01	3,000
Strontium-90	.01	90
Sulfur-35	.5	900
Technitium-99	.01	10,000
Technitium-99m	.01	400,000
Tellurium-127m	.01	5,000
Tellurium-129m	.01	5,000
Terbium-160	.01	4,000
Thulium-170	.01	4,000
Tin-113	.01	10,000
Tin-123	.01	3,000
Tin-126	.01	1,000
Titanium-44	.01	100
Vanadium-48	.01	7,000
Xenon-133	1.0	900,000
Yttrium-91	.01	2,000
Zinc-65	.01	5,000
Zirconium-93	.01	400
Zirconium-95	.01	5,000
Any other beta-gamma emitter	.01	10,000
Mixed fission products	.01	1,000
Mixed corrosion products	.01	10,000
Contaminated equipment beta-gamma	.001	10,000
Irradiated material, any form other than solid noncombustible	.01	1,000
Irradiated material, solid noncombustible	.001	10,000
Mixed radioactive waste, beta-gamma	.01	1,000
Packaged mixed waste, beta-gamma[4]	.001	10,000
Any other alpha emitter	.001	2
Contaminated equipment, alpha	.0001	20
Packaged waste, alpha[4]	.0001	20
Combinations of radioactive materials listed above[1]		

[1] For combinations of radioactive materials, consideration of the need for an emergency plan is required if the sum of the ratios of the quantity of each radioactive material authorized to the quantity listed for that material in Schedule C exceeds one.

[2] Waste packaged in Type B containers does not require an emergency plan.

APPENDIX A

CRITERIA RELATING TO USE OF FINANCIAL TESTS AND PARENT COMPANY GUARANTEES FOR PROVIDING REASONABLE ASSURANCE OF FUNDS FOR DECOMMISSIONING

I. *Introduction*. An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on obtaining a parent company guarantee that funds will be available for decommissioning costs and on a demonstration that the parent company passes a financial test. This appendix established criteria for passing the financial test and for obtaining the parent company guarantee.

II. *Financial Test.* A. To pass the financial test, the parent company must meet the criteria of either paragraph A.1 or A.2 of this section:

1. The parent company must have:

i. Two of the following three ratios: A ratio of total liabilities to net worth less than 2.0; a ratio of the sum of net income plus depreciation, depletion, and amortization to total liabilities greater than 0.1; and a ratio of current assets to current liabilities greater than 1.5; and

ii. Net working capital and tangible net worth each at least six times the current decommissioning cost estimates (or prescribed amount if a certification is used); and

iii. tangible net worth of at least $10 million; and

iv. assets located in the United States amounting to at least 90 percent of total assets or at least six times the current decommissioning cost estimates (or prescribed amount if a certification is used).

2. The parent company must have:

i. A current rating for its most recent bond issuance of AAA, AA, A or BBB as issued by Standard and Poor's or Aaa, Aa, A or Baa as issued by Moody's; and

ii. tangible net worth of at least $10 million; and

iii. tangible net worth at least six times the current decommissioning cost estimate (or prescribed amount if a certification is used); and

iv. assets located in the United States amounting to at least 90 percent of total assets or at least six times the current decommissioning cost estimates (or prescribed amount if a certification is used).

B. The parent company's independent certified public accountant must have compacted the data used by the parent company in the financial test, which is derived from the independently audited, year-end financial statements for the latest fiscal year, with the amounts in such financial

statement. In connection with that procedure, the licensee shall inform the Department within 90 days of any matters coming to the auditor's attention which cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

C. 1. After the initial financial test, the parent company must repeat the passage of the test within 90 days after the close of each succeeding fiscal year.

2. If the parent company no longer meets the requirements of paragraph A of this section, the license, the licensee must send notice to the Department of intent to establish alternate financial assurance as specified in this Code. The notice must be sent by certified mail within 90 days after the end of the fiscal year for which the year-end financial data show that the parent company no longer meets the financial test requirements. The licensee must provide alternate financial assurance within 120 days after the end of such fiscal year.

III. *Parent Company Guarantee.* The terms of a parent company guarantee which an applicant or licensee obtains must provide that:

A. The parent company guarantee will remain in force unless the guarantor sends notice of cancellation by certified mail to the licensee and the Department. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by both the licensee and the Department, as evidenced by the return receipts.

B. If the licensee fails to provide alternate financial assurance as specified by this Code within 90 days after receipt by the licensee and Department of a notice of cancellation of the parent company guarantee from the guarantor, the guarantor will provide such alternative financial assurance in the name of the licensee.

C. The parent company guarantee and financial test provisions must remain in effect until the Department has terminated the license.

D. If a trust is established for decommissioning costs, the trustee and trust must be acceptable to the Department. An acceptable trustee includes an appropriate state or federal government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a federal or state agency.

APPENDIX B

QUANTITIES OF LICENSED MATERIAL REQUIRING LABELING

Materials	Microcuries
Americium-241	.01
Antimony-122	100
Antimony-124	10
Antimony-125	10
Arsenic-73	100
Arsenic-74	10

Arsenic-76	10
Arsenic-77	100
Barium-131	10
Barium-133	10
Barium-140	10
Bismuth-210	1
Bromine-82	10
Cadmium-109	10
Cadmium-115m	10
Cadmium-115	100
Calcium-45	10
Calcium-47	10
Carbon-14	100
Cerium-141	100
Cerium-143	100
Cerium-144	1
Cesium-131	1,000
Cesium-134m	100
Cesium-134	1
Cesium-135	10
Cesium-136	10
Cesium-137	10
Chlorine-36	10
Chlorine-38	10
Chromium-51	1,000
Cobalt-58m	10
Cobalt-58	10
Cobalt-60	1
Copper-64	100
Dysprosium-165	10
Dysprosium-166	100
Erbium-169	100

Erbium-171	100
Europium-152 9.2h	100
Europium-152 13 yr	1
Europium-154	1
Europium-155	10
Fluorine-18	1,000
Gadolinium-153	10
Gadolinium-159	100
Gallium-72	10
Germanium-71	100
Gold-198	100
Gold-199	100
Hafnium-181	10
Holmium-166	100
Hydrogen-3	1,000
Indium-113m	100
Indium-114m	10
Indium-115m	100
Indium-115	10
Iodine-125	1
Iodine-126	1
Iodine-129	0.1
Iodine-131	1
Iodine-132	10
Iodine-133	1
Iodine-134	10
Iodine-135	10
Iridium-192	10
Iridium-194	100
Iron-55	100
Iron-59	10
Krypton-85	100

Krpton-87	10
Lanthanum-140	10
Lutetium-177	100
Manganese-52	10
Manganese-54	10
Manganese-56	10
Mercury-197m	100
Mercury-197	100
Mercury-203	10
Molbdenum-99	100
Neodymium-147	100
Neodymium-149	100
Nickel-59	100
Nickel-63	10
Nickel-65	100
Niobium-93m	10
Niobium-95	10
Niobium-97	10
Osmium-185	10
Osmium-191m	100
Osmium-191	100
Osmium-193	100
Palladium-103	100
Palladium-109	100
Phosphorus-32	10
Platinum-191	100
Platinum-193m	100
Platinum-193	100
Platinum-197m	100
Platinum-197	100
Plutonium-239	.01
Polonium-210	0.1

Potassium-42	10
Praseodymium-142	100
Praseodymium-143	100
Promethium-147	10
Promethium-149	10
Radium-226	.01
Rhenium-186	100
Rhenium-188	100
Rhodium-103m	100
Rhodium-105	100
Rubidium-86	10
Rubidium-87	10
Ruthenium-97	100
Ruthenium-103	10
Ruthenium-105	10
Ruthenium-106	1
Samarium-151	10
Samarium-153	100
Scandium-46	10
Scandium-47	100
Scandium-48	10
Seleium-75	10
Silicon-31	100
Silver-105	10
Silver-110m	1
Silver-111	100
Sodium-24	10
Strontium-85	10
Strontium-89	1
Strontium-90	0.10
Strontium-91	10
Strontium-92	10

Sulphur-35	100
Tantalum-182	10
Technetium-96	10
Technetium-97m	100
Technetium-97	100
Technetium-99m	100
Technetium-99	10
Tellurium-125m	10
Tellurium127m	10
Tellurium-127	100
Tellurium129m	10
Tellurium-129	100
Tellurium-131m	10
Tellurium-132	10
Terbium-160	10
Thallium-200	100
Thallium-201	100
Thallium-202	100
Thallium-204	10
Thorium (natural)[1]	100
Thulium-170	10
Thulium-171	10
Tin-113	10
Tin-125	10
Tungsten-181	10
Tungsten-185	10
Tungsten-187	100
Uranium (natural)[2]	100
Uranium-233	.01
Uranium-234--Uranium-235	.01
Vandium-48	10
Xenon-131m	1,000

Xenon-133	100
Xenon-135	100
Ytterbium-175	100
Yttrium-90	10
Yttrium-91	10
Yttrium-92	100
Yttrium-93	100
Zinc-65	10
Zinc-69m	100
Zinc-69	1,000
Zirconium-93	10
Zirconium-95	10
Zirconium-97	10
Any alpha emitting radionuclide not listed above or mixtures of alpha emitters of unknown composition	.01
Any radionuclide other than alpha emitting radio-nuclides, not listed above or mixtures of beta emitters of unknown composition	.1

[1]Based on alpha disintegration rate of Th-232, Th-230 and their daughter products.

[2]Based on alpha disintegration rate of U-238, U-234, and U-235.

Source: 10 CFR Appendix B to Part 30—Quantities of Licensed Material Requiring Labeling

APPENDIX C

CRITERIA RELATING TO USE OF FINANCIAL TESTS AND SELF GUARANTEES FOR PROVIDING REASONABLE ASSURANCE OF FUNDS FOR DECOMMISSIONING

I. *Introduction*

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the company passes the financial test of Section II of this appendix. The terms of the self-guarantee are in Section III of this appendix. This appendix establishes criteria for passing the financial test for the self guarantee and establishes the terms for a self-guarantee.

II. *Financial Test*

A. To pass the financial test a company must meet all of the criteria set forth in this section. For purposes of applying the Appendix C criteria, tangible net worth must be calculated to exclude all intangible assets and the net book value of the nuclear facility and site, and total net worth, which may include intangible assets, must be calculated to exclude the net book value and goodwill of the nuclear facility and site. These criteria include:

(1) Tangible net worth of at least $21 million, and total net worth at least 10 times the amount of decommissioning funds being assured by a self-guarantee for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor for the total of all nuclear facilities or parts thereof (or the current amount required if certification is used).

(2) Assets located in the United States amounting to at least 90 percent of total assets or at least 10 times the amount of decommissioning funds being assured by a self-guarantee, for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor for the total of all nuclear facilities or parts thereof (or the current amount required if certification is used).

(3) A current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A (including adjustments of + and –) as issued by Standard and Poor's, or Aaa, Aa, or A (including adjustments of 1, 2, or 3) as issued by Moody's.

B. To pass the financial test, a company must meet all of the following additional requirements:

(1) The company must have at least one class of equity securities registered under the Securities Exchange Act of 1934.

(2) The company's independent certified public accountant must compare the data used by the company in the financial test, which is derived from the independently audited, year-end financial statements for the latest fiscal year, with the amounts in such financial statement. The accountant must evaluate the company's off-balance sheet transactions and provide an opinion on whether those transactions could materially adversely affect the company's ability to pay for decommissioning costs. The accountant must verify that a bond rating, if used to demonstrate passage of the financial test, meets the requirements of Section II, paragraph A of this appendix. In connection with the auditing procedure, the licensee must inform the NRC within 90 days of any matters coming to the auditor's attention which cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

(3) After the initial financial test, the company must annually pass the test and provide documentation of its continued eligibility to use the self-guarantee to the Department within 90 days after the close of each succeeding fiscal year.

C. If the licensee no longer meets the requirements of Section II.A. of this appendix, the licensee must send immediate notice to the Department of its intent to establish alternate financial assurance as specified in the Department's regulations within 120 days of such notice.

III. *Company Self-Guarantee*

The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

A. The guarantee will remain in force unless the licensee sends notice of cancellation by certified mail to the Department. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by the Department, as evidenced by the return receipt.

B. The licensee shall provide alternative financial assurance as specified in the Department's regulations within 90 days following receipt by the Department of a notice of cancellation of the guarantee.

C. The guarantee and financial test provisions must remain in effect until the Department has terminated the license or until another financial assurance method acceptable to the Department has been put in effect by the licensee.

D. The licensee will promptly forward to the Department and the licensee's independent auditor all reports covering the latest fiscal year filed by the licensee with the Securities and Exchange Commission pursuant to the requirements of section 13 of the Securities and Exchange Act of 1934.

E. (1) If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A–" and above by Standard and Poor's or in any category of "A3" and above by Moody's, the licensee will notify the Department in writing within 20 days after publication of the change by the rating service.

(2) If the licensee's most recent bond issuance ceases to be rated in any category of A or above by both Standard and Poo's and Moody's, the licensee no longer meets the requirements of Section II.A. of this appendix.

F. The applicant or licensee must provide to the Department a written guarantee (a written commitment by a corporate officer) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the Department, the licensee will fund the standby trust in the amount guaranteed by the self-guarantee agreement.

G. (1) A standby trust to protect public health and safety and the environment must be established for decommissioning costs before the self-guarantee agreement is submitted.

(2) The trustee and trust must be acceptable to the Department. An acceptable trustee includes an appropriate State or Federal Government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency. The

Commission has the right to change the trustee. An acceptable trust will meet the regulatory criteria established in these regulations that govern the issuance of the license for which the guarantor has accepted the obligation to pay for decommissioning costs.

H. The guarantor must agree that if the guarantor admits in writing its inability to pay its debts generally, or makes a general assignment for the benefit of creditors, or any proceeding is instituted by or against the guarantor seeking to adjudicate it as bankrupt or insolvent, or seeking dissolution, liquidation, winding-up, reorganization, arrangement, adjustment, protection, relief or composition of it or its debts under any law relating to bankruptcy, insolvency, or reorganization or relief of debtors, or seeking the entry of an order for relief or the appointment of a receiver, trustee, custodian, or other similar official for the guarantor or for any substantial part of its property, or the guarantor takes any action to authorize or effect any of the actions stated in this paragraph, then the Department may:

(1) Declare that the financial assurance guaranteed by the self-guarantee agreement is immediately due and payable to the standby trust set up to protect the public health and safety and the environment, without diligence, presentment, demand, protest or any other notice of any kind, all of which are expressly waived by guarantor; and

(2) Exercise any and all of its other rights under applicable law.

I. The guarantor must notify the Department, in writing, immediately following the occurrence of any event listed in paragraph H of this appendix, and must include a description of the event, including major creditors, the amounts involved, and the actions taken to assure that the amount of funds guaranteed by the self-guarantee agreement for decommissioning will be transferred to the standby trust as soon as possible.

§175.102 Requirements for specific types of radioactive materials licenses.

(a) *Types of license.* (1) For the purposes of §5.07(a) and §175.05 of this Code, the following special designations of radioactive materials licenses shall apply:

(i) A specific license of limited scope for teletherapy means a license that authorizes receipt, acquisition, ownership, possession, use and transfer of specified quantities and types of radioactive material for use in teletherapy programs.

(ii) A specific license of limited scope for medical use means a license that authorizes receipt, acquisition, ownership, possession, use and transfer of specified quantities and types of radioactive material for use in or on humans in a medical program, but does not include teletherapy.

(iii) A specific license of limited scope for other use means a license that authorizes receipt, production, acquisition, ownership, possession, use and transfer of specified quantities and types of radioactive material for uses other than in or on humans.

(iv) A specific license of broad scope for medical use means a license that authorizes receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of the radioactive materials specified in the license, for use in or on humans in a medical program, but does not include teletherapy.

(v) A specific license of broad scope for research and development means a license that authorizes receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive materials specified in the license, in quantities not exceeding those specified in the license, for uses other than in or on humans.

(b) The requirements specified in this section are in addition to, and not in substitution for, others in this Code. In particular, the provisions of §175.101 apply to all license applications and all specific radioactive materials licenses.

(c) *Specific licenses for human use of radioactive materials in institutions.* (1) An application by an institution for a specific license for medical use of radioactive material will be approved if:

(i) the applicant satisfies the requirements specified in §175.101 and §175.103 of this Code; and

(ii) the applicant possesses adequate facilities for the clinical care of patients; and

(iii) the physician(s) designated on the application as the individual authorized user(s) has training and experience as specified in §175.103(j) in the proposed use, the handling and administration of radionuclides and the clinical management of radioactive patients. The physician shall furnish evidence of such experience with his/her application. A statement from his/her preceptor at the institution where he/she acquired such training and experience, indicating their amount and nature, may be submitted as evidence of such experience.

(iv) If the application is for a license to use unspecified quantities or multiple types of radioactive materials with atomic numbers 3 through 83 the applicant shall have had previous experience operating under a specific institutional license and have been engaged in the use of radioisotopes in medical research, as well as routine diagnosis and therapy.

(v) The license application is signed by the chairman of the radiation safety committee and an authorized representative of the institution.

(d) *Specific licenses to individual physicians for human use of radioactive materials.* (1) An application by an individual physician for a specific license for human use of radioactive material will be approved if:

(i) the applicant satisfies the requirements specified in §175.101 and §175.103 of this Code; and

(ii) the applicant has training and experience as specified in §175.103(j) in the proposed use, the handling and administration of radionuclides, and the clinical management of radioactive patients. The physician shall furnish evidence of such training and experience with his/her application. A statement from his/her preceptor at the institution where he/she acquired such training and experience, indicating their amount and nature, may be submitted as evidence of such experience.

(e) *Specific licenses of broad scope.* (1) A specific license of broad scope shall be issued only to medical institutions or institutions of higher education; such licenses shall not be issued to individuals.

(2) An application for a specific license of broad scope will be approved if:

(i) the applicant satisfies the general requirements specified in §175.101(e) of this Code; and

(ii) the applicant has engaged in a reasonable number of activities involving the use of radioactive material; and

(iii) the applicant has established administrative controls and provisions relating to organization and management, procedures, recordkeeping, material control, and accounting and management review that are necessary to assure safe operations, including:

(A) the establishment of a radiation safety committee pursuant to §175.03 of this Code; and

(B) the appointment of a full-time radiation safety officer pursuant to §175.03 of this Code; and

(C) the establishment of appropriate administrative procedures to assure:

(a) control of procurement and use of radioactive material; and

(b) completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and

(c) review, approval, and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with §175.102(e)(2)(iii)(C)(*b*) prior to the use of radioactive materials.

(3) The following are conditions of all specific licenses of broad scope:

(i) Unless specifically authorized pursuant to other provisions of this Code, broad scope licensees shall not:

(A) conduct tracer studies in the environment involving direct release of radioactive material;

(B) receive, acquire, own, possess, use, transfer, or import devices containing 3.7 E6 GBq (100,000 Ci) or more of radioactive material in sealed sources used for irradiation of materials;

(C) add, or cause the addition of, radioactive material to any food, beverage, cosmetic, drug or other product designed for ingestion by, or application to, a human being except as authorized in the license.

(f) *Specific licenses for non-human use.* (1) An application for a specific license authorizing non-human use of radioactive materials will be approved if:

(i) the applicant satisfies the general requirements specified in §175.101(e) of this Code; and

(ii) the applicant, or the applicant's personnel, has training and experience commensurate with the proposed amounts, types and uses of radioactive materials which shall include at a minimum:

(A) a college degree at the bachelor level in a physical, biological, environmental or engineering science; and

(B) at least forty (40) hours of training and experience in the safe handling of radioactive materials appropriate to the type and forms of such materials to be used, which shall include:

(a) characteristics of ionizing radiation;

(b) units of radiation dose and quantities;

(c) radiation detection instrumentation; and

(d) biological hazards of exposure to radiation.

(g) *General licenses.* (1) A general license is hereby issued to own radioactive material without regard to quantity. Notwithstanding any other provisions of this Code, this general license does not authorize the manufacture, production, transfer, receipt, possession or use of radioactive material.

(2) *Source material.* (i) A general license is hereby issued authorizing use and transfer of not more than 6.8 kilograms (15 pounds) of source material at any one time by persons in the following categories:

(A) pharmacists using the source material solely for the compounding of medicinals; (B) physicians using the source material for medicinal purposes;

(C) persons receiving possession of source material from pharmacists and physicians in the form of medicinals or drugs;

(D) commercial and industrial firms, and research, educational, and medical institutions for research, development, educational or commercial purposes;

and provided, that no such person shall, pursuant to this general license, receive more than 68 kilograms (150 pounds) of source material in any one (1) calendar year.

(ii) Persons who transfer, receive, possess or use source material pursuant to the general license issued in §175.102(g)(2)(i) are exempt from the provisions of §175.03, §175.04, §175.06, §175.104 and §175.105 of this Code to the extent that such transfer, receipt, possession or use is within the terms of such general license, provided however, that this exemption shall not be deemed to apply to any such person who is also in possession of source material under a specific license issued pursuant to this Code.

(iii) A general license is hereby issued authorizing the receipt of title to source material without regard to quantity. This general license does not authorize any person to transfer, receive, possess or use source material.

(3) *Certain devices and equipment.* (i) A general license is hereby issued to transfer, receive, possess or use radioactive material incorporated in the following devices or equipment which have been manufactured, tested and labeled in accordance with a specific license issued by the Department, the U.S. Nuclear Regulatory Commission or an agreement state, authorizing distribution under this general license or its equivalent.

(A) Static elimination devices. Devices designed for use as static eliminators which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 18.5 MBq (500 mCi) of polonium-210 per device.

(B) Ion generating tubes. Devices designed for ionization of air which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 18.5 MBq (500 mCI) of polonium-210 per device or a total of not more than 1.85 GBq (50 mCi) per device.

(4) *Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere.*

(i) A general license is hereby issued to commercial and industrial firms and research, educational and medical institutions, individuals in the conduct of their business, and federal, state or local government agencies to acquire, receive, possess, use or transfer, in accordance with the provisions of subparagraphs (ii), (iii) and (iv) of this paragraph, byproduct material contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

(ii)(A) The general license in subparagraph (i) of this paragraph applies only to byproduct material contained in devices which have been manufactured or initially transferred and labeled in accordance with the specifications contained in:

(a) A specific license issued under 10 CFR §32.51;

(b) An equivalent specific license issued by an agreement state; or

(c) An equivalent specific license issued by a state with provisions comparable to 10 CFR §32.51.

(B) The devices must have been received from one of the specific licensees described in clause (ii)(A) of this section or through a transfer made under clause (iii)(I) of this paragraph.

(iii) Any person who acquires, receives, possesses, uses or transfers byproduct material in a device pursuant to the general license in subparagraph (i) of this section:

(A) hall assure that all labels affixed to the device at the time of receipt remain affixed, and bearing a statement that removal of the label is prohibited, and must comply with all instructions and precautions provided by such labels;

(B) hall assure that the device is tested for leakage of radioactive material and proper operation

of the on-off mechanism and indicator, if any, at no longer than six month intervals or as frequently as is specified in the label; however:

(a) Devices containing only krypton need not be tested for leakage of radioactive material, and

(b) Devices containing only tritium or not more than 100 microcuries of other beta and/or gamma emitting material or 10 microcuries of alpha emitting material, and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose;

(C) Shall assure that the tests required by clause (iii)(B) of this paragraph and other testing, installation, servicing, and removal from installation involving the radioactive materials, its shielding or containment, are performed:

(a) In accordance with the instructions provided by the labels; or

(b) By a person holding a specific license pursuant to Parts 30 and 32 of 10 CFR or from an agreement state to perform such activities;

(D) hall maintain records showing compliance with the requirements of clauses (iii)(B) and (iii)(C) of this paragraph. The records must show the results of tests. The records also must show the dates of performance of, and the names of persons performing, testing, installing, servicing, and removing from the installation radioactive material and its shielding or containment. The licensee shall retain these records as follows:

(a) Each record of a test for leakage or radioactive material required by clause (iii)(B) of this paragraph must be retained for three years after the next required leak test is performed or until the sealed source is transferred or disposed of.

(b) Each record of a test of the on-off mechanism and indicator required by clause (iii)(B) of this paragraph must be retained for three years after the next required test of the on-off mechanism and indicator is performed or until the sealed source is transferred or disposed of.

(c) Each record that is required by clause (iii)(C) of this paragraph must be retained for three years from the date of the recorded event or until the device is transferred or disposed of.

(E) hall immediately suspend operation of the device if there is a failure of, or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 185 bequerel (0.005 microcurie) or more removable radioactive material. The device may not be operated until it has been repaired by the manufacturer or other person holding a specific license to repair such devices that was issued under parts 30 and 32 or by an agreement state. The device and any radioactive material from the device may only be disposed of by transfer to a person authorized by a specific license to receive the byproduct material in the device or as otherwise approved by the U.S. Nuclear Regulatory Commission. A report containing a brief description of the event and the remedial action taken; and, in the case of detection of 0.005 microcurie or more removable radioactive material, or failure of or damage to a source likely to result in contamination of the premises or the environs, a plan for ensuring that the premises and environs are acceptable for unrestricted use, must be furnished to the Department by the licensee within 5 days as required by §175.03(l)(7). Upon such a failure, damage, or possible indication of failure or damage, the Department may determine to apply the criteria set out in 10 CFR §20.1402;

(F) hall not abandon the device containing byproduct material;

(G) hall not export the device containing byproduct material except in accordance with 10 CFR Part 110:

(H)*(a)* Except as provided in item (iii)(H)(*c*) of this paragraph, shall transfer or dispose of the device containing byproduct material only by: export as provided by clause (iii)(G) of this paragraph; transfer to another general licensee as authorized in clause (iii)(I) of this paragraph;

transfer to a person authorized to receive the device by a specific license issued under Parts 30 and 32 of 10 CFR; transfer to a person authorized to collect waste under Part 30 of 10 CFR or the equivalent regulation of an agreement state; or transfer as otherwise approved under item (iii)(H)(*c)* of this paragraph.

(b) Shall, within 30 days after the transfer of a device to a specific licensee or export, furnish a report to the Department. The report must contain: (I) The identification of the device by the manufacturer's (or initial transferor's) name, model number, and serial number;

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

(III) The date of the transfer.

(c) Shall obtain written Department approval before transferring the device to any licensee not specifically identified in item (iii)(H)(*a*) of this paragraph; however, a holder of a specific license may transfer a device for possession and use under its own specific license without prior approval, if, the holder:

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

(II) emoves, alters, covers, or clearly and unambiguously augments the existing label (otherwise required by clause (iii)(A) of this paragraph) so that the device is labeled in compliance with 10 CFR § 20.1904; however the manufacturer, model number, and serial number must be retained;

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

(IV) Reports the transfer under item (iii)(H)(b) of this paragraph.

(I) hall transfer the device to another general licensee only if:

(a) The device remains in use at a particular location. In this case, the transferor must give the transferee a copy of this section, copies of 19 CFR §§ 20.2201, 20.2202, 30.51, and 31.2, and any safety documents identified in the label of the device. Within 30 days of such a transfer, the transferor shall report to the Department:

(I) The manufacturer's (or initial transferor's) name;

(II) The model number and the serial number of the device transferred;

(III) The transferee's name and mailing address for the location of use; and

(IV) The name, title, and phone number of the responsible individual identified by the transferee in accordance with clause (iii)(L) of this paragraph to have knowledge of and authority to take actions to ensure compliance with the appropriate regulations and requirements; or

(*b*) The device is held in storage in the original shipping container by an intermediate person at its intended location of use prior to initial use by a general licensee.

(J) hall comply with the provisions of 10 CFR §§ 20.2201 and 20.2202 for reporting radiation incidents, theft or loss of licensed material, but pursuant to title 10 of the code of federal regulations, is exempt from the other requirements of 10 CFR Parts 19, 20, and 21.

(K) hall respond to written requests from the Department or U.S. Nuclear Regulatory Commission to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it must, within that same time period, request more time to supply the information by providing a written justification for the request to the Department.

(L) hall appoint an individual responsible for having knowledge of the appropriate regulations

and requirements and the authority for taking required actions to comply with appropriate regulations and requirements. The general licensee, through this individual, must ensure the day-to-day compliance with appropriate regulations and requirements. This appointment does not relieve the general licensee of any of its responsibility in this regard.

(M)*(a)* Except as provided in item (iii)(M)(*d*) of this paragraph, shall register, in accordance with items (iii)(M)(*b*) and (*c*) of this paragraph, devices containing at least 370 megabecquerels (10 millicuries) of cesium-137, 3.7 megabecquerels (0.1 millicurie) of strontium-90, 37 megabecquerels (1 millicurie) of cobalt-60, 3.7 megabecquerels (0.1 millicurie) of radium-226, or 37 megabecquerels (1 millicurie) of americium-241 or any other transuranic (i.e., element with atomic number greater than uranium (92)), based on the activity indicated on the label. Each address for a location of use, as described under subitems (iii)(M)(*c*)(IV) of this paragraph, represents a separate general licensee and requires a separate registration and fee as specified in this Code.

(b) If in possession of a device meeting the criteria of item (iii)(M)(*a*) of this paragraph, must register these devices annually with the Department and must pay the fee required by §5.07 of this Code. Registration must be done by verifying, correcting, and/or adding to the information provided in a request for registration received from the Department. The registration information must be submitted to the Department within 30 days of the date of the request for registration or as otherwise indicated in the request. In addition, a general licensee holding devices meeting the criteria of item (iii)(M)(*a*) of this paragraph is subject to the bankruptcy notification requirement in 10 CFR § 30.34(h) and §175.101(k)(1)(vi).

(c) In registering any device meeting the criteria listed in item (iii)(M)(*a*) of this paragraph, the general licensee must furnish the following information and any other information specifically requested by the Department:

(I) ame and mailing address of the general licensee.

(II) Information about each device: the manufacturer (or initial transferor), model number, serial number, the radioisotope and activity (as indicated on the label).

(III) Name, title, and telephone number of the responsible person designated as a representative of the general licensee under clause (i)(L) of this paragraph.

(IV) Address or location at which each device is used or stored. For portable devices, the address of the primary place of storage.

(V) ertification by the responsible representative of the general licensee that the information concerning each device has been verified through a physical inventory and checking of label information.

(VI) ertification by the responsible representative of the general licensee that they are aware of the requirements of the general license.

(d) A person generally licensed by an agreement state with respect to any device meeting the criteria in item (iii)(M)(*a*) of this paragraph are not subject to the registration requirements of this clause if the device is used in an area subject to NRC jurisdiction for less than 180 days in any calendar year. The Department will not request registration information from such a licensee.

(N) hall report any change to the mailing address for the location of use (including change in name of general licensee) to the Department within 30 days of the effective date of the change. For a portable device, a report of address change is only required for a change in the device's primary place of storage.

(O) ay not hold any device that is not in use for longer than 2 years. When any device with shutters is not being used, the shutter must be locked in the closed position. The testing required

by clause (iii)(B) of this paragraph need not be performed during a period of storage only. However, when a device is put back into service or transferred to another person, and has not been tested within the required test interval, it must be tested for leakage before use or transfer, and the shutter tested before use. Any devices kept in standby for future use is excluded from the two-year time limit in this clause if the general licensee performs quarterly physical inventories of any such device while it is in standby.

(iv) The general license in subparagraph (i) of this paragraph does not authorize the manufacture or import of devices containing byproduct material.

(5) *Labeling of devices*

(i) (A) Each person licensed under 10 CFR § 32.57 shall affix to each source, or storage container for the source, a label which contains sufficient information relative to safe use and storage of the source and includes the following statement, or a substantially similar statement which contains the information called for in the following statement:

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

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

_____

(*Name of manufacturer or initial transferor*)"

(C) such devices are installed on the premises of the general licensee by a person authorized to install such devices under a specific license issued to the installer by the Department, the U.S. Nuclear Regulatory Commission or an agreement state, if a label affixed to the device at the time of receipt states that installation by a specific licensee is required. This requirement does not apply while devices are held in storage in the original shipping container pending installation by a specific licensee.

(ii) Persons who receive, possess or use a device pursuant to the general license issued under this subdivision:

(A) shall, within ten (10) days after the receipt of the device, notify the Department of the type of device and the name and address of the supplier;

(B) shall not transfer, abandon, or dispose of the device except by transfer to a person duly authorized to receive such device by a specific license issued by the Department, the U.S. Nuclear Regulatory Commission or an agreement state, and shall furnish to the Department, within thirty (30) days after any such transfer, a report containing the name of the manufacturer of the device, the type of device, the manufacturer's serial number of the device, and the name and address of the person receiving the device;

(C) shall assure that all labels affixed to the device at the time of receipt and bearing the statement, "Removal of this label is prohibited" are maintained thereon and shall comply with all instructions contained in such labels;

(D) shall have the device tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at the time of installation of the device or replacement of the radioactive material on the premises of the general licensee and thereafter at no longer than six

(6) month intervals or at such longer intervals not to exceed three (3) years as are specified in the label required by §175.102(g)(5)(i)(A), provided, that devices containing only krypton-85 need

not be tested for leakage, and devices containing only hydrogen-3 need not be tested for any purpose;

(E) shall have all the tests required by §175.102(g) and all other services involving the radioactive material, its shielding and containment, performed by the supplier or other person duly authorized by a specific license issued by the Department, the U.S. Nuclear Regulatory Commission or an agreement state, to manufacture, install or service such devices;

(F) shall, within thirty (30) days after the occurrence of a failure or of damage to the shielding of the radioactive material or the on-off mechanism or indicator or upon the detection of 0.185 kBq (0.005 mCi) or more of removable radioactive material, furnish to the Department a report containing the name of the manufacturer of the device and a brief description of the event and the remedial action taken; and shall maintain records of all tests performed on the devices as required herein, including the dates and results of the tests and the names of the persons conducting the tests;

(G) shall, upon the occurrence of a failure of or damage to, or any indication of a possible failure of or damage to, the shielding or containment of the radioactive material or the on-off mechanism or indicator, immediately suspend operation of the device until it has been repaired by a person holding a specific license issued by the Department, the U.S. Nuclear Regulatory Commission or an agreement state, to manufacture, install or service such devices, or disposed of by transfer to a person holding a specific license issued by the Department, the U.S. Nuclear Regulatory Commission or an agreement state to receive the radioactive material contained in the device;

(H) shall be exempt from the provisions of §175.03, §175.04, §175.06, §175.104 and §175.105 of this Code, except that such persons shall comply with the provisions of §175.03(l)(1).

(iii) Any holder of a license issued by the Department, the U.S. Nuclear Regulatory Commission or an agreement state which authorizes the holder to manufacture, install or service a device subject to the general license in §175.102(g)(3)(i), and which is not limited as to specific installation or installations, may install or service such devices without obtaining a license from the Department provided that:

(A) such person shall file a report with the Department within thirty (30) days after the end of each calendar quarter in which any device is transferred to or installed within the Department's jurisdiction. Each such report shall identify the name and address of each person receiving a device, the type of device transferred, and the quantity and type of radioactive material contained in the device;

(B) the device is manufactured, labeled, installed and serviced in accordance with terms and conditions of the license issued to such person;

(C) such person shall assure that any labels required to be affixed to the device bear a statement that "Removal of this label is prohibited"; and

(D) the person to whom such device is transferred, or on whose premises such device is installed or serviced, has a copy of the general license requirements or equivalent requirements specified in §175.102(g)(3)(ii).

(iv) The Department may withdraw, limit or qualify its acceptance of any specific license issued by another agency, or any product distributed pursuant to such licensing document, upon determining that such action is necessary to prevent undue hazard to public health and safety or property.

(6) *Luminous safety devices for aircraft.* (i) A general license is hereby issued to receive, possess or use hydrogen-3 or promethium-147 contained in luminous safety devices for use in aircraft, provided:

(A) each device contains not more than 370 GBq (10 Ci) of hydrogen-3 or 11.1 GBq (300 mCi) of promethium-147; and

(B) each device has been manufactured, assembled or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or each device has been manufactured, assembled or imported in accordance with the specifications contained in a specific license issued by the Department or an agreement state pursuant to licensing requirements equivalent to those in §32.53 of 10 CFR Part 32.

(ii) Persons who receive, possess or use luminous safety devices pursuant to the general license in §175.102(g)(4)(i) are exempt from the provisions of §175.03, §175.04, §175.06, §175.104 and §175.105 of this Code, except that such persons shall comply with the provisions of §175.03(l)(1).

(iii) This general license does not authorize the manufacture, assembly or repair of luminous safety devices containing hydrogen-3 or promethium-147.

(iv) This general license does not authorize the receipt, possession or use of promethium-147 contained in instrument dials.

(7) *Calibration and reference sources.* (i) A general license is hereby issued to those persons listed below to transfer, receive, possess or use, in accordance with the provisions of §175.102(g)(5)(iii) and (iv), americium-241 in the form of calibration or reference sources:

(A) any person who holds a specific license issued by the Department, the New York State Department of Health or the New York State Department of Labor which authorizes the transfer, receipt, possession or use of radioactive material; and

(B) any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission which authorizes the transfer, receipt, possession or use of special nuclear material.

(ii) A general license is hereby issued to transfer, receive, possess or use plutonium in the form of calibration or reference sources in accordance with the provisions of §175.102(g)(5)(iv) and (v) to any person who holds a specific license issued by the Department, the New York State Department of Health or the New York State Department of Labor which authorizes the transfer, receipt, possession or use of radioactive material.

(iii) The general licenses in §175.102(g)(5)(i) and (ii) apply only to calibration or reference sources which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer or importer of the sources by the U.S. Nuclear Regulatory Commission pursuant to §32.57 of 10 CFR Part 32 or §70.39 of 10 CFR Part 70 or which have been manufactured or imported in accordance with the specifications contained in a specific license issued by the Department or an agreement state pursuant to licensing requirements equivalent to those contained in §32.57 of 10 CFR Part 32 or §70.39 of 10 CFR Part 70.

(iv) Persons who transfer, receive, possess or use one or more calibration or reference sources pursuant to these general licenses:

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

(B) shall not transfer, receive, possess or use such source unless the source, or the storage container, bears a label which includes the following statement or a substantially similar statement which contains the information called for in the following statement:

The transfer, receipt, possession or use of this device, Model_____, Serial number _____, are subject to a general license and the regulations of the U.S. Nuclear Regulatory Commission or of a State with which the Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label. CAUTION—RADIOACTIVE MATERIAL—THIS SOURCE CONTAINS (AMERICIUM-241) (PLUTONIUM)[3]*. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.*

_____

(Name of manufacturer or importer);

(C) shall not transfer, abandon or dispose of such source except by transfer to a person authorized by a license from the Department, the U.S. Nuclear Regulatory Commission or an agreement state to receive the source;

(D) shall store such source, except when the source is being used, in a closed container adequately designed and constructed to contain americium-241 or plutonium which might otherwise escape during storage; and

(E) shall not use such source for any purpose other than the calibration of radiation detectors or the standardization of other sources.

(v) These general licenses do not authorize the manufacture of calibration or reference sources containing americium-241 or plutonium.

(vi) A general license is hereby issued to transfer, receive, possess or use sealed radioactive materials sources in individual quantities each of which does not exceed the applicable quantity set forth in Appendix B of §175.101 of this Code, to any person who holds a specific license issued by the Department.

(vii) Persons who transfer, receive, possess or use sources pursuant to the general license in §175.102(g)(5)(vi):

(A) shall not transfer, abandon or dispose of such sources except by transfer to a person duly authorized to receive such sources by the Department, the U.S. Nuclear Regulatory Commission or an agreement state; and

(B) shall store such sources, except when being used, in a secure location.

(8) *Ice detection devices.* (i) A general license is hereby issued to transfer, receive, possess or use strontium-90 contained in ice detection devices, provided each device contains not more than 1.85 MBq (50 mCi) of strontium-90 and each device has been manufactured or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to §32.61 of 10 CFR Part 32 or by the Department or an agreement state pursuant to licensing requirements equivalent to those contained in §32.61 of 10 CFR Part 32.

(ii) Persons who transfer, receive, possess or use strontium-90 contained in ice detection devices pursuant to this general license:

(A) shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating, to the device, discontinue use of the device until it has been inspected, tested for leakage and repaired by a person holding a specific license from the U.S. Nuclear Regulatory Commission or an agreement state to manufacture or service such devices; or shall dispose of the device pursuant to §175.104 of this Code;

(B) shall assure that all labels affixed to the device at the time of receipt, and which bear a statement which prohibits removal of the labels, are maintained thereon; and

(C) are exempt from the provisions of §175.03, §175.04, §175.06 and §175.105 of this Code, except that such persons shall comply with the provisions of §175.03(l)(1).

(iii) This general license does not authorize the manufacture, assembly, disassembly or repair of strontium-90 sources in ice detection devices.

(9) *Certain items and self-luminous products containing radium-226.*

(i) A general license is hereby issued to any person to acquire, receive, possess, use, or transfer, in accordance with the provisions of subparagraphs (i), (ii), and (iii) of this paragraph, radium-226 contained in the following products manufactured prior to November 30, 2007.

(A) Antiquities originally intended for use by the general public. For the purposes of this clause, "antiquities" means products originally intended for use by the general public and distributed in the late 19th and early 20th centuries, such as radium emanator jars, revigators, radium water jars, radon generators, refrigerator cards, radium bath salts, and healing pads.

(B) Intact timepieces containing greater than 0.037 megabecquerel (1 microcurie), nonintact timepieces, and timepiece hands and dials no longer installed in timepieces.

(C) Luminous items installed in air, marine, or land vehicles.

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

(E) mall radium sources containing no more than 0.037 megabecquerel (1 microcurie) of radium-226. For the purposes of this clause, "small radium sources" means discrete survey instrument check sources, sources contained in radiation measuring instruments, sources used in educational demonstrations (such as cloud chambers and spinthariscopes), electron tubes, lightning rods, ionization sources, static eliminators, or other items as designated by the U.S. Nuclear Regulatory Commission.

(ii) Persons who acquire, receive, possess, use, or transfer byproduct material under the general license issued in subparagraph (i) of this paragraph are exempt from the applicable provisions of this Code, to the extent that the receipt, possession, use, or transfer of byproduct material is within the terms of the general license; provided, however, that this exemption does not apply to any such person specifically licensed under this Code.

(iii) Any person who acquires, receives, possesses, uses, or transfers byproduct material in accordance with the general license in subparagraph (i) of this paragraph:

(A) hall notify the Department and the U.S. Nuclear Regulatory Commission if there is any indication of possible damage to the product that appears as if it could result in a loss of the radioactive material. A report containing a brief description of the event and the remedial action taken, must be furnished to the Department and to the Director of the Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001 within 30 days.

(B) hall not abandon or dispose of products containing radium-226. The product, and any radioactive material from the product, may only be disposed of according to 10 CFR § 20.2008 or by transfer to a person authorized by a specific license to receive the radium-226 in the product or as otherwise approved by the Department.

(C) Shall not export products containing radium-226 except in accordance with 10 CFR Part 110.

(D) hall dispose of products containing radium-226 at a disposal facility authorized to dispose of radioactive material in accordance with any federal, state or City solid or hazardous waste law, including the federal Solid Waste Disposal Act, by transfer to a person authorized to receive radium-226 by a specific license issued under §175.101 of this Code, or equivalent regulations of

U.S. Nuclear Regulatory Commission or of an agreement state, or as otherwise approved by the U.S. Nuclear Regulatory Commission.

(E) hall respond to written requests from the Department or the U.S. Nuclear Regulatory Commission to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by providing the Department or the U.S. Nuclear Regulatory Commission a written justification for the request.

(iv) The general license in subparagraph (i) of this paragraph does not authorize the manufacture, assembly, disassembly, repair, or import of products containing radium-226, except that timepieces may be disassembled and repaired.

§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.*

(i) 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.

(ii) 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—

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

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

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

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

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

(iv) 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, or other Federal, and State requirements governing radioactive drugs or devices.

(4) *Implementation.*

(i) 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, shall comply with the requirements of 10 CFR Part 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, shall comply with the requirements of 10 CFR Part 35, including provisions that are specific to licensees, on August 8, 2009, or earlier as noticed by the NRC.

(ii) Reserved.

(iii) Reserved.

(iv) If a license condition exempted a licensee from a provision of 10 CFR Part 35 on October 24, 2002, then the license condition continues to exempt the licensee from the requirements in the corresponding provision of 10 CFR §§35.1—35.4002.

(v) 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) of this Code until there is a license amendment or renewal that modifies the license condition.

(vi) When a requirement in this Code differs from the requirement in an existing license condition, the more restrictive (i.e., more protective of health and safety) requirement shall govern.

(5) *License required.*

(i) 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 subparagraph (ii) of this subdivision.

(ii) An individual may—

(A) eceive, 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) of this Code, unless prohibited by license condition; or

(B) repare 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) of this Code, unless prohibited by license condition.

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

(i) An application for a license for medical use of byproduct material shall be submitted and signed by the applicant or a licensee's management. 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.

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

(A) 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

(B) ubmitting procedures required by §§175.103(h)(5), (h)(12), (h)(13) and (h)(14) of this Code as applicable.

(iii) A request for a license renewal shall be made by—

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

(B) ubmitting procedures required by §§175.103(h)(5), (h)(12), (h)(13) and (h)(14) of this Code, as applicable.

(iv) A request for a license amendment shall be made by—

(A) ubmitting an original and one copy of either—

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

(b) A letter requesting the amendment; and

(B) ubmitting procedures required by §§175.103(h)(5), (h)(12), (h)(13) and (h)(14) of this Code, as applicable.

(v) In addition to the requirements in subparagraphs (ii) through (iv) of this paragraph, an application for a license or amendment for medical use of byproduct material as described in §175.103(i)(1) of this Code shall 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 Part 35.

(A) The applicant shall also provide specific information on—

(a) Radiation safety precautions and instructions;

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

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

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

(vi) An applicant that satisfies the requirements specified in §33.13 of Title 10 of the CFR may apply for a specific license of broad scope.

(7) *License amendments.* A licensee shall apply for and shall receive a license amendment—

(i) 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—

(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 Part 35 until the date of the NRC's final licensing determination, provided that the licensee has submitted an amendment application on or before June 2, 2008.

(B) Except as provided in clause (A) of this subparagraph, 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 Part 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.

(ii) 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—

(A) For an authorized user, an individual who meets the requirements in §§175.103(j)(4)(i), 175.103(j)(5)(i), 175.103(j)(6)(i), 175.103(j)(7)(i), 175.103(j)(8)(i), 175.103(j)(10)(i), 175.103(j)(12)(i), and 175.103(j)(13)(i) of this Code;

(B) For an authorized nuclear pharmacist, an individual who meets the requirements in §§175.103(j)(3) and 175.103(j)(15) of this Code;

(C) For an authorized medical physicist, an individual who meets the requirements in §§175.103(j)(2) and 175.103(j)(15) of this Code;

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

(a) 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;

(b) 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;

(c) 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

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

(E) 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.

(iii) Before it changes Radiation Safety Officers, except as provided in §175.103(b)(2)(iii) of this Code;

(iv) 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;

(v) 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) of this Code 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) of this Code are exempt;

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

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

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

(8) *Notifications.*

(i) 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)(ii) of this Code. For individuals permitted to work under §175.103(a)(7)(ii)(D) of this Code, within the same 30-day time frame, the licensee shall also provide, as appropriate, verification of completion of;

(A) Any additional case experience required in §175.103(j)(6)(ii)(A) for an authorized user under §175.103(e)(1) of this Code;

(B) Any additional training required in §175.103(j)(13)(iii) for an authorized user under §175.103(h)(1) of this Code; and

(C) Any additional training required in §175.103(j)(2)(iii) of this Code for an authorized medical physicist.

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

(A) 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) of this Code.

(B) 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) of this Code, 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) of this Code.

(C) The licensee's mailing address changes;

(D) The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in 10 CFR §30.34(b); or

(E) 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) of this Code 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.

(iii) The licensee shall send the documents required in this section to the Department at the address identified in §175.01 of this Code.

(9) *Exemptions regarding specific licenses of broad scope.* A licensee possessing a specific license of broad scope for medical use, issued under 10 CFR Part 33, is exempt from—

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

(ii) The provisions of §175.103(a)(7)(ii) of this Code;

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

(iv) The provisions of §175.103(a)(8)(i) of this Code;

(v) The provisions of §175.103(a)(8)(ii)(A) of this Code for an authorized user, an authorized nuclear pharmacist, or an authorized medical physicist;

(vi) The provisions of §175.103(a)(8)(ii)(E) of this Code.

(vii) The provisions of §175.103(b)(6)(i) of this Code.

(10) *License issuance.*

(i) The Department shall issue a license for the medical use of byproduct material if— (A) The applicant has filed RAD-1, "Application for Radioactive Material License" in accordance with the instructions in §175.103(a)(6) of this Code;

(B) The applicant has paid any applicable fee;

(C) 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

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

(ii) The Department shall issue a license for mobile medical service if the applicant:

(A) eets the requirements in subparagraph (i) of this paragraph; and

(B) 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) of this Code.

(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 to be As Low As Reasonably Achievable (ALARA) in accordance with this subdivision.

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

(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 subparagraph (iv) of this paragraph 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 shall include:

(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) ersonnel 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) *Authority and responsibilities for the radiation protection program.*

(i) 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.

(ii) The radiation safety officer shall:

(A) nvestigate overexposures, medical events, 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.* Each medical institution licensee shall establish a radiation safety committee to oversee the use of radioactive material.

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

(A) Licensees that are authorized for two or more different types of uses of byproduct material under Subparts E, F, and H of 10 CFR Part 35, or two or more types of units under Subpart H of 10 CFR Part 35, shall establish a Radiation Safety Committee to oversee all uses of byproduct material permitted by the license. The Committee shall 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 by §175.103(b)(1)(iv) and (b)(3)(ii) of this Code.

(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) e 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) eview 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) of this Code;

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

(H) eview 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) of this Code. 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) of this Code until the license has been renewed or terminated. The record shall 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) dentify radiation safety problems;

(B) nitiate, 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

(5) *Supervision.* (i) 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)(ii)(A) of this Code, shall--

(A) 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

(B) equire 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.

(ii) 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)(ii)(B) of this Code, shall—

(A) 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

(B) equire 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) Personnel, duly licensed by the New York State Department of Health to practice nuclear medicine technology, other than physicians or registered professional nurses, at 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) ave 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) ossess certification as a nuclear medicine technologist by the American Registry of Radiologic Technologists or certification by the Nuclear Medicine Technology Board; and

(C) 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) of this Code 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 when parenteral administration of radioactive material for diagnostic testing is performed by a qualified nuclear medicine technologist.

(iv) A licensee that permits supervised activities under subparagraphs (i) and (ii) of this paragraph is responsible for the acts and omissions of the supervised individual.

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

(A) 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 shall be documented as soon as possible in writing in the patient's record. A written directive shall be prepared within 48 hours of the oral directive.

(ii) The written directive shall contain the patient or human research subject's name and the following information—

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

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

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

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

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

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

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

(b) 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).

(iii) 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.

(A) 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 shall be documented as soon as possible in the patient's record. A revised written directive shall be signed by the authorized user within 48 hours of the oral revision.

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

(7) *Procedures for administrations requiring a written directive.*

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

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

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

(ii) At a minimum, the procedures required by subparagraph (i) of this paragraph shall address the following items that are applicable to the licensee's use of byproduct material—

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

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

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

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

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

(8) *Suppliers.* For medical use, a licensee may only use—

(i) 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;

(ii) Sealed sources or devices non-commercially transferred from a 10 CFR Part 35 licensee or an Agreement State medical use licensee;

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

(iv) 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

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

(B) est 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 (10mCi) for radium-226 and 1.85 MBq (50mCi) for any other photon-emitting radionuclide, and at least one of which has a principal photon energy between 100 keV and 500 keV;

(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 (10mCi) and the highest dosage that will be administered; and

(D) est 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) of this Code, a licensee that shall 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) of this

Code 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) of this Code.

(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 (10mCi) 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) of this Code following adjustment or repair of the dose calibrator.

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

(A) for §175.103(c)(1)(ii)(A) of this Code, 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) of this Code, 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) of this Code, 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) of this Code, 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.

(2) *Possession, use, and calibration of instruments used to measure the activity of unsealed byproduct material.*

(i) For direct measurements performed in accordance with §175.103(c)(4) of this Code, 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.

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

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

(3) *Calibration of survey instruments.*

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

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

(A) alibrate 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) alibrate 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) of this Code, 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) of this Code, 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) of this Code.

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

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

(ii) This determination shall be made by direct measurement of radioactivity.

(iii) 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.

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

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

(i) 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.

(ii) 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.

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

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

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

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

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

(ii) A licensee in possession of a sealed source shall—

(A) 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

(B) 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.

(iii) 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 mCi) of radioactive material in the sample.

(iv) A licensee shall retain leak test records in accordance with §175.03(k)(17)(i) of this Code.

(v) If the leak test reveals the presence of 185 Bq (0.005 mCi) or more of removable contamination, the licensee shall—

(A) 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

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

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

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

(B) ources containing only byproduct material as a gas;

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

(D) eeds of iridium-192 encased in nylon ribbon; and

(E) ources 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.

(vii) 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)(ii) of this Code.

(viii) 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.

(ix) licensee shall retain a record of each survey required in §175.103(c)(5)(iii) of this Code for 3 years. The record shall 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 shall be labeled to identify the radioactive drug. Each syringe shield and vial shield shall also be labeled unless the label on the syringe or vial is visible when shielded.

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

(i) 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 all areas where unsealed byproduct material requiring a written directive was prepared for use or administered.

(ii) 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) of this Code.

(iii) 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.

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

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

(vi) 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.

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

(viii) 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.

(ix) 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 shall 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 Sv (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.

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

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

(i) 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).*

(ii) 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 shall also include-

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

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

(iii) A licensee shall maintain a record of the basis for authorizing the release of an individual in accordance with §175.03(k)(19)(i) of this Code.

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

(v) *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 shall 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.

(11) *Decay-in-storage.*

(i) 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—

(A) onitors 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

(B) emoves 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.

(ii) A licensee shall retain a record of each disposal permitted under subparagraph (i) of this paragraph in accordance with §175.03(k)(21) of this Code.

(12) *Provision of mobile medical service.*

(i) A licensee providing mobile medical service shall—

(A) 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;

(B) heck 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 clause shall include a constancy check;

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

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

(ii) 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 shall be received and handled in conformance with the client's license.

(iii) A licensee providing mobile medical services shall retain the letter required in clause (A) of subparagraph (i) of this paragraph and the record of each survey required in clause (D) of subparagraph (i) of this paragraph in accordance with §175.03(k)(20)(i) and (ii) of this Code, 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)(6) of this Code, a licensee may use any unsealed byproduct material prepared for medical use for uptake, dilution, or excretion studies that is—

(i) Obtained from:

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

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

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

(A) An authorized nuclear pharmacist;

(B) A physician who is an authorized user and who meets the requirements specified in §§175.103(j)(5), or 175.103(j)(6) of this Code; or

(C) An individual under the supervision, as specified in §175.103(b)(3) of this Code, of the authorized nuclear pharmacist in clause (A) of this subparagraph or the physician who is an authorized user in clause (B) of this subparagraph; or

(iii) 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

(iv) 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)(6) of this Code, a licensee may use any unsealed byproduct material prepared for medical use for imaging and localization studies that is—

(i) Obtained from:

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

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

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

(A) An authorized nuclear pharmacist;

(B) A physician who is an authorized user and who meets the requirements specified in §175.103(j)(5), or 175.103(j)(6) of this Code; or

(C) An individual under the supervision, as specified in §175.103(b)(3) of this Code, of the authorized nuclear pharmacist in clause (A) of this subparagraph or the physician who is an authorized user in clause (B) of this subparagraph;

(iii) 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

(iv) 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.

(v) A licensee may use generators upon approval of the Department.

(vi) Provided the conditions of §175.103(e)(3) of this Code are met, a licensee may 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.*

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

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

(B) ore 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).

(ii) 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 subparagraph (i) of this paragraph.

(iii) 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 subparagraph (i) of this paragraph.

(iv) 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) of this Code.

(v) A licensee shall report immediately to the Office of Radiological Health each occurrence of molybdenum-99 concentration exceeding the limits specified in §175.103(e)(3)(i)(A) of this Code.

(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) of this Code 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) of this Code 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) of this Code.

(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:

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

(b) 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:

(a) An authorized nuclear pharmacist;

(b) A physician who is an authorized user and who meets the requirements specified in §§175.103(j)(5), 175.103(j)(6) of this Code, or

(c) An individual under the supervision, as specified in §175.103(b)(3) of this Code, of the authorized nuclear pharmacist in item (a) of this clause, or the physician who is an authorized user as indicated in item (b) of this clause; 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) repared 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,

(i) 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) of this Code. To satisfy this requirement, the instruction shall be commensurate with the duties of the personnel and include—

(A) atient or human research subject control;

(B) Visitor control, including—

(a) Routine visitation to hospitalized individuals in accordance with 10 CFR §20.1301(a)(1); and

(b) Visitation authorized in accordance with 10 CFR §20.1301(c);

(C) Contamination control;

(D) aste control; and

(E) 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.

(ii) A licensee shall retain a record of individuals receiving instruction in accordance with §175.03(k)(23) of this Code.

(3) *Safety precautions.*

(i) For each patient or human research subject who cannot be released under §175.103(c)(9) of this Code, a licensee shall—

(A) Quarter the patient or the human research subject either in—

(a) A private room with a private sanitary facility; or

(b) 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) of this Code;

(B) Visibly post the patient's or the human research subject's room with a "Radioactive Materials" sign.

(C) 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

(D) 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

(E) romptly 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.

(F) urvey 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 shall not be reassigned until removable contamination is less than 5 Bq (300 disintegrations per minute) per 100 square centimeters.

(G) 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) of this Code 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.

(ii) 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) *Manual Brachytherapy.*

(1) *Use of sources for manual brachytherapy.* A licensee shall use only brachytherapy sources for therapeutic medical uses:

(i) As approved in the Sealed Source and Device Registry; or

(ii) In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of §175.103(b)(6)(i) of this Code are met.

(2) *Surveys after source implant and removal.*

(i) 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.

(ii) 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.

(iii) A licensee shall retain a record of the surveys required by subparagraphs (i) and (ii) of this paragraph in accordance with §175.03(k)(24) of this Code.

(3) *Brachytherapy sources accountability.* (i) A licensee shall maintain accountability at all times for all brachytherapy sources in storage or use.

(ii) 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.

(iii) A licensee shall maintain a record of the brachytherapy source accountability in accordance with §175.03(k)(25) of this Code.

(4) *Safety instruction.* In addition to the requirements of 10 CFR §19.12, a licensee shall:

(i) 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) of this Code. To satisfy this requirement, the instruction shall be commensurate with the duties of the personnel and include the—

(A) ize and appearance of the brachytherapy sources;

(B) afe handling and shielding instructions;

(C) Procedures for patient or human research subject control;

(D) rocedures for visitor control, including both:

(a) Routine visitation of hospitalized individuals in accordance with 10 CFR §20.1301(a)(1); and

(b) Visitation authorized in accordance with 10 CFR §20.1301(c); and

(E) rocedures 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.

(ii) A licensee shall retain a record of individuals receiving instruction in accordance with §175.03(k)(23) of this Code.

(5) *Safety precautions.*

(i) For each patient or human research subject who is receiving brachytherapy and cannot be released under §175.103(c)(9) of this Code, a licensee shall—

(A) Not quarter the patient or the human research subject in the same room as an individual who is not receiving brachytherapy;

(B) Visibly post the patient's or human research subject's room with a "Radioactive Materials" sign; and

(C) 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.

(D) romptly 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

(E) rovide 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.

(ii) A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source—

(A) Dislodged from the patient; and

(B) Lodged within the patient following removal of the source applicators.

(iii) 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.*

(i) Before the first medical use of a brachytherapy source on or after October 24, 2002, a licensee shall have—

(A) Determined the source output or activity using a dosimetry system that meets the requirements of §175.103(h)(8)(i) of this Code;

(B) Determined source positioning accuracy within applicators; and

(C) Used published protocols currently accepted by nationally recognized bodies to meet the requirements of clauses (A) and (B) of this subparagraph.

(ii) Instead of a licensee making its own measurements as required in subparagraph (i) of this paragraph, 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 subparagraph (i) of this paragraph.

(iii) A licensee shall mathematically correct the outputs or activities determined in subparagraph (i) of this paragraph for physical decay at intervals consistent with 1 percent physical decay.

(iv) A licensee shall retain a record of each calibration in accordance with §175.03(k)(26) of this Code.

(8) *Decay of strontium-90 sources for ophthalmic treatments.*

(i) 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 shall be based on the activity determined under §175.103(f)(7) of this Code..

(ii) A licensee shall retain a record of the activity of each strontium-90 source in accordance with §175.03(k)(27) of this Code.

(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 shall include, as applicable, verification of:

(i) The source-specific input parameters required by the dose calculation algorithm;

(ii) The accuracy of dose, dwell time, and treatment time calculations at representative points;

(iii) The accuracy of isodose plots and graphic displays; and

(iv) 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) of this Code..

(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:

(i) As approved in the Sealed Source and Device Registry; or

(ii) In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA, provided the requirements of §175.103(b)(6)(i) of this Code. are met.

(2) *Surveys of patients and human research subjects treated with a remote afterloader unit.*

(i) 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.

(ii) A licensee shall retain a record of these surveys in accordance with §175.03(k)(24) of this Code.

(3) *Installation, maintenance, adjustment, and repair.*

(i) 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).

(ii) 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.

(iii) 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.

(iv) 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) of this Code.

(4) *Amendments.* In addition to the requirements specified in §175.103(a)(5) of this Code, 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.*

(i) A licensee shall—

(A) ecure the unit, the console, the console keys, and the treatment room when not in use or unattended;

(B) ermit 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);

(C) Prevent dual operation of more than one radiation producing device in a treatment room if applicable; and

(D) 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 shall include—

(a) Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;

(b) The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

(c) 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.

(ii) A copy of the procedures required by clause (D) of subparagraph (i) of this paragraph shall be physically located at the unit console.

(iii) A licensee shall post instructions at the unit console to inform the operator of—

(A) The location of the procedures required by clause (D) of subparagraph (i) of this paragraph; and

(B) 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.

(iv) 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—

(A) The procedures identified in subparagraph (i) of this paragraph; and

(B) The operating procedures for the unit.

(v) A licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

(vi) A licensee shall retain a record of individuals receiving instruction required by subparagraph (iv) of this paragraph, in accordance with §175.03(k)(23) of this Code.

(vii) A licensee shall retain a copy of the procedures required by §§175.103(h)(5)(i)(D) and 175.103(h)(5)(iv)(B) in accordance with §175.03(k)(29) of this Code.

(6) *Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.*

(i) A licensee shall control access to the treatment room by a door at each entrance.

(ii) A licensee shall equip each entrance to the treatment room with an electrical interlock system that will—

(A) revent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;

(B) ause the source(s) to be shielded when an entrance door is opened; and

(C) 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.

(iii) A licensee shall equip each entrance to the teletherapy room with a beam condition indicator light.

(iv) A licensee shall have in each teletherapy room a permanent radiation monitor capable of continuously monitoring beam status.

(A) 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 shall be observable by an individual entering the teletherapy room.

(B) 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.

(C) 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.

(D) radiation monitor shall be checked with a dedicated check source for proper operation each day before the teletherapy unit is used for treatment of patients.

(E) licensee shall maintain a record of the check required by §175.103(i)(7)(iv) of this Code 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.

(F) 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) of this Code.

(G) licensee shall promptly repair or replace the radiation monitor if it is inoperable.

(v) 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.

(vi) 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.

(vii) In addition to the requirements specified in subparagraphs (i) through (vi) of this paragraph, a licensee shall—

(A) For medium dose-rate and pulsed dose-rate remote afterloader units, require—

(a) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit to be physically present during the initiation of all patient treatments involving the unit; and

(b) An authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who has been trained to remove the source applicator(s) in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit.

(B) For high dose-rate remote afterloader units, require—

(a) An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and

(b) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, to be physically present during continuation of all patient treatments involving the unit.

(C) 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.

(D) 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.

(viii) A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source—

(A) emaining in the unshielded position; or

(B) 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) of this Code.

(8) *Dosimetry equipment.*

(i) 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 shall be met.

(A) The system shall 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 shall have been performed within the previous 2 years and after any servicing that may have affected system calibration; or

(B) The system shall have been calibrated within the previous 4 years. Eighteen to thirty months after that calibration, the system shall 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 shall 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.

(ii) 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 subparagraph (i) of this paragraph. This comparison shall have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in subparagraph (i) of this paragraph.

(iii) The licensee shall retain a record of each calibration, intercomparison, and comparison in accordance with §175.03(k)(30) of this Code.

(9) *Full calibration measurements on teletherapy units.*

(i) A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit—

(A) Before the first medical use of the unit; and

(B) Before medical use under the following conditions:

(a) 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;

(b) Following replacement of the source or following reinstallation of the teletherapy unit in a new location;

(c) 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

(C) At intervals not exceeding 1 year.

(ii) To satisfy the requirement of subparagraph (i) of this paragraph, full calibration measurements shall include determination of—

(A) The output within /- 3 percent for the range of field sizes and for the distance or range of distances used for medical use;

(B) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(C) The uniformity of the radiation field and its dependence on the orientation of the useful beam;

(D) Timer accuracy and linearity over the range of use;

(E) On-off error; and

(F) The accuracy of all distance measuring and localization devices in medical use.

(iii) A licensee shall use the dosimetry system described in §175.103(h)(8)(i) of this Code to measure the output for one set of exposure conditions. The remaining radiation measurements required in subparagraph (ii) of this paragraph may be made using a dosimetry system that indicates relative dose rates.

(iv) A licensee shall make full calibration measurements required by subparagraph (i) of this paragraph in accordance with published protocols accepted by nationally recognized bodies.

(v) A licensee shall mathematically correct the outputs determined in clause (A) of subparagraph (ii) of this paragraph 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.

(vi) Full calibration measurements required by subparagraph (i) of this paragraph and physical decay corrections required by subparagraph (v) of this paragraph shall be performed by the authorized medical physicist named on the license.

(vii) A licensee shall retain a record of each calibration in accordance with §175.03(k)(31) of this Code.

(10) *Full calibration measurements on remote afterloader units.*

(i) A licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit—

(A) Before the first medical use of the unit;

(B) Before medical use under the following conditions:

(a) Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and

(b) 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

(C) 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

(D) At intervals not exceeding 1 year for low dose-rate remote afterloader units.

(ii) To satisfy the requirement of subparagraph (i) of this paragraph, full calibration measurements shall include, as applicable, determination of:

(A) The output within ±5 percent;

(B) ource positioning accuracy to within ±1 millimeter;

(C) Source retraction with backup battery upon power failure;

(D) Length of the source transfer tubes;

(E) Timer accuracy and linearity over the typical range of use;

(F) Length of the applicators; and

(G) Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

(iii) A licensee shall use the dosimetry system described in §175.103(h)(8)(i) of this Code to measure the output.

(iv) A licensee shall make full calibration measurements required by subparagraph (i) of this paragraph in accordance with published protocols accepted by nationally recognized bodies.

(v) In addition to the requirements for full calibrations for low dose-rate remote afterloader units in subparagraph,(ii) of this paragraph, a licensee shall perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding 1 quarter.

(vi) For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with subparagraphs (i) through (v) of this paragraph.

(vii) A licensee shall mathematically correct the outputs determined in clause (A) of subparagraph (ii) of this paragraph for physical decay at intervals consistent with 1 percent physical decay.

(viii) Full calibration measurements required by subparagraph (i) of this paragraph and physical decay corrections required by subparagraph (vii) of this paragraph shall be performed by the authorized medical physicist.

(ix) licensee shall retain a record of each calibration in accordance with §175.03(k)(31) of this Code.

(11) *Full calibration measurements on gamma stereotactic radiosurgery units.*

(i) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each unit—

(A) Before the first medical use of the unit;

(B) Before medical use under the following conditions—

(a) 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;

(b) Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and

(c) 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

(C) 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.

(ii) To satisfy the requirement of subparagraph (i) of this paragraph, full calibration measurements shall include determination of—

(A) The output within ±3 percent;

(B) elative helmet factors;

(C) Isocenter coincidence;

(D) Timer accuracy and linearity over the range of use;

(E) On-off error;

(F) Trunnion centricity;

(G) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

(H) Helmet microswitches;

(I) Emergency timing circuits; and

(J) tereotactic frames and localizing devices (trunnions).

(iii) A licensee shall use the dosimetry system described in §175.103(h)(8)(i) of this Code to measure the output for one set of exposure conditions. The remaining radiation measurements required in clause (A) of subparagraph (ii) of this paragraph may be made using a dosimetry system that indicates relative dose rates.

(iv) A licensee shall make full calibration measurements required by subparagraph (i) of this paragraph in accordance with published protocols accepted by nationally recognized bodies.

(v) A licensee shall mathematically correct the outputs determined in clause (A) of subparagraph (ii) of this paragraph at intervals not exceeding 1 month for cobalt-60 and at intervals consistent with 1 percent physical decay for all other radionuclides.

(vi) Full calibration measurements required by subparagraph (i) of this paragraph and physical decay corrections required by subparagraph (v) of this paragraph shall be performed by the authorized medical physicist.

(vii) A licensee shall retain a record of each calibration in accordance with §175.03(k)(31) of this Code.

(12) *Periodic spot-checks for teletherapy units.*

(i) 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—

(A) Timer accuracy, and timer linearity over the range of use;

(B) On-off error;

(C) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(D) The accuracy of all distance measuring and localization devices used for medical use;

(E) The output for one typical set of operating conditions measured with the dosimetry system described in §175.103(h)(8)(ii) of this Code; and

(F) The difference between the measurement made in clause (E) of this subparagraph 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).

(ii) A licensee shall use the dosimetry system described in §175.103(i)(9) to measurements required in §175.103(i)(11)(ii)(E) of this Code.

(iii) A licensee shall perform measurements required by subparagraph (i) of this paragraph in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot-check measurements.

(iv) 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.

(v) 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—

(A) Electrical interlocks at each teletherapy room entrance;

(B) 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);

(C) Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;

(D) Viewing and intercom systems;

(E) Treatment room doors from inside and outside the treatment room; and

(F) Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

(vi) If the results of the checks required in subparagraph (iv) of this paragraph 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.

(vii) A licensee shall retain a record of each spot-check required by subparagraphs (i) and (iv) of this paragraph, and a copy of the procedures required by subparagraph (ii), in accordance with §175.03(k)(32) of this Code.

(13) *Periodic spot-checks for remote afterloader units.*

(i) 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—

(A) Before the first use of a high dose-rate, medium dose-rate, or pulsed dose-rate remote afterloader unit on a given day;

(B) Before each patient treatment with a low dose-rate remote afterloader unit; and

(C) After each source installation.

(ii) A licensee shall perform the measurements required by subparagraph (i) of this paragraph in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

(iii) 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.

(iv) To satisfy the requirements of subparagraph (i) of this paragraph, spot-checks shall, at a minimum, assure proper operation of—

(A) Electrical interlocks at each remote afterloader unit room entrance;

(B) ource exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(C) Viewing and intercom systems in each high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader facility;

(D) Emergency response equipment;

(E) adiation monitors used to indicate the source position;

(F) Timer accuracy;

(G) lock (date and time) in the unit's computer; and

(H) Decayed source(s) activity in the unit's computer.

(v) If the results of the checks required in subparagraph (iv) of this paragraph 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.

(vi) A licensee shall retain a record of each check required by subparagraph (iv) of this paragraph and a copy of the procedures required by subparagraph (ii) of this paragraph in accordance with §175.03(k)(33) of this Code.

(14) *Periodic spot-checks for gamma stereotactic radiosurgery units.*

(i) 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—

(A) onthly;

(B) Before the first use of the unit on a given day; and

(C) After each source installation.

(ii) A licensee shall—

(A) erform the measurements required by subparagraph (i) of this paragraph in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

(B) 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.

(iii) To satisfy the requirements of subparagraph (i) of this paragraph, spot-checks shall, at a minimum—

(A) Assure proper operation of—

(a) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

(b) Helmet microswitches;
(c) Emergency timing circuits; and
(d) Stereotactic frames and localizing devices (trunnions).
(B) Determine—
(a) The output for one typical set of operating conditions measured with the dosimetry system described in §175.103(h)(8)(ii) of this Code;
(b) The difference between the measurement made in item (a) of this clause (B) 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);
(c) Source output against computer calculation;
(d) Timer accuracy and linearity over the range of use;
(e) On-off error; and
(f) Trunnion centricity.
(iv) To satisfy the requirements of clauses (B) and (C) of subparagraph (i) of this paragraph, spot-checks shall assure proper operation of—
(A) Electrical interlocks at each gamma stereotactic radiosurgery room entrance;
(B) ource exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;
(C) Viewing and intercom systems;
(D) Timer termination;
(E) adiation monitors used to indicate room exposures; and
(F) Emergency off buttons.
(v) A licensee shall arrange for the repair of any system identified in subparagraph (iii) of this paragraph that is not operating properly as soon as possible.
(vi) If the results of the checks required in subparagraph (iv) of this paragraph 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.
(vii) A licensee shall retain a record of each check required by subparagraphs (iii) and (iv) and a copy of the procedures required by subparagraph (ii) of this paragraph in accordance with §175.03(k)(34) of this Code.
(15) *Additional technical requirements for mobile remote afterloader units.*
(i) A licensee providing mobile remote afterloader service shall—
(A) heck survey instruments before medical use at each address of use or on each day of use, whichever is more frequent; and
(B) Account for all sources before departure from a client's address of use.
(ii) In addition to the periodic spot-checks required by §175.103(h)(13) of this Code, 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 shall be made to verify the operation of—
(A) Electrical interlocks on treatment area access points;
(B) ource exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;
(C) Viewing and intercom systems;
(D) Applicators, source transfer tubes, and transfer tube-applicator interfaces;
(E) adiation monitors used to indicate room exposures;
(F) ource positioning (accuracy); and

(G) adiation monitors used to indicate whether the source has returned to a safe shielded position.

(iii) In addition to the requirements for checks in subparagraph (ii) of this paragraph, 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.

(iv) If the results of the checks required in subparagraph (ii) of this paragraph 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.

(v) A licensee shall retain a record of each check required by subparagraph (ii) of this paragraph in accordance with §175.03(k)(35) of this Code.

(16) *Radiation surveys*.

(i) In addition to the survey requirement in §175.03 of this Code, a person licensed under this section shall make surveys to ensure that:

(A) he 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 of this Code; and

(b) radiation levels in unrestricted areas do not exceed the limits specified in §175.03 of this Code.

(ii) If the results of the surveys required in §175.103(h)(16)(i) of this Code indicate any radiation levels in excess of the respective limit specified in §175.103(h)(16)(i)(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) ntil the licensee has received a specific exemption from the Department.

(iii) The licensee shall make the survey required by subparagraph (i) of this paragraph 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).

(iv) A licensee shall retain a record of the radiation surveys required by subparagraph (i) of this paragraph in accordance with §175.03(k)(36) of this Code.

(17) *Reports of teletherapy and gamma stereotactic radiosurgery surveys, checks, tests, and measurements.* A licensee shall furnish a copy of the records required in §175.103(h)(9) and (11) of this Code 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(h)(16) of this Code to the 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.* If the survey required by §175.103(h)(16) of this Code indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by §175.03 of this Code, before beginning the treatment program, the licensee shall:

(i) either equip the unit with stops or add additional radiation shielding to ensure compliance with §175.03 of this Code;

(ii) perform the survey required by §175.103(h)(16) of this Code again; and

(iii) include in the report required by §175.103(h)(17) of this Code the results of the initial survey, a description of the modification made to comply with §175.103(h)(16)(i) of this Code and the results of the second survey; or

(iv) request and receive a license amendment that authorizes radiation levels in unrestricted areas greater than those permitted by §175.03 of this Code.

(19) *Five-year inspection for teletherapy and gamma stereotactic radiosurgery units.*

(i) 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.

(ii) This inspection and servicing may only be performed by persons specifically licensed to do so by the Commission or an Agreement State.

(iii) A licensee shall keep a record of the inspection and servicing in accordance with §175.03(k)(37) of this Code.

(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 shall include, as applicable, verification of:

(i) The source-specific input parameters required by the dose calculation algorithm;

(ii) The accuracy of dose, dwell time, and treatment time calculations at representative points;

(iii) The accuracy of isodose plots and graphic displays;

(iv) The accuracy of the software used to determine sealed source positions from radiographic images; and

(v) 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.* 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) of this Code if—

(1) The applicant or licensee has submitted the information required by §175.103(a)(6)(ii) through (iv) of this Code; and

(2) 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.

(j) *Training and experience requirements.*

(1) *Radiation safety officer.* Except as provided in §175.103(j)(14) of this Code, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in §175.103(b)(2) of this Code 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 subparagraphs (iii) and

(iv) of this paragraph. (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) of this Code;

(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

(D) Has completed a structured educational program consisting of both:

(a) 200 hours of classroom and laboratory training in the following areas—

(I) adiation physics and instrumentation;

(II) adiation protection;

(III) Mathematics pertaining to the use and measurement of radioactivity;

(IV) Radiation biology; and

(V) adiation dosimetry; and

(b) 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) hipping, 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

(VII) Disposing of byproduct material; or

(E) eserved.

(ii)(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)(i) 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 subparagraphs (iii) and (iv) of this paragraph; 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,

(iii) Has obtained written attestation, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in subparagraph (iv) of this paragraph and in items (a) and (b) of clause (A) of subparagraph (i) of this paragraph or items (a) and (b) of clause (B) of subparagraph (i) of this paragraph or clause (D) of subparagraph (ii) of this paragraph or clauses (A) or (B) of subparagraph (ii) of this paragraph, and has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee; and

(iv) 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) of this Code, 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 clause (B) of subparagraph (ii) and subparagraph (iii) of this paragraph. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC website.) 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) of this Code; 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

(D) Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and has completed 1 year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type(s) of use for which the individual is seeking authorization. This training and work experience shall be conducted in clinical radiation facilities that provide high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services and shall include:

(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

(e) Has obtained written attestation that the individual has satisfactorily completed the requirements in item (f) of clause (D) of subparagraph (i) and clauses (A) and (B) of subparagraph (i), or clause (D) of subparagraph (i) of this paragraph, and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation shall be signed by a preceptor authorized medical physicist who meets the requirements in §§175.103(j)(2), 175.103(j)(14), or equivalent NRC or 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

(f) 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) of this Code, the licensee shall require the authorized nuclear pharmacist to be a pharmacist 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 item (f) of clause (G) of subparagraph (ii) of this paragraph. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC website.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(A) 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;

(B) Hold a current, active license to practice pharmacy;

(C) 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

(D) ass 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

(ii) Has completed 700 hours in a structured educational program consisting of both:

(A) 00 hours of classroom and laboratory training in the following areas—

(B) adiation physics and instrumentation;

(C) Radiation protection;

(D) athematics pertaining to the use and measurement of radioactivity;

(E) hemistry of byproduct material for medical use; and

(F) adiation biology; and

(G) upervised 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

(f) Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in clauses (A) through (C) of subparagraphs (i) or clause (A) of subparagraph (ii) of this paragraph 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) of this Code, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under §175.103(d)(1) of this Code to be a physician who—

(i) 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 clause (B) of subparagraph (iii) of this paragraph. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC website.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(A) omplete 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 clause (A) of subparagraph (iii) of this paragraph; and

(B) ass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

(ii) Is an authorized user under §§175.103(j)(5), 175.103(j)(6) of this Code, or equivalent NRC or Agreement State requirements;

(iii)(A) 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 shall include—

(a) Classroom and laboratory training in the following areas—

(I) adiation physics and instrumentation;

(II) adiation protection;

(III) Mathematics pertaining to the use and measurement of radioactivity;

(IV) Chemistry of byproduct material for medical use; and

(V) adiation biology; and

(b) 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) of this Code, or NRC or equivalent Agreement State requirements, involving—

(I) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(II) erforming 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 of radioactive drugs to patients or human research subjects; and

(B) 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) of this Code, or NRC or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in clause (A) of subparagraph (i) or clause (A) of subparagraph (iii) of this paragraph 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) of this Code.

(5) *Training for imaging and localization studies.* Except as provided in §175.103(j)(14) of this Code, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under §175.103(d)(2) of this Code to be a physician who—

(i) 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 clause (B) of subparagraph (iii) of this paragraph. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC website.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(A) omplete 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 that includes the topics listed in items (a) through (b) of clause (A) of subparagraph (iii) of this paragraph; and

(B) ass an examination, administered by diplomates of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

(ii) Is an authorized user under §175.103(j)(6) and meets the requirements in §175.103(j)(5)(iii)(A)(b)(VII) of this Code, or equivalent NRC or Agreement State requirements; or

(iii)(A) 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 shall include, at a minimum—

(a) Classroom and laboratory training in the following areas—

(I) adiation physics and instrumentation;

(II) adiation protection;

(III) Mathematics pertaining to the use and measurement of radioactivity;

(IV) Chemistry of byproduct material for medical use;

(V) adiation biology; and

(b) Work experience, under the supervision of an authorized user who meets the requirements in §§175.103(j)(14), 175.103(j)(5), or 175.103(j)(5)(iii)(A)(b)(VII) and 175.103(j)(6) of this Code or equivalent NRC or Agreement State requirements, involving—

(I) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(II) erforming 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 safely contain spilled radioactive material and using proper decontamination procedures;

(VI) Administering dosages of radioactive drugs to patients or human research subjects; and

(VII) 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

(B) 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) (iii) (A)(b)(VII) of this Code or equivalent NRC or Agreement State requirements, that the individual has satisfactorily completed the requirements in clause (A) of subparagraph (i) or clause (A) of subparagraph (iii) of this paragraph 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) of this Code.

(6) *Training for use of unsealed byproduct material for which a written directive is required.* Except as provided in §175.103(j)(14) of this Code, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under §175.103(e)(1) of this Code to be a physician who—

(i) 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 number (VII) of item (b) of clause (A) and clause (B) of subparagraph (ii) of this paragraph. (Specialty boards whose certification processes have been recognized by the Commission or an Agreement State will be posted on the NRC website.) To be recognized, a specialty board shall require all candidates for certification to:

(A) uccessfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs shall include 700 hours of training and experience as described in item (a) of clause (A) through number (V) of item (b) of clause (A) of subparagraph (ii) of this paragraph. Eligible training programs shall 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

(B) ass 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

(ii)(A) 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 shall include—

(a) Classroom and laboratory training in the following areas—

(I) adiation physics and instrumentation;

(II) adiation protection;
(III) Mathematics pertaining to the use and measurement of radioactivity;
(IV) Chemistry of byproduct material for medical use; and
(V) adiation biology; and

(b) Work experience, under the supervision of an authorized user who meets the requirements in §§175.103(j)(14), 175.103(j)(6) of this Code, or equivalent NRC or Agreement State requirements. A supervising authorized user, who meets the requirements in §175.103(j)(6)(ii) of this Code, shall also have experience in administering dosages in the same dosage category or categories (i.e., §175.103(j)(6)(ii)(A)(b)(VII) of this Code) as the individual requesting authorized user status. The work experience shall involve—

(I) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(II) erforming 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;

(VI) eserved.

(VII) 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

(B) Has obtained written attestation that the individual has satisfactorily completed the requirements in clause (A) of subparagraph (i) and number (VII) of item (b) of clause (A) of subparagraph (ii) or clause (A) of subparagraph (ii) of this paragraph, 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) of this Code. The written attestation shall be signed by a preceptor authorized user who meets the requirements in §§175.103(j)(14), 175.103(j)(6) of this Code, or equivalent Agreement State requirements. The preceptor authorized user, who meets the requirements in §175.103(j)(6)(ii) of this Code shall have experience in administering dosages in the same dosage category or categories (i.e., §175.103(j)(6)(ii)(a)(VII) of this Code) 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) of this Code, 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—

(i) Is certified by a medical specialty board whose certification process includes all of the requirements in clauses (A) and (B) of subparagraphs (iii) of this paragraph and whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in clause (C) of subparagraph (iii) of this paragraph. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC website.); or

(ii) Is an authorized user under §175.103(j)(6) for uses listed in §175.103(j)(6)(ii)(A) (b)(VIII)(1) or (2), §175.103(j)(8) of this Code, or equivalent NRC or Agreement State requirements; or

(iii)(A) Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training shall include—

(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

(B) 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) of this Code, or equivalent NRC or Agreement State requirements. A supervising authorized user who meets the requirements in §175.103(j)(6)(ii shall also have experience in administering dosages as specified in §§175.103(j)(6) (ii)(A)(b)(VII)(1) or 175.103(j)(6)(ii)(A)(b)(VII)(2) of this Code. The work experience shall 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 byproduct material;

(e) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(f) 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

(C) Has obtained written attestation that the individual has satisfactorily completed the requirements in clauses (A) and (B) of subparagraph (iii) of this paragraph, and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under §175.103(e)(1) of this Code. The written attestation shall 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) of this Code, or equivalent NRC or Agreement State requirements. A preceptor authorized user, who meets the requirement in §175.103(j)(6)(b), shall also have experience in administering dosages as specified in §§175.103(j)(6 ii)(A)(b)(VII)(1) or 175.103(j)(6)(ii)(A)(b)(VII)(2) of this Code.

(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) of this Code, 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—

(i) Is certified by a medical specialty board whose certification process includes all of the requirements in clauses (A) and (B) of subparagraph (iii) of this paragraph , and whose certification has been recognized by the NRC or an Agreement State, and who meets the requirements in clause (C) in subparagraph (iii) of this paragraph. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC website.); or

(ii) Is an authorized user under §175.103(j)(6) for uses listed in §175.103(j)(6)(ii)(A) (b)(VII)(2) of this Code or equivalent NRC or Agreement State requirements; or

(iii)(A) Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training shall include—

(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

(B) 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) of this Code, or equivalent NRC or Agreement State requirements. A supervising authorized user, who meets the requirements in §175.103(j)(6)(ii) of this Code, shall also have experience in administering dosages as specified in §175.103(j)(6)(ii)(A)(b)(VII)(2) of this Code. The work experience shall 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 byproduct material;

(e) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(f) 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

(C) Has obtained written attestation that the individual has satisfactorily completed the requirements in clauses (A) and (B) of subparagraph (iii) of this paragraph, and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under §175.103(e)(1) of this Code. The written attestation shall be signed by a preceptor authorized user who meets the requirements in §§175.103(j)(14), 175.103(j)(6), 175.103(j)(8) of this Code, or equivalent NRC or Agreement State requirements. A preceptor authorized user, who meets the requirements in §175.103(j)(6)(b), shall also have experience in administering dosages as specified in §175.103(j)(6)(ii)(A)(b)(VII)(2) of this Code.

(9) *Training for the parenteral administration of unsealed byproduct material requiring a written directive.* Except as provided in §175.103(j)(14) of this Code, the licensee shall require

an authorized user for the parenteral administration requiring a written directive, to be a physician who—

(i) Is an authorized user under §175.103(j)(6) for uses listed in §§175.103(j)(6) (ii)(A)(b)(VII)(3) or 175.103(j)(6) (ii)(A)(b)(VII)4) of this Code, or equivalent NRC or Agreement State requirements; or

(ii) Is an authorized user under §§175.103(j)(10), 175.103(j)(13) of this Code, or equivalent NRC or Agreement State requirements and who meets the requirements in sub paragraph (iv) of this section; or

(iii) 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) of this Code, and who meets the requirements in subparagraph (iv) of this section.

(iv)(A) Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. The training shall include—

(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

(B) 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) of this Code, or equivalent NRC or 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) of this Code shall have experience in administering dosages as specified in §§175.103(j)(6) (ii)(A)(b)(VII)(3) and/or 175.103(j)(6) (ii)(A)(b)(VII)(4) of this Code. The work experience shall 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; and

(f) 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

(C) Has obtained written attestation that the individual has satisfactorily completed the requirements in subparagraphs (ii) or (iii) of this paragraph, 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 shall be signed by a preceptor authorized user who meets the requirements in §§175.103(j)(14), 175.103(j)(6), 175.103(j)(9) of this Code, or equivalent NRC or Agreement State requirements. A preceptor authorized user, who meets the requirements in §175.103(j)(6) of this Code, shall have experience in administering dosages as specified in §§175.103(j)(6) (ii)(A)(b)(VII)(3) and/or 175.103(j)(6) (ii)(A)(b)(VII)(4) of this Code.

(10) *Training for use of manual brachytherapy sources.* Except as provided in §175.103(j)(14) of this Code, a 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 —

(i) 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 clause (C) of subparagraph (ii) of this paragraph. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC website.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(A) 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

(B) ass 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

(ii)(A) Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes—

(a) 200 hours of classroom and laboratory training in the following areas—

(I) adiation physics and instrumentation;

(II) adiation protection;

(III) Mathematics pertaining to the use and measurement of radioactivity; and

(IV) Radiation biology; and

(b) 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) of this Code, or equivalent NRC or Agreement State requirements at a medical institution, involving—

(I) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(II) ecking survey meters for proper operation;

(III) Preparing, implanting, and removing brachytherapy sources;

(IV) Maintaining running inventories of material on hand;

(V) Using administrative controls to prevent a medical event involving the use of byproduct material;

(VI) Using emergency procedures to control byproduct material; and

(B) 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) of this Code, or equivalent NRC or 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 item (a) of clause (A) of subparagraph (ii) of this paragraph; and

(C) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§175.103(j)(14), 175.103(j)(10) of this Code, or equivalent NRC or Agreement State requirements, that the individual has satisfactorily completed the requirements in clause (A) of subparagraph (i), or clauses (A) and (B) of subparagraph (ii) of this paragraph 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) of this Code.

(11) *Training for ophthalmic use of strontium-90.* Except as provided in §175.103(j)(14) of this Code, the licensee shall require the authorized user of strontium-90 for ophthalmic radiotherapy to be a physician who—

(i) Is an authorized user under §175.103(j)(10) of this Code or equivalent NRC or Agreement State requirements; or

(ii)(A) Has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training shall include—

(a) Radiation physics and instrumentation;

(b) Radiation protection;

(c) Mathematics pertaining to the use and measurement of radioactivity; and

(d) Radiation biology; and

(B) upervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution, clinic, or private practice that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training shall involve—

(a) Examination of each individual to be treated;

(b) Calculation of the dose to be administered;

(c) Administration of the dose; and

(d) Follow up and review of each individual's case history; and

(C) 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) of this Code, or equivalent NRC or Agreement State requirements, that the individual has satisfactorily completed the requirements in subparagraphs (i) and (ii) of this paragraph 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) of this Code, the licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized under §175.103(g)(1) of this Code to be a physician, dentist, or podiatrist who—

(i) Is certified by a specialty board whose certification process includes all of the requirements in subparagraphs (ii) and (iii) of this paragraph 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 website.); or

(ii) Has completed 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training shall include—

(A) adiation physics and instrumentation;

(B) adiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity; and
(D) adiation biology; and
(iii) 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) of this Code, the licensee shall require an authorized user of a sealed source for a use authorized under §175.103(h)(1) of this Code to be a physician who—

(i) 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 clause (C) of subparagraph (ii) and subparagraph (iii) of this paragraph. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC website.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(A) uccessfully 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

(B) ass 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

(ii)(A) 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—

(a) 200 hours of classroom and laboratory training in the following areas—
(I) adiation physics and instrumentation;
(II) adiation protection;
(III) Mathematics pertaining to the use and measurement of radioactivity; and
(IV) Radiation biology; and

(b) 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) of this Code, or equivalent NRC or Agreement State requirements at a medical institution, involving—

(I) eviewing full calibration measurements and periodic spot-checks;
(II) reparing treatment plans and calculating treatment doses and times;
(III) Using administrative controls to prevent a medical event involving the use of byproduct material;
(IV) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;
(V) hecking and using survey meters; and
(VI) lecting the proper dose and how it is to be administered; and

(B) 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) of this Code, or equivalent NRC or 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 bysub paragraph (ii)(A)(b) of this section; and

(C) Has obtained written attestation that the individual has satisfactorily completed the requirements in clause (A) of subparagraph (i) or clauses (A) and (B) of subparagraph (ii) of this paragraph, and subparagraph (iii) of this paragraph, and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation shall be signed by a preceptor authorized user who meets the requirements in §§175.103(j)(14), 175.103(j)(13) of this Code, or equivalent NRC or Agreement State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; and

(iii) 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.*

(i)(A) 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) of this Code, respectively.

(B) 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) of this Code, respectively.

(C) 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) of this Code, 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.

(ii)(A) 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 Part 35.

(B) hysicians, 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 Part 35.

(C) 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 10 CFR Part 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.

(iii) 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 Department 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) of this Code shall have been obtained within the 7 years preceding the date of application or the individual shall have had related continuing education and experience since the required training and experience was completed.

§175.104 Waste disposal.

(a) *General requirements.* (1) A licensee shall dispose of licensed material only:

(i) by transfer to an authorized recipient as provided in §175.101 or §175.104(f) of this Code, or to the U.S. Department of Energy; or

(ii) by decay in storage; or

(iii) by release in effluents within the limits in §175.03(d); or

(iv) as authorized under 10CFR §§20.2002, 20.2003, 20.2004, 20.2005, or 20.2006.

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

(i) treatment prior to disposal; or

(ii) treatment or disposal by incineration; or

(iii) decay in storage; or

(iv) disposal at a land disposal facility licensed pursuant to 10 CFR Part 61 or the equivalent regulations of an agreement state; or

(v) disposal at a geologic repository under 10 CRF Parts 60 or 63.

(3)(i) The licensed material that is described in subparagraphs (iii) and (iv) of the definition of byproduct material set forth in paragraph (34) of §175.02, may be disposed of in accordance with 10 CFR Part 61 or the equivalent regulations of an agreement state, even though it is not defined

as low-level radioactive waste. Therefore, any licensed byproduct material being disposed of at a facility, or transferred for ultimate disposal at a facility licensed under 10 CFR Part 61 must meet the requirements of 10 CFR § 20.2006.

(ii) A licensee may dispose of byproduct material described in subparagraphs (iii) and (iv) of the definition of byproduct material set forth in paragraph (34) of §175.02, at a disposal facility authorized to dispose of such material in accordance with any federal, state or City solid or hazardous waste law, including the federal Solid Waste Disposal Act, as authorized under the federal Energy Policy Act of 2005.

(4) A licensee or applicant for a license shall obtain any permits required by the New York State Department of Environmental Conservation pursuant to 6 NYCRR Part 380, or any successor law or regulation.

(5) A licensee or applicant for a license shall develop, document and implement a discharge minimization program required by the New York State Department of Environmental Conservation pursuant to 6 NYCRR Section 380-7, or any successor law or regulation.

(b) *Method for obtaining approval of proposed disposal procedures.* (1) A licensee or applicant for a license may apply to the Department for approval of proposed disposal procedures, not otherwise authorized in this Code, but which will conform to state and federal regulations, to dispose of licensed material generated in the licensee's operations. Each application shall include:

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

(ii) an analysis and evaluation of pertinent information on the nature of the environment; and

(iii) the nature and location of other potentially affected facilities; and

(iv) analyses and procedures to ensure that doses are maintained ALARA and within the dose limits in §175.03.

(c) *Disposal by release into sanitary sewerage.* (1) A licensee may discharge licensed material into sanitary sewerage if each of the following conditions is satisfied:

(i) the material is readily soluble in water or is biological material that is readily dispersible in water; and

(ii) the quantity of licensed radioactive material that the licensee releases into the sewer in 1 month divided by the average monthly volume of water released into the sewer by the licensee does not exceed the concentration listed in Table 3 of Appendix B of §175.03; and

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

(A) the licensee shall determine the fraction of the limit in Table 3 of Appendix B of §175.03 represented by discharges into sanitary sewerage by dividing the actual monthly average concentration of each radionuclide released by the licensee into the sewer by the concentration of that radionuclide listed in Table 3 of Appendix B of §175.03; and

(B) the sum of the fractions for each radionuclide required by §175.104(c)(1)(iii)(A) does not exceed unity; and

(iv) the total quantity of licensed radioactive material that the licensee releases into the sanitary sewerage in a year does not exceed 37 GBq (1 Ci) of all radioactive materials combined.

(2) Excreta from individuals undergoing medical diagnosis or therapy with radioactive material are not subject to the limitations contained in §175.104(c)(1).

(d) *Treatment or disposal by incineration or burial.* (1) No person shall treat or dispose of licensed radioactive material by incineration except as specifically approved by the Department pursuant to §175.104(b).

(2) No person shall bury any licensed radioactive materials within this City.

(e) *Disposal of specific wastes.* (1) A licensee may ship for disposal outside of this City the following licensed material as if it were not radioactive, provided however, that the receiving jurisdiction regulates such materials as if they were not radioactive:

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

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

(2) A licensee shall not dispose of tissue pursuant to §175.104(e)(1)(ii) in a manner that would permit its use either as food for humans or as animal feed.

(3) The licensee shall maintain records in accordance with §175.03(k)(l0).

(f) *Transfer for disposal and manifests.* (1) The requirements of §175.104(f) and Appendix A of §175.104 are designed to control transfers of low-level radioactive waste intended for disposal at a licensed low-level radioactive waste disposal facility, establish a manifest tracking system, and supplement existing requirements concerning transfers and recordkeeping for those wastes.

(2) Each shipment of radioactive waste designated for disposal at a licensed low-level radioactive waste disposal facility shall be accompanied by a shipment manifest as specified in Section I of Appendix A of §175.104.

(3) Each shipment manifest shall include a certification by the waste generator as specified in Section II of Appendix A of §175.104.

(4) Each person involved in the transfer of waste for disposal or in the disposal of waste, including the waste generator, waste collector, waste processor, and disposal facility operator, shall comply with the requirements specified in Section III of Appendix A of §175.104.

(5) Any licensee shipping byproduct material described in the definition of byproduct material set forth in subparagraphs (iii) and (iv) of paragraph (34) of §175.02, intended for ultimate disposal at a land disposal facility licensed under 10 CFR Part 61 must document the information required on the NRC's Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with 10 CFR Part 20, Appendix G.

(5) The licensee or applicant for a license shall comply with the requirements of the New York State Department of Environmental Conservation as codified in 6 NYCRR Part 381, or any successor law or regulation.

(g) *Compliance with environmental and health protection regulations.*

(1) Nothing in this section relieves the licensee from complying with other applicable Federal, State and local regulations governing any other toxic or hazardous properties of materials that may be disposed of pursuant to this section.

(h) *Records of waste disposal.* (1) The licensee shall maintain records of the disposal of licensed materials made under §175.104(b), (c), (d), (e) and 10 CFR Part 61 or the equivalent regulations of an agreement state.

(2) The licensee shall retain the records required by §175.104(h)(1) until the Department authorizes disposition.

§175.105 Transportation and Packaging of Radioactive Materials.

Table of Contents for §175.105

Table A-2—General Values for A_1 and A_2

(a) *General Provisions.* (1) *Purpose and Scope.*

(i) This section establishes requirements for packaging, preparation for shipment, and transportation of licensed material. The packaging and transport of licensed material are also subject to other sections of this Code (e.g., §§175.03, 175.101) and to the regulations of other agencies (e.g., the U.S. Nuclear Regulatory Commission (NRC), the U.S. Department of Transportation (USDOT) and the U.S. Postal Service*) having jurisdiction over means of transport and other applicable state and local laws and regulations. The requirements of this section are in addition to, and not in substitution for, other requirements.

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

(iii) The requirements of this section apply to any person who has a license or who is required to obtain a license pursuant to this Code, if the person delivers radioactive material to a common or contract carrier for transport or transports the material outside the confines of the person's facility or other authorized place of use.

(2) *Records.* Each record required by this section must be legible throughout the retention period specified by this Code. 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. The licensee shall maintain adequate safeguards against tampering with and loss of records.

(3) *Completeness and accuracy of information.*

(i) Information provided to the Department by an applicant for a license, or by a licensee, or information required by applicable laws or regulations, or licensed conditions to be maintained by the applicant or the licensee must be complete and accurate in all material respects.

(ii) Each applicant or licensee shall notify the Department of information identified by the applicant or licensee as having, for the regulated activity, a significant implication for public health and safety or common defense and security. An applicant or licensee violates this requirement if the applicant or licensee fails to notify the Department of information that the applicant or licensee has identified as having a significant implication for public health and safety or common defense and security. Notification must be provided to the Department within two working days of identifying the information. This requirement is not applicable to information that is already required to be provided to the Department by other reporting or updating requirements.

(4) *Requirement for license.*

(i) Except as authorized in a general license or a specific license issued by the Department, or as exempted in this section, no person may—

(A) Deliver licensed material to a carrier for transport; or

(B) Transport licensed material.

(ii) Exemptions from the requirement for license in §175.105(a)(4) are specified in §175.105(b)(2). General licenses for which no NRC package approval is required are issued in §§175.105(c)(3) and 175.105(c)(4). The general license in §175.105(c)(1) requires that an NRC certificate of compliance or other package approval be issued for the package to be used under the general license. The transport of licensed material or delivery of licensed material to a carrier for transport is subject to the operating controls and procedures requirements of §175.105(d), to the quality assurance requirements of §175.105(e), and to the general provisions of §175.105(a), including USDOT regulations referenced in §175.105(a)(6).

(5) *Definitions.* The following terms are defined herein for the purpose of this section. These definitions are in addition to those in §175.02. To ensure compatibility with international transportation standards, all limits in this section are given in terms of dual units: The International System of Units (SI) followed or preceded by U.S. standard or customary units. The U.S. customary units are not exact equivalents, but are rounded to a convenient value, providing a functionally equivalent unit. For the purpose of this section, either unit may be used.

(i) "Certificate holder" means a person who has been issued a certificate of compliance or other package approval by the U.S. Nuclear Regulatory Commission.

(ii) "Certificate of Compliance (CoC)" means the certificate issued by the NRC which approves the design of a package for the transportation of radioactive material.

(iii) "Close reflection by water" means immediate contact by water of sufficient thickness for maximum reflection of neutrons.

(iv) "Containment system" means the assembly of components of the packaging intended to retain the radioactive material during transport.

(v) "Criticality Safety Index (CSI)" means the dimensionless number (rounded up to the next tenth) assigned to and placed on the label of a fissile material package, to designate the degree of control of accumulation of packages containing fissile material during transportation. Determination of the criticality safety index is described in 10 CFR §§71.22, 71.23, and 71.59.

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

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

(viii) "Low toxicity alpha emitters" means natural uranium, depleted uranium, natural thorium; uranium-235, uranium-238, thorium-232, thorium-228 or thorium-230 when contained in ores or physical or chemical concentrates or tailings; or alpha emitters with a half-life of less than 10 days.

(ix) "Maximum normal operating pressure" means the maximum gauge pressure that would develop in the containment system in a period of 1 year under the heat condition specified in 10 CFR 71.71(c)(1), in the absence of venting, external cooling by an ancillary system, or operational controls during transport.

(x) "Natural thorium" means thorium with the naturally occurring distribution of thorium isotopes (essentially 100 weight percent thorium-232).

(xi) "Optimum interspersed hydrogenous moderation" means the presence of hydrogenous material between packages to such an extent that the maximum nuclear reactivity results.

(xii) "Spent nuclear fuel" means fuel that has been withdrawn from a nuclear reactor following irradiation, has undergone at least 1 year's decay since being used as a source of energy in a

power reactor, and has not been chemically separated into its constituent elements by reprocessing. Spent fuel includes the special nuclear material, byproduct material, source material, and other radioactive materials associated with fuel assemblies.

(xiii) "Surface Contaminated Object (SCO)" means a solid object that is not itself classed as radioactive material, but which has radioactive material distributed on any of its surfaces. SCO must be in one of two groups with surface activity not exceeding the following limits:

(A) CO-1: A solid object on which:

(a) The non-fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 4 Bq/cm^2 (10^{-4} microcurie/cm^2) for beta and gamma and low toxicity alpha emitters, or 0.4 Bq/cm^2 (10^{-5} microcurie/cm^2) for all other alpha emitters;

(b) The fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 4×10^4 Bq/cm^2 (1.0 microcurie/cm^2) for beta and gamma and low toxicity alpha emitters, or 4×10^3 Bq/cm^2 (0.1 microcurie/cm^2) for all other alpha emitters; and

(c) The non-fixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 4×10^4 Bq/cm^2 (1 microcurie/cm^2) for beta and gamma and low toxicity alpha emitters, or 4×10^3 Bq/cm^2 (0.1 microcurie/cm^2) for all other alpha emitters.

(B) CO-II: A solid object on which the limits for SCO-I are exceeded and on which:

(a) The non-fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 400 Bq/cm^2 (10^{-2} microcurie/cm^2) for beta and gamma and low toxicity alpha emitters or 40 Bq/cm^2 (10^{-3} microcurie/cm^2) for all other alpha emitters;

(b) The fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 8×10^5 Bq/cm^2 (20 microcuries/cm^2) for beta and gamma and low toxicity alpha emitters, or 8×10^4 Bq/cm^2 (2 microcuries/cm^2) for all other alpha emitters; and

(c) The non-fixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 8×10^5 Bq/cm^2 (20 microcuries/cm^2) for beta and gamma and low toxicity alpha emitters, or 8×10^4 Bq/cm^2 (2 microcuries/cm^2) for all other alpha emitters.

(xiv) "Unirradiated uranium" means uranium containing not more than 2 x 103 Bq of plutonium per gram of uranium-235, not more than 9 x 106 Bq of fission products per gram of uranium-235, and not more than 5 x 10-3 g of uranium-236 per gram of uranium-235.

(xv) Uranium—natural, depleted, enriched

(A) "Natural uranium" means uranium with the naturally occurring distribution of uranium isotopes (approximately 0.711 weight percent uranium-235, and the remainder by weight essentially uranium-238).

(B) "Depleted uranium" means uranium containing less uranium-235 than the naturally occurring distribution of uranium isotopes.

(C) "Enriched uranium" means uranium containing more uranium-235 than the naturally occurring distribution of uranium isotopes.

(6) *Transportation of licensed material.*

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

transport, shall comply with the applicable requirements of the USDOT regulations in 49 CFR Parts 107, 171 through 180 and 390 through 397 appropriate to the mode of transport.

(A) The licensee shall particularly note USDOT regulations in the following areas:

(a) Packaging—49 CFR Part 173; Subparts A and B and I.

(b) Marking and labeling—49 CFR Part 172: Subpart D; and Sections 172.400 through 172.407 and Sections 172.436 through 172.441 of Subpart E.

(c) Placarding—49 CFR Part 172: Subpart F, especially Sections 172.500 through 172.519, 172.556, and Appendices B and C.

(d) Accident reporting—49 CFR Part 171: Sections 171.15 and 171.16.

(e) Shipping papers and emergency information—49 CFR Part 172: Subparts C and G.

(f) Hazardous material employee training—49 CFR Part 172: Subpart H.

(g) Security plans—49 CFR Part 172: subpart I.

(h) Hazardous material shipper/carrier registration—49 CFR Part 107: Subpart G.

(B) The licensee shall also note USDOT regulations pertaining to the following modes of transportation:

(a) Rail—49 CFR Part 174: Subparts A through D and K.

(b) Air—49 CFR Part 175.

(c) Vessel—49 CFR Part 176: Subparts A through F and M.

(d) Public Highway—49 CFR Part 177 and Parts 390 through 397.

(ii) If USDOT regulations are not applicable to a shipment of licensed material, the licensee shall conform to the standards and requirements of the USDOT specified in §175.105(a)(6)(i) to the same extent as if the shipment or transportation were subject to USDOT regulations. A request for modification, waiver, or exemption from those requirements, and any notification referred to in those requirements, must be filed with, or made to, the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

(b) *Exemption.* (1) *Exemption of physicians.* Any physician licensed by a State to dispense drugs in the practice of medicine is exempt from §175.105(a)(6) with respect to transport by the physician of licensed material for use in the practice of medicine. However, any physician operating under this exemption must be licensed under applicable sections of this Code, 10 CFR Part 35 or the equivalent Agreement State regulations. Such transport must not be by public modes of transportation including, but not limited to, buses, subways, trams, taxicabs, car services, trains, ferries, or other means which would be returned immediately to public use after transporting licensed material.

(2) *Exemption for low-level materials.*

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

(A) Natural material and ores containing naturally occurring radionuclides that are not intended to be processed for use of these radionuclides, provided the activity concentration of the material does not exceed 10 times the values specified in Appendix A, Table A-2 of this section.

(B) Materials for which the activity concentration is not greater than the activity concentration values specified in Appendix A, Table A-2 of this section , or for which the consignment activity is not greater than the limit for an exempt consignment found in Appendix A, Table A-2 of this section.

(3) *Exemption from classification as fissile material.*

(i) Fissile material meeting the requirements of at least one of the paragraphs of this section are exempt from classification as fissile material and from the fissile material package standards of 10 CFR §§71.55 and 71.59, but are subject to all other requirements of this part, except as noted.

(ii) Individual package containing 2 grams or less of fissile material

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

(iv) Low concentrations of solid fissile material commingled with solid nonfissile material provided that:

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

(B) There is no more than 180 grams of fissile material distributed within 360 kg of contiguous nonfissile material.

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

(v) Uranium enriched in uranium-235 to a maximum of 1 percent by weight, and with a total plutonium and uranium-233 content of up to 1 percent of the mass of the uranium235, provided that the mass of any beryllium, graphite, and hydrogenous material enriched in deuterium constitutes less than 5 percent of the uranium mass.

(vi) Liquid solutions of uranyl nitrate enriched in uranium-235 to a maximum of 2 percent by mass, with a total plutonium and uranium-233 content not exceeding 0.002 percent of the mass of uranium, and with a minimum nitrogen to uranium atomic ratio (N/U) of 2. The material must be contained in at least a DOT Type A package.

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

(c) *General Licenses.* (1) *General license: NRC-approved package.*

(i) A general license is hereby issued to any licensee of the Department to transport, or to deliver to a carrier for transport, licensed material in a package for which a license, certificate of compliance, or other approval has been issued by the NRC.

(ii) This general license applies only to a licensee who—

(A) Has a quality assurance program approved by the Department as satisfying the provisions of §175.105(e) of this Code.

(B) Has a copy of the certificate of compliance, or other approval of the package, and has the drawings and other documents referenced in the approval relating to the use and maintenance of the packaging and to the actions to be taken before shipment;

(C) Complies with the terms and conditions of the license, certificate, or other approval, as applicable, and applicable provisions of the operating controls and procedures requirements of §175.105(d), the quality assurance requirements of §175.105(e), and the general provisions of §175.105(a); and

(D) ubmits in writing to the Department, before the licensee's first use of the package, the licensee's name and license number and the package identification number specified in the package approval.

(iii) This general license applies only when the package approval authorizes use of the package under this general license.

(iv) For a Type B or fissile material package, the design of which was approved by NRC before April 1, 1996, the general license is subject to the additional restrictions contained in 10 CFR 71.13.

(2) *Previously approved package.*

(i) A Type B package previously approved by NRC but not designated as B(U) or B(M) in the identification number of the NRC Certificate of Compliance, may be used under the general license of §175.105(c)(1) with the following additional conditions:

(A) Fabrication of the packaging was satisfactorily completed by August 31, 1986, as demonstrated by application of its model number in accordance with §175.105(d)(2)(iii); (B) A package used for a shipment to a location outside the United States is subject to multilateral approval, as defined in USDOT regulations at 49 CFR 173.403; and

(C) A serial number that uniquely identifies each packaging which conforms to the approved design is assigned to, and legibly and durably marked on, the outside of each packaging.

(ii) A Type B(U) package, a Type B(M) package, a low specific activity (LSA) material package or a fissile material package, previously approved by the NRC but without the designation "-85" in the identification number of the NRC Certificate of Compliance, may be used under the general license of §175.105(c)(1) with the following additional conditions:

(A) abrication of the package is satisfactorily completed by April 1, 1999 as demonstrated by application of its model number in accordance with §175.105(d)(2)(iii) of this Code;

(B) A package used for a shipment to a location outside the United States is subject to multilateral approval as defined in USDOT regulations at 49 CFR 173.403; and

(C) A serial number which uniquely identifies each packaging which conforms to the approved design is assigned to and legibly and durably marked on the outside of each packaging.

(3) *General license: U.S. Department of Transportation specification container.*

(i) A general license is issued to any licensee of the Department to transport, or to deliver to a carrier for transport, licensed material in a specification container for fissile material or for a Type B quantity of radioactive material as specified in USDOT regulations at 49 CFR Parts 173 and 178.

(ii) This general license applies only to a licensee who has a quality assurance program approved by the Department as satisfying the provisions of §175.105(e) of this Code.

(iii) This general license applies only to a licensee who—

(A) Has a copy of the specification; and

(B) omplies with the terms and conditions of the specification and the applicable provisions of the operating and procedures requirements in §175.105(d), the quality assurance requirements in §175.105(e) and the general provisions contained in §175.105(a).

(iv) This general license is subject to the limitation that the specification container may not be used for a shipment to a location outside the United States, except by multilateral approval, as defined in USDOT regulations at 49 CFR 173.403.

(v) The requirements of §175.105(c)(3) shall expire October 1, 2008.

(4) *General License: Use of foreign approved package.*

(i) A general license is issued to any licensee of the Department to transport, or to deliver to a carrier for transport, licensed material in a package the design of which has been approved in a foreign national competent authority certificate that has been revalidated by USDOT as meeting the applicable requirements of 49 CFR 171.12.

(ii) Except as otherwise provided herein, the general license applies only to a licensee who has a quality assurance program approved by the Department as satisfying the applicable provisions of §175.105(e) of this Code.

(iii) This general license applies only to shipments made to or from locations outside the United States.

(iv) This general license applies only to a licensee who—

(A) Has a copy of the applicable certificate, the revalidation, and the drawings and other documents referenced in the certificate, relating to the use and maintenance of the packaging and to the actions to be taken before shipment; and

(B) omplies with the terms and conditions of the certificate and revalidation, and with the applicable provisions of the operating and procedures requirements in §175.105(d), the quality assurance requirements in §175.105(e) and the general provisions in §175.105(a). With respect to the quality assurance provisions of §175.105(e) of this Code, the licensee is exempt from design, construction, and fabrication consid- erations.

(5) *General License: Fissile Material.*

(i) A general license is issued to any licensee of the Department to transport fissile material, or to deliver fissile material to a carrier for transport, if the material is shipped in accordance with this section. The fissile material need not be contained in a package which meets the standards of- subparts E and F of 10 CFR 71.22; however the material must be contained in a Type A package. The Type A package must also meet the DOT requirements of 49 CFR 173.417(a).

(ii) The general license applies only to a licensee who has a quality assurance program approved by the Department as satisfying the provisions of §175.105(e) of this part

(iii) The general license applies only when a package's contents:

(A) Contain less than a Type A quantity of fissile material; and

(B) Contains less than 500 total grams of beryllium, graphite, or hydrogenous material enriched in deuterium.

(iv) The general license applies only to packages containing fissile material that are labeled with a CSI which:

(A) Has been determined in accordance with section (5) of this section

(B) Has a value less than or equal to 10; and

(C) For a shipment of multiple packages containing fissile material, the sum of the CSIs must be less than or equal to 50 (for shipment on a nonexclusive use conveyance) and less than or equal to 100 (for shipment on an exclusive use conveyance).

(v) (A) The value for the CSI must be greater than or equal to the number calculated by the following equation:

$$CSI = 10\left[\frac{\text{grams of } {}^{233}U}{X} + \frac{\text{grams of } {}^{233}U}{Y} + \frac{\text{grams of Pu}}{Z}\right];$$

(B) The calculated CSI must be rounded up to the first decimal place;

(C) The values of X, Y, and Z used in the CSI equation must be taken from Tables-71.1 or 71.2, as appropriate;

(D) If Table 71-2 is used to obtain the value of X, then the values of the terms in the equation for uranium-233 and plutonium must be assumed to be zero; and,

(E) Table 71-1 values for X, Y, and Z must be used to determine the CSI if:

(a) Uranium-233 is present in the package;

(b) The mass of plutonium exceeds 1 percent of the mass of uranium-235;

(c) The uranium is of unknown uranium-235 enrichment or greater than 24 weight percent enrichment; or

(d) Substances having a moderating effectiveness (i.e., an average hydrogen density greater than H2O) (e.g., certain hydrocarbon oils or plastics) are present in any form, except as polyethylene used for packing or wrapping.

(6) *General license: Plutonium/Beryllium special form material.*

(i) A general license is issued to any licensee of the Department to transport fissile material in the form of plutonium-beryllium (Pu-Be) special form sealed sources, or to deliver Pu-Be sealed sources to a carrier for transport, if the material is shipped in accordance with this section. This material need not be contained in a package which meets the standards of subparts E and F of 10 CFR Part 71; however, the material must be contained in a Type A package. The Type A package must also meet the USDOT requirements of 49 CFR §173.417(a).

(ii) The general license applies only to a licensee who has a quality assurance program approved by the Department as satisfying §175.105(e)(1) of this section.

(iii) The general license applies only when a package's contents:

(A) Contain less than a Type A quantity of material; and

(B) Contain less than 1000 g of plutonium, provided that: plutonium-239, plutonium-241, or any combination of these radionuclides, constitute less than 240 g of the total quantity of plutonium in the package.

(iv) The general license applies only to packages labeled with a CSI which:

(A) Has been determined in accordance with part (v) of this section;

(B) Has a value less than or equal to 100;

(C) For a shipment of multiple packages containing Pu-Be sealed sources, the sum of the CSI must be less than or equal to 50 (for shipment on a nonexclusive use conveyance) and less than or equal to 100 (for shipment on an exclusive use conveyance).

(v) (A) The value for the CSI must be greater than or equal to the number calculated by the following equation:

$$CSI = 10\left[\frac{\text{grams of } {}^{233}U}{X} + \frac{\text{grams of } {}^{233}U}{Y} + \frac{\text{grams of Pu}}{Z}\right];$$

(B) The calculated CSI must be rounded up to the first decimal place.

(d) *Operating Controls and Procedures.* (1) *Applicability of operating controls and procedures.* A licensee subject to this section, who, under a general or specific license, transports licensed material or delivers licensed material to a carrier for transport, shall comply with the requirements of this subsection, with the quality assurance requirements of §175.105(e), and with the general provisions of §175.105(a) of this Code.

(2) *Preliminary determinations.* Before the first use of any packaging for the shipment of licensed material—

(i) The licensee shall ascertain that there are no cracks, pinholes, uncontrolled voids, or other defects that could significantly reduce the effectiveness of the packaging:

(ii) Where the maximum normal operating pressure will exceed 35 kPa (5 lbf/in^2) gauge, the licensee shall test the containment system at an internal pressure at least 50 percent higher than

the maximum normal operating pressure, to verify the capability of that system to maintain its structural integrity at that pressure; and

(iii) The licensee shall conspicuously and durably mark the packaging with its model number, serial number, gross weight, and a package identification number assigned by the NRC. Before applying the model number, the licensee shall determine that the packaging has been fabricated in accordance with the design approved by the NRC.

(3) *Routine determinations.* Before each shipment of licensed material, the licensee shall ensure that the package with its contents satisfies the applicable requirements of this section and of the license. The licensee shall determine that—

(i) The package is proper for the contents to be shipped;

(ii) The package is in unimpaired physical condition except for superficial defects such as marks or dents;

(iii) Each closure device of the packaging, including any required gasket, is properly installed and secured and free of defects;

(iv) Any system for containing liquid is adequately sealed and has adequate space or other specified provision for expansion of the liquid;

(v) Any pressure relief device is operable and set in accordance with written procedures;

(vi) The package has been loaded and closed in accordance with written procedures;

(vii) Any structural part of the package that could be used to lift or tie down the package during transport is rendered inoperable for that purpose, unless it satisfies the design requirements of 10 CFR 71.45;

(viii) The level of non-fixed (removable) radioactive contamination on the external surfaces of each package offered for shipment is as low as reasonably achievable, and within the limits specified in USDOT regulations in 49 CFR 173.443;

(ix) External radiation levels around the package and around the vehicle, if applicable, will not exceed the limits specified in 10 CFR 71.47 at any time during transportation;

(x) Accessible package surface temperatures will not exceed the limits specified in 10 CFR 71.43(g) at any time during transportation; and

(xi) For fissile material, any moderator or neutron absorber, if required, is present and in proper condition.

(xii) When the isotopic abundance, mass, concentration, degree of irradiation, degree of moderation, or other pertinent property of fissile material in any package is not known, the licensee shall package the fissile material as if the unknown properties have credible values that will cause the maximum neutron multiplication.

(4) *Air transport of plutonium.*

(i) Notwithstanding the provisions of any general licenses and notwithstanding any exemptions stated directly in this section or included indirectly by citation of 49 CFR chapter I, as may be applicable, the licensee shall assure that plutonium in any form, whether for import, export, or domestic shipment, is not transported by air or delivered to a carrier for air transport unless:

(A) The plutonium is contained in a medical device designed for individual human application; or

(B) The plutonium is contained in a material in which the specific activity is less than or equal to the activity concentration values for plutonium specified in Appendix A, Table A-2, of this section and in which the radioactivity is essentially uniformly distributed; or

(C) The plutonium is shipped in a single package containing no more than an A_2 quantity of plutonium in any isotope or form, and is shipped in accordance with §175.105(a)(6); or

(D) The plutonium is shipped in a package specifically authorized for the shipment of plutonium by air in the Certificate of Compliance for that package issued by the NRC.

(ii) Nothing in §175.105(d)(4)(i) is to be interpreted as removing or diminishing the requirements of 10 CFR 73.24

(iii) For a shipment of plutonium by air which is subject to §175.105(d)(4)(i)(D), the licensee shall, through special arrangement with the carrier, require compliance with 49 CFR 175.704, U.S. Department of Transportation regulations applicable to the air transport of plutonium.

(5) *Opening instructions.* Before delivery of a package to a carrier for transport, the licensee shall ensure that any special instructions needed to safely open the package have been sent to, or otherwise made available to, the consignee for the consignee's use in accordance with §175.03(j)(6) of this Code.

(6) *Records.*

(i) Each licensee shall maintain, for a period of 3 years after shipment, a record of each shipment of licensed material not exempt under §175.105(b)(2), showing where applicable—

(A) Identification of the packaging by model number and serial number;

(B) Verification that there are no significant defects in the packaging, as shipped;

(C) Volume and identification of coolant;

(D) Type and quantity of licensed material in each package, and the total quantity of each shipment;

(E) For each item of irradiated fissile material—

(a) Identification by model number and serial number;

(b) Irradiation and decay history to the extent appropriate to demonstrate that its nuclear and thermal characteristics comply with license conditions; and

(c) Any abnormal or unusual condition relevant to radiation safety;

(F) ate of the shipment;

(G) For fissile packages and for Type B packages, any special controls exercised;

(H) Name and address of the transferee;

(I) Address to which the shipment was made; and

(J) esults of the determinations required by §175.105(d)(3) and by the conditions of the package approval.

(ii) The licensee shall make available to the Department for inspection, upon reasonable notice, all records required by this section. Records are only valid if stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated.

(iii) The licensee shall maintain sufficient written records to furnish evidence of the quality of packaging. The records to be maintained include results of the determinations required by §175.105(d)(2); design, fabrication, and assembly records, results of reviews, inspections, tests, and audits; results of monitoring work performance and materials analyses; and results of maintenance, modification and repair activities. Inspection, test, and audit records must identify the inspector or data recorder, the type of observation, the results, the acceptability and the action taken in connection with any deficiencies noted. The records must be retained for 3 years after the life of the packaging to which they apply.

(7) *Inspection and tests.*

(i) The licensee or certificate holder shall permit the Department, at all reasonable times, to inspect the licensed material, packaging, premises, and facilities in which the licensed material or packaging is used, provided, constructed, fabricated, tested, stored, or shipped.

(ii) The licensee shall perform, and permit the Department to perform, any tests the Department deems necessary or appropriate for the administration of the requirements of this section.

(iii) The licensee shall notify the Department at least 45 days before fabrication of a package to be used for the shipment of licensed material having a decay heat load in excess of 5kW or with a maximum normal operating pressure in excess of 103kPa (15 lbf/in^2) gauge.

(8) *Reports.* The licensee shall report to the Department within 30 days—

(i) Any instance in which there is significant reduction in the effectiveness of any approved Type B, or fissile, packaging during use;

(ii) Details of any defects with safety significance in Type B, or fissile, packaging after first use, with the means employed to repair the defects and prevent their recurrence; or

(iii) Instances in which the conditions of approval in the certificate of compliance were not observed in making a shipment.

(9) *Advance notification of shipment of irradiated reactor fuel and nuclear waste.*

(i) As specified in §§175.105(d)(9)(ii), (iii) and (iv), each licensee shall provide advance notification to the governor of a State, or the governor's designee, and the Department, of the shipment of licensed material, through, or across the boundary of the State, before the transport, or delivery to a carrier, for transport, of licensed material outside the confines of the licensee's plant or other place of use or storage.

(ii) Advance notification is required under this subdivision for shipments of irradiated reactor fuel in quantities less than that subject to advance notification requirements of 10 CFR 73.37(f). Advance notification is also required under this subdivision for shipment of licensed material; other than irradiated fuel, meeting the following three conditions:

(A) The licensed material is required by this section to be in Type B packaging for transportation;

(B) The licensed material is being transported to or across a State boundary en route to a disposal facility or to a collection point for transport to a disposal facility; and

(C) The quantity of licensed material in a single package exceeds the least of the following:

(a) 3000 times the A_1 value of the radionuclides as specified in appendix A. Table A-1 for special form radioactive material;

(b) 3000 times the A_2 value of the radionuclides as specified in appendix A. Table A-1 for normal form radioactive material; or

(c) 1000 TBq (27,000 Ci).

(iii) Procedures for submitting advance notification.

(A) The notification must be made in writing to the office of each appropriate governor or governor's designee and to the Department.

(B) A notification delivered by mail must be postmarked at least 7 days before the beginning of the 7-day period during which departure of the shipment is estimated to occur.

(C) A notification delivered by any means other than mail must reach the office of the governor or of the governor's designee and the Department at least 4 days before the beginning of the 7-day period during which departure of the shipment is estimated to occur.

(a) A list of the names and mailing addresses of the governors' designees receiving advance notification of transportation of nuclear waste was published in the Federal Register on June 30, 1995 (60 FR 34306).

(b) The list will be published annually in the Federal Register on or about June 30 to reflect any changes in information.

(c) A list of the names and mailing addresses of the governors' designees is available on request from the Director, Office of State Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

(D) The licensee shall retain a copy of the notification as a record for 3 years.

(iv) Information to be furnished in advance notification of shipment. Each advance notification of shipment of irradiated reactor fuel or nuclear waste must contain the following information:

(A) The name, address, and telephone number of the shipper, carrier, and receiver of the irradiated reactor fuel or nuclear waste shipment;

(B) A description of the irradiated reactor fuel or nuclear waste contained in the shipment, as specified in the regulations of USDOT in 49 CFR 172.202 and 172.203(d);

(C) The point of origin of the shipment and the 7-day period during which departure of the shipment is estimated to occur;

(D) The 7-day period during which arrival of the shipment at State boundaries is estimated to occur;

(E) The destination of the shipment, and the 7-day period during which arrival of the shipment is estimated to occur; and

(F) point of contact, with a telephone number, for current shipment information.

(v) *Revision notice.* A licensee who finds that schedule information previously furnished to a governor or governor's designee, or the Department, in accordance with this subdivision, will not be met, shall telephone a responsible individual in the office of the governor of the State or of the governor's designee, and the Department, and inform that individual of the extent of the delay beyond the schedule originally reported. The licensee shall maintain a record of the name of the individual contacted for 3 years.

(vi) *Cancellation notice.*

(A) Each licensee who cancels an irradiated reactor fuel or nuclear waste shipment for which advance notification has been sent shall send a cancellation notice to the governor of each State or to the governor's designee previously notified, and to the Department.

(B) The licensee shall state in the notice that it is a cancellation and identify the advance notification that is being canceled. The licensee shall retain a copy of the notice as a record for 3 years.

(e) *Quality Assurance.* (1) *Quality assurance requirements.*

(i) *Purpose.* This subsection describes quality assurance requirements applying to design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, and modification of components of packaging that are important to safety. As used in this subsection, "quality assurance" comprises all those planned and systematic actions necessary to provide adequate confidence that a system or component will perform satisfactorily in service. Quality assurance includes quality control, which comprises those quality assurance actions related to control of the physical characteristics and quality of the material or component to predetermined requirements.

(ii) *Establishment of program.* Each licensee shall establish, maintain, and execute a quality assurance program satisfying each of the applicable criteria of §§175.105(e)(1) through 175.105(e)(19) and satisfying any specific provisions that are applicable to the licensee's activities including procurement of packaging. The licensee shall apply each of the applicable criteria in a graded approach, i.e., to an extent that is consistent with its importance to safety.

(iii) *Approval of program.* Before the use of any package for the shipment of licensed material subject to this subsection each licensee shall obtain Department approval of its quality assurance

program. Each licensee shall file a description of its quality assurance program, including a discussion of which requirements of this subsection are applicable and how they will be satisfied, with the Department.

(iv) Repealed.

(v) Repealed.

(vi) *Previously approved programs.* An NRC-approved quality assurance program that satisfies the applicable criteria of Appendix B of 10 CFR Part 50, and that is established, maintained, and executed with regard to transport packages, will be accepted as satisfying the requirements of §175.105(e)(1)(ii) of this Code. Before first use, the licensee shall notify the NRC and the Department of its intent to apply its previously approved Appendix B program to transportation activities. The licensee shall identify the program by date of submittal to the NRC and date of NRC approval.

(2) *Quality assurance organization.*

(i) The licensee shall be responsible for the establishment and execution of the quality assurance program. The licensee may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, or any part of the quality assurance program, but shall retain responsibility for the program. The licensee shall clearly establish and delineate, in writing, the authority and duties of persons and organizations performing activities affecting the safety-related functions of structures, systems, and components. These activities include performing the functions associated with attaining quality objectives and the quality assurance functions.

(ii) The quality assurance functions are—

(A) Assuring that an appropriate quality assurance program is established and effectively executed; and

(B) Verifying, by procedures such as checking, auditing, and inspection, that activities affecting the safety-related functions have been performed correctly.

(iii) The persons and organizations performing quality assurance functions must have sufficient authority and organizational freedom to—

(A) Identify quality problems;

(B) Initiate, recommend, or provide solutions; and

(C) Verify implementation of solutions.

(iv) The persons and organizations performing quality assurance functions shall report to a management level that assures that the required authority and organizational freedom, including sufficient independence from cost and schedule, when opposed to safety considerations, are provided.

(v) Because of the many variables involved, such as the number of personnel, the type of activity being performed, and the location or locations where activities are performed, the organizational structure for executing the quality assurance program may take various forms, provided that the persons and organizations assigned the quality assurance functions have the required authority and organizational freedom.

(vi) Irrespective of the organizational structure, the individual(s) assigned the responsibility for assuring effective execution of any portion of the quality assurance program, at any location where activities subject to this subsection are being performed, must have direct access to the levels of management necessary to perform this function.

(3) *Quality assurance program.*

(i) The licensee shall establish, at the earliest practicable time consistent with the schedule for accomplishing the activities, a quality assurance program that complies with the requirements of §§175.105(e)(1) through 175.105(e)(19). The licensee shall document the quality assurance program by written procedures or instructions and shall carry out the program in accordance with those procedures throughout the period during which the packaging is used. The licensee shall identify the material and components to be covered by the quality assurance program, the major organizations participating in the program, and the designated functions of these organizations.

(ii) The licensee, through its quality assurance program, shall provide control over activities affecting the quality of the identified materials and components to an extent consistent with their importance to safety, and as necessary to assure conformance to the approved design of each individual package used for the shipment of radioactive material. The licensee shall assure that activities affecting quality are accomplished under suitably controlled conditions. Controlled conditions include the use of appropriate equipment; suitable environmental conditions for accomplishing the activity, such as adequate cleanliness; and assurance that all prerequisites for the given activity have been satisfied. The licensee shall take into account the need for special controls, processes, test equipment, tools, and skills to attain the required quality, and the need for verification of quality by inspection and test.

(iii) The licensee shall base the requirements and procedures of its quality assurance program on the following considerations concerning the complexity and proposed use of the package and its components:

(A) The impact of malfunction or failure of the item to safety;

(B) The design and fabrication complexity or uniqueness of the item;

(C) The need for special controls and surveillance over processes and equipment;

(D) The degree to which functional compliance can be demonstrated by inspection or test; and

(E) The quality history and degree of standardization of the item.

(iv) The licensee shall provide for indoctrination and training of personnel performing activities affecting quality, as necessary to assure that suitable proficiency is achieved and maintained. The licensee shall review the status and adequacy of the quality assurance program at established intervals. Management of other organizations participating in the quality assurance program shall review regularly the status and adequacy of that part of the quality assurance program which they are executing.

(4) *Package design control.*

(i) The licensee shall establish measures to assure that applicable requirements and the package design, as specified in the license for those materials and components to which this subdivision applies, are correctly translated into specifications, drawings, procedures, and instructions. These measures must include provisions to assure that appropriate quality standards are specified and included in design documents and that deviations from standards are controlled. Measures must be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related functions of the materials, parts, and components of the packaging.

(ii) The licensee shall establish measures for the identification and control of design interfaces and for coordination among participating design organizations. These measures must include the establishment of written procedures, among participating design organizations, for the review, approval, release, distribution, and revision of documents involving design interfaces. The design control measures must provide for verifying or checking the adequacy of design, by methods such as design reviews, alternate or simplified calculational methods, or by a suitable testing program.

For the verifying or checking process, the licensee shall designate individuals or groups other than those who were responsible for the original design, but who may be from the same organization. Where a test program is used to verify the adequacy of a specific design feature in lieu of other verifying or checking processes, the licensee shall include suitable qualification testing of a prototype or sample unit under the most adverse design conditions. The licensee shall apply design control measures to items such as the following:

(A) riticality physics, radiation shielding, stress, thermal, hydraulic, and accident analyses;

(B) ompatibility of materials;

(C) Accessibility for inservice inspection, maintenance, and repair;

(D) eatures to facilitate decontamination; and

(E) Delineation of acceptance criteria for inspections and tests.

(iii) The licensee shall subject design changes, including field changes, to design control measures commensurate with those applied to the original design. Changes in the conditions specified in the package approval require the Department's approval.

(5) *Procurement document control.* The licensee shall establish measures to assure that adequate quality is required in the documents for procurement of material, equipment, and services, whether purchased by the licensee or by its contractors or subcontractors. To the extent necessary, the licensee shall require contractors or subcontractors to provide a quality assurance program consistent with the applicable provisions of this section.

(6) *Instructions, procedures, and drawings.* The licensee shall prescribe activities affecting quality by documented instructions, procedures, or drawings of a type appropriate to the circumstances and shall require that these instructions, procedures, and drawings be followed. The instructions, procedures, and drawings must include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished.

(7) *Document control.* The licensee shall establish measures to control the issuance of documents such as instructions, procedures, and drawings, including changes, which prescribe all activities affecting quality. These measures must assure that documents, including changes, are reviewed for adequacy, approved for release by authorized personnel, and distributed and used at the location where the prescribed activity is performed. These measures must assure that changes to documents are reviewed and approved.

(8) *Control of purchased material, equipment, and services.*

(i) The licensee shall establish measures to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures must include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products on delivery.

(ii) The licensee shall have available documentary evidence that material and equipment conform to the procurement specifications before installation or use of the material and equipment. The licensee shall retain, or have available, this documentary evidence for the life of the package to which it applies. The licensee shall assure that the evidence is sufficient to identify the specific requirements met by the purchased material and equipment.

(iii) The licensee shall assess the effectiveness of the control of quality by contractors and subcontractors at intervals consistent with the importance, complexity, and quantity of the product or services.

(9) *Identification and control of materials, parts, and components.* The licensee shall establish measures for the identification and control of materials, parts, and components. These measures must assure that identification of the item is maintained by heat number, part number, or other appropriate means, either on the item or on records traceable to the item, as required throughout fabrication, installation, and use of the item. These identification and control measures must be designed to prevent the use of incorrect or defective materials, parts, and components.

(10) *Control of special processes.* The licensee shall establish measures to assure that special processes, including welding, heat treating, and nondestructive testing, are controlled and accomplished by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements.

(11) *Internal inspection.* The licensee shall establish and execute a program for inspection of activities affecting quality by or for the organization performing the activity, to verify conformance with the documented instructions, procedures, and drawings for accomplishing the activity. The inspection must be performed by individuals other than those who performed the activity being inspected. Examination, measurements, or tests of material or products processed must be performed for each work operation where necessary to assure quality. If direct inspection of processed material or products is not carried out, indirect control by monitoring processing methods, equipment, and personnel must be provided. Both inspection and process monitoring must be provided when quality control is inadequate without both. If mandatory inspection hold points, which require witnessing or inspecting by the licensee's designated representative and beyond which work should not proceed without the consent of its designated representative, are required, the specific hold points must be indicated in appropriate documents.

(12) *Test control.* The licensee shall establish a test program to assure that all testing required to demonstrate that the packaging components will perform satisfactorily in service is identified and performed in accordance with written test procedures that incorporate the requirements of this section and the requirements and acceptance limits contained in the package approval. The test procedures must include provisions for assuring that all prerequisites for the given test are met, that adequate test instrumentation is available and used, and that the test is performed under suitable environmental conditions. The licensee shall document and evaluate the test results to assure that test requirements have been satisfied.

(13) *Control of measuring and test equipment.* The licensee shall establish measures to assure that tools, gauges, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified times to maintain accuracy within necessary limits.

(14) *Handling, storage, and shipping control.* The licensee shall establish measures to control, in accordance with instructions, the handling, storage, shipping, cleaning, and preservation of materials and equipment to be used in packaging to prevent damage or deterioration. When necessary for particular products, special protective environments, such as inert gas atmosphere, and specific moisture content and temperature levels must be specified and provided.

(15) *Inspection, test, and operating status.* (i) The licensee shall establish measures to indicate, by the use of markings such as stamps, tags, labels, routing cards, or other suitable means, the status of inspections and tests performed upon individual items of the packaging. These measures must provide for the identification of items that have satisfactorily passed required inspections and tests, where necessary to preclude inadvertent bypassing of the inspections and tests.

(ii) The licensee shall establish measures to identify the operating status of components of the packaging, such as tagging valves and switches, to prevent inadvertent operation.

(16) *Nonconforming materials, parts, or components.* The licensee shall establish measures to control materials, parts, or components that do not conform to the licensee's requirements to prevent their inadvertent use or installation. These measures must include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations. Nonconforming items must be reviewed and accepted, rejected, repaired, or reworked in accordance with documented procedures.

(17) *Corrective action.* The licensee shall establish measures to assure that conditions adverse to quality, such as deficiencies, deviations, defective material and equipment, and nonconformances, are promptly identified and corrected. In the case of a significant condition adverse to quality, the measures must assure that the cause of the condition is determined and corrective action taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken must be documented and reported to appropriate levels of management.

(18) *Quality assurance records.* The licensee shall maintain sufficient written records to describe the activities affecting quality. The records must include the instructions, procedures, and drawings required by subdivision (6) of this subsection, to prescribe quality assurance activities and must include closely related specifications such as required qualifications of personnel, procedures, and equipment. The records must include the instructions or procedures which establish a records retention program that is consistent with applicable requirements and designates factors such as duration, location, and assigned responsibility. The licensee shall retain these records for 3 years beyond the date when the licensee last engages in the activity for which the quality assurance program was developed. If any portion of the written procedures or instructions is superseded, the licensee shall retain the superseded material for 3 years after it is superseded.

(19) *Audits.* The licensee shall carry out a comprehensive system of planned and periodic audits, to verify compliance with all aspects of the quality assurance program, and to determine the effectiveness of the program. The audits must be performed in accordance with written procedures or checklists by appropriately trained personnel not having direct responsibilities in the areas being audited. Audited results must be documented and reviewed by management having responsibility in the area audited. Follow-up action, including reaudit of deficient areas, must be taken where indicated.