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

Residual Radioactivity means radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee's control. This includes radioactivity from all licensed and unlicensed sources used by the licensee, but excludes background radiation. It also includes radioactive materials remaining at the site as a result of routine or accidental releases of radioactive materials at the site and previous burials at the site, even if those burials were made in accordance with the provisions of 105 CMR 120.200.

Restricted Area means an area, access to which is limited by the licensee or registrant for the purpose of protecting individuals against undue risks from exposure to sources of radiation. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

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

Scattered Primary Radiation means that scattered radiation that has been deviated in direction only by materials irradiated by the useful beam.

Scattered Radiation means ionizing radiation emitted by the interaction of ionizing radiation with matter, the interaction being accompanied by a change in direction of the radiation.

Sealed Source means any radioactive material that is used as a source of radiation and is encased in a capsule designed to prevent leakage or escape of the radioactive material.

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

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

Shallow Dose Equivalent (H_s), which applies to the external exposure of the skin or an extremity, means the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm^2).

Shutter means a device attached to the tube housing assembly which can totally intercept the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

SI means the abbreviation for the International System of Units.

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

Site Area Emergency means events may occur, are in progress, or have occurred that could lead to a significant release of radioactive material and that could require a response by off-site response organizations to protect persons offsite.

Site Boundary means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee or registrant.

Source Material means:

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

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(2) ores which contain by weight $^1/_{20}$ of one percent (0.05%) or more of:
(a) uranium;
(b) thorium; or
(c) any combination thereof.
Source material does not include special nuclear material.

Source Material Milling means any activity that results in the production of byproduct material as defined by 105 CMR 120.005: Byproduct Material(2).

Source of Radiation means any radioactive material or any device or equipment emitting, or capable of producing, radiation.

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

Special Form Radioactive Material means radioactive material which satisfies the following conditions:
(1) It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;
(2) The piece or capsule has at least one dimension not less than five millimeters (0.2 inch); and
(3) It satisfies the requirements of 10 CFR 71.75. A special form encapsulation designed in accordance with the Nuclear Regulatory Commission requirements of 10 CFR 71.4 in effect on June 30, 1983 (*see* 10 CFR part 71, revised as of January 1, 1983), and constructed prior to July 1, 1985, may continue to be used. A special form encapsulation designed in accordance with the Nuclear Regulatory Commission requirements of 10 CFR 71.4 in effect on March 31, 1996 (*see* 10 CFR part 71, revised as of January 1, 1996), and constructed prior to April 1, 1998, may continue to be used. Special form material that was successfully tested before September 10, 2015 in accordance with the Nuclear Regulatory Commission requirements of 10 CFR 71.75(d) in effect before September 10, 2015 may continue to be used. Any other special form encapsulation must meet the specifications of Special Form Radioactive Material.

Special Nuclear Material means:
(1) Plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material that the U.S. Nuclear Regulatory Commission, pursuant to the provisions of § 51 of the Atomic Energy Act of 1954, as amended, determines to be special nuclear material, but does not include source material; or
(2) Any material artificially enriched by any of the foregoing but does not include source material.

Special Nuclear Material in Quantities not Sufficient to Form a Critical Mass means uranium enriched in the isotope U-235 in quantities not exceeding 350 grams of contained U-235; uranium-233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams; or any combination of them in accordance with the following formula: For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all of the kinds of special nuclear material in combination shall not exceed one. For example, the following quantities in combination would not exceed the limitation and are within the formula:

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

Supplied Air Respirator (SAR) or Airline Respirator means an atmosphere supplying respirator for which the source of breathing air is not designed to be carried by the user.

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

Test means the process of verifying compliance with an applicable regulation.

Tight-fitting Facepiece means a respiratory inlet covering that forms a complete seal with the face.

Total Effective Dose Equivalent (TEDE) means the sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

Total Organ Dose Equivalent (TODE) means the sum of the deep dose equivalent and the committed dose equivalent to the organ receiving the highest dose as described in 105 CMR 120.267(A)(6).

Traceable to National Standard (*See* Instrument Traceability or Source Traceability)

U.S. Department of Energy means the Department of Energy established by Public Law 95-91, August 4, 1977, 91 Stat. 565, 42 U.S.C. 7101 *et seq.*, to the extent that the Department exercises functions formerly vested in the U.S. Atomic Energy Commission, its Chairman, members, officers and components and transferred to the U.S. Energy Research and Development Administration and to the Administrator thereof pursuant to sections 104(b), (c) and (d) of the Energy Reorganization Act of 1974 (Public Law 93-438, October 11, 1974, 88 Stat. 1233 at 1237, effective January 19, 1975) and retransferred to the Secretary of Energy pursuant to section 301(a) of the Department of Energy Organization Act (Public Law 95-91, August 4, 1977, 91 Stat. 565 at 577-578, 42 U.S.C. 7151, effective October 1, 1977).

Unrefined and Unprocessed Ore means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or refining. Processing does not include sieving or encapsulating of ore or preparation of samples for laboratory analysis.

Unrestricted Area (Uncontrolled Area) means area access to which is neither limited nor controlled by the licensee or registrant. For purposes of 105 CMR 120.000, Uncontrolled Area is an equivalent term.

User Seal Check (Fit Check) means an action conducted by the respirator user to determine if the respirator is properly seated to the face. Examples include negative pressure check, positive pressure check, irritant smoke check, or isoamyl acetate check.

Vendor means a supplier of products or services to be used by a licensee or registrant or a licensed or registered facility or activity.

Very High Radiation Area means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving an absorbed dose in excess of 5 Gy (500 rad) in one hour at one meter from a source of radiation or one meter from any surface that the radiation penetrates. [*Note*: At very high doses rates, units of adsorbed dose, gray and rad, are appropriate, rather than units of dose equivalent, sievert and rem].

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(d) The actual or potential damage or injury to the public health or environment;
(e) The actual and potential cost of such damage or injury;
(f) The actual or potential cost to the Commonwealth of enforcing provisions of 105 CMR 120.000;
(g) Whether the person being assessed the civil penalty did everything reasonable to prevent failure to, to come into compliance promptly, and to remedy and mitigate whatever harm might have been done as a result of the failure to comply;
(h) Whether the person being assessed the civil penalty has previously failed to comply with any order issued pursuant to M.G.L. c. 111, §§ 5N through 5P;
(i) Whether imposition of a civil penalty is likely to deter future non-compliance;
(j) The financial condition of the person being assessed the civil penalty; and
(k) The public interest.

(H) Escalation of Enforcement Sanctions.
(1) The Department considers violations of Severity Levels I, II or III to be of significant regulatory concern. When Severity Level I, II or III violations occur, the Department will, where necessary, issue orders in conjunction with civil penalties to achieve immediate corrective actions and to deter further recurrence of serious violations. The Department carefully considers the circumstances of each case in selecting and applying the sanction(s) appropriate to the case in accordance with the criteria described in 105 CMR 120.016(D).
(2) The progression of enforcement actions for similar violations will usually be based on similar violations at an individual facility and not on similar violations under the same license. However, under some circumstances, *e.g.*, where there is common control over some facet of facility operations, similar violations may be charged even though the second violation occurred at a different facility or under a different license. For example, a health physics violation at one division of a dual unit hospital that repeats an earlier violation of the other division might be considered similar.

(I) Criminal Enforcement. The Department may elect to enforce any section of 105 CMR 120.000 or provision of M.G.L. c. 111, § 5P by seeking to have criminal sanctions imposed. Any person who violates M.G.L. c. 111, § 5N or § 5O or any rule, regulation, license, registration, or order adopted or issued under said M.G.L. c. 111, § 5N or § 5O shall be fined not less than $100 nor more than $2,000, or be imprisoned for a period of not more than two years, or both. Any person who continues to violate the provisions of the aforementioned laws after due notice by the Department shall be fined not less than $1,000 nor more than $20,000 or be imprisoned for a period of not more than 20 years, or both. After due notice has been issued by the Department, each day of such violation shall constitute a separate offense.

(J) Judicial Enforcement. The Department may apply directly to the Supreme Judicial Court or Superior Court to enforce any provision of M.G.L. c. 111, §§ 5N through 5P and/or any rule or regulation, license, registration, or order adopted and issued thereunder by the Department. When a person is engaged in or about to engage in any act or practice which constitutes or will constitute a violation of such provision, rule, regulation, license, registration, or order, the Department may seek to restrain such act or practice or the use or occupation of premises or parts thereof or such other equitable relief as public health and safety requires.

(K) Nonexclusivity of Enforcement Procedures. None of the enforcement procedures contained in 105 CMR 120.000 are mutually exclusive. Any enforcement procedures may be invoked simultaneously if the situation so requires.

(L) Deliberate Misconduct.
(1) Any licensee; certificate of registration holder; quality assurance program approval holder; applicant for a license or certificate of registration or quality assurance program approval; employee of a licensee, certificate of registration holder, quality assurance program approval holder or applicant; or any contractor (including a supplier or consultant), subcontractor, employee of a contractor or subcontractor of any licensee or certificate of registration holder, quality assurance program approval holder or applicant for a license or certificate of registration or quality assurance program approval, who knowingly provides to any licensee, applicant, certificate holder, quality assurance program approval holder, contractor, or subcontractor, any components, equipment, materials, or other goods or services that relate to a licensee's, certificate holder's, quality assurance program approval holder's or applicant's activities in this part, may not:

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(a) Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee, certificate of registration holder, quality assurance program approval holder or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license or certificate of registration or quality assurance program approval issued by the Agency; or

(b) Deliberately submit to the Agency, a licensee, certificate of registration holder, quality assurance program approval holder, an applicant, or a licensee's, certificate holder's, quality assurance program approval holder's or applicant's contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the Agency.

(2) A person who violates 105 CMR 120.016(L)(1)(a) or (b) may be subject to enforcement action in accordance with the procedures in 105 CMR 120.016.

(3) For the purposes of 105 CMR 120.016(L)(1)(a), deliberate misconduct by a person means an intentional act or omission that the person knows:

(a) Would cause a licensee, certificate of registration holder, quality assurance program approval holder or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation, of any license issued by the Agency; or

(b) Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, certificate of registration holder, quality assurance program approval holder, applicant, contractor, or subcontractor.

120.017: Severability

The provisions of 105 CMR 120.000 are severable. If any section, subsection, paragraph or provision is declared unconstitutional or invalid by a court of competent jurisdiction, the validity of the remaining provisions shall not be so affected.

120.018: Public Disclosure of Enforcement Actions

In accordance with M.G.L. c. 30A, the Administrative Procedures Act, all enforcement actions and licensees' responses are publicly available for inspection. In addition, press releases may be issued for civil penalties related to violations at Severity Level I, II, or III.

120.019: Appendix A – Severity Categories

The following examples of severity levels are neither exhaustive nor controlling. They reflect only the seriousness of the violation and not the intent of the violator, the history of the violator, the amount necessary to deter future violations, or efforts to correct the violation.

(A) Severity Level 1 – Most Significant Violations.

(1) Health Physics.

(a) Single exposure of a worker in excess of 25 rems of radiation to the whole body, 150 rems to the skin of the whole body, or 375 rems to the feet, ankles, hands or forearms;

(b) Annual whole body exposure of a member of the public in excess of 2.5 rems of radiation;

(c) Release of radioactive material to an unrestricted area in excess of ten times the limits of 105 CMR 120.253;

(d) Disposal of licensed material in quantities or concentrations in excess of ten times the limits of 105 CMR 120.253;

(e) Exposure of a worker in restricted areas of ten times the limits of 105 CMR 120.212.

(2) Transportation.

(a) Annual whole body radiation exposure of a member of the public in excess of 0.5 rems of radiation; or

(b) Breach of package integrity resulting in surface contamination or external radiation levels in excess of ten times the Agency limits.

(3) Materials Operations.

(a) Radiation levels, contamination levels, or releases that exceed ten times the limits specified in the license;

(b) A system designed to prevent or mitigate a serious safety event not being operable when actually required to perform its design function.

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(7) Building of service facilities (*e.g.*, paved roads, parking lots, railroad spurs, exterior utility and lighting systems, potable water systems, sanitary sewerage treatment facilities, and transmission lines);
(8) Procurement or fabrication of components or portions of the proposed facility occurring at other than the final, in-place location at the facility; or
(9) Taking any other action that has no reasonable nexus to radiological health and safety.

Decommissioning Funding Plan means a written document that contains a cost estimate for decommissioning and a description of the method for assuring for decommissioning, including means of adjusting cost estimates and associated funding levels periodically over the life of the facility.

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

Financial Surety means the method of assuring that sufficient funds will be available at the time of license termination and decommissioning of the facility to cover all costs associated with the decommissioning.

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

Site Area Emergency means events may occur, are in progress, or have occurred that could lead to a significant release of radioactive material and that could require a response by offsite response organizations to protect persons offsite.

120.103: Source Material

(A) Any person is exempt from 105 CMR 120.100 to the extent that such person receives, possesses, uses, owns, 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% (0.05%) of the mixture, compound, solution, or alloy.

(B) Any person is exempt from 105 CMR 120.100 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, such person shall not refine or process such ore.

(C) Any person is exempt from 105 CMR 120.100, 120.200 and 120.750 to the extent that such person receives, possesses, uses, or transfers:
(1) 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 two grams of thorium;
(f) rare earth metals and compounds, mixtures, and products containing not more than 0.25% by weight 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;
(2) source material contained in the following products:
(a) glazed ceramic tableware manufactured before August 27, 2013, provided that the glaze contains not more than 20% by weight source material;
(b) glassware containing not more than 2% by weight source material or, for glassware manufactured before August 27, 2013, 10% by weight source material; but not including commercially manufactured glass brick, pane glass, ceramic tile, or other glass or ceramic used in construction;

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(c) glass enamel or glass enamel frit containing not more than 10% by weight 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% by weight source material.

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

(4) any finished product or part fabricated of, or containing, tungsten-thorium or magnesium-thorium alloys, provided that the thorium content of the alloy does not exceed 4% 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;

(5) 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 has been impressed with the following legend clearly legible through any plating or other covering: "DEPLETED URANIUM"[1];

(b) each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: "UNAUTHORIZED ALTERATIONS PROHIBITED"[1]; and

(c) 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.

(6) 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 of minimum wall thickness of ⅛ inch (3.2 mm);

(7) thorium or uranium contained in or on finished optical lenses and mirrors, provided that each lens or mirror does not contain more than 10% by weight of thorium or uranium or, for lenses manufactured before August 27, 2013, 30% 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 mirror or manufacturing processes other than the assembly of such lens or mirror into optical systems and devices without any alteration of the lens or mirror; or

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

(8) 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% by weight.

(D) The exemptions in 105 CMR 120.103(C) do not authorize the manufacture of any of the products described.

(E) No person may initially transfer for sale or distribution a product containing source material to persons exempt under 105 CMR 120.103(C), or equivalent regulations of the NRC or an Agreement State, unless authorized by a license issued by the NRC under 10 CFR 40.52 to initially transfer such products for sale or distribution. Persons authorized to manufacture, process, or produce these materials or products containing source material under a specific license issued by the Agency, and persons who import finished products or parts, for sale or distribution must be authorized by a license issued by NRC under 10 CFR 40.52 for distribution only and are exempt from the requirements of 10 CFR 19, 20 and 40.32(b) and (c).

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[1] The requirements specified in 105 CMR 120.103(C)(5)(a) and (b) need not be met by counterweights manufactured prior to December 31, 1969; provided that such counterweights were manufactured under a specific license issued by the Atomic Energy Commission and are impressed with the legend, "CAUTION - RADIOACTIVE MATERIAL - URANIUM", as previously required by 105 CMR 120.000.

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2. Each instrument contains no more than ten exempt quantities. For purposes of this requirement, an instrument's source(s) may contain either one or different types of radionuclides and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in 105 CMR 120.196: *Appendix B, Table 1*, provided that the sum of such fractions shall not exceed unity.

3. For americium-241, 0.05 microcurie (1.85 kBq) is considered an exempt quantity under 105 CMR 120.104(C)(1)(f).

(g) 1. Static elimination devices which contain, as a sealed source or sources, byproduct material consisting of a total of not more than 18.5 MBq (500 μCi) of polonium-210 per device.

2. Ion generating tubes designed for ionization of air that contain, as a sealed source or sources, byproduct material consisting of a total of not more than 18.5 MBq (500 μCi) of polonium-210 per device or of a total of not more than 1.85 GBq (50 mCi) of hydrogen-3 (tritium) per device.

3. Such devices authorized before October 23, 2012 for use under the general license then provided in 105 CMR 120.122(A) and equivalent regulations of the U.S. Nuclear Regulatory Commission and Agreement States and manufactured, tested, and labeled by the manufacturer in accordance with the specifications contained in a specific license issued by the U.S. Nuclear Regulatory Commission.

(h) Any person who desires to apply byproduct material to, or to incorporate byproduct material into, the products exempted in 105 CMR 120.104(C)(1), or who desires to initially transfer for sale or distribution such products containing byproduct material, should apply to the Nuclear Regulatory Commission for a specific license pursuant to 10 CFR 32.14, which license states that the product may be distributed by the licensee to persons exempt from the regulations pursuant to 105 CMR 120.104(C)(1) or equivalent regulations of the Nuclear Regulatory Commission, 10 CFR 30.15(a).

(2) Self-luminous Products Containing Radioactive Material.

(a) Tritium, Krypton-85, or Promethium-147. Except for persons who manufacture, process, produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147, any person is exempt from 105 CMR 120.100 to the extent that such person receives, possesses, uses, transfers, owns, or acquires tritium, krypton-85 or promethium-147 in self-luminous products manufactured, processed, produced, or initially transferred in accordance with a specific license issued by the NRC pursuant to 10 CFR Part 32, § 32.22 which license authorizes the transfer of the product to persons who are exempt from regulatory requirements.

Any person who desires to manufacture, process, or produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147 for use under 105 CMR 120.104(C)(2), should apply to the NRC for a license under 10 CFR 32.22 and for a certificate of registration in accordance with 105 CMR 120.128(N). The exemption in 105 CMR 120.104(C)(2) does not apply to tritium, krypton-85, or promethium-147 used in products primarily for frivolous purposes or in toys or adornments.

(b) Radium-226. Any person is exempt from 105 CMR 120.100 to the extent that such person receives, possesses, uses, transfers, or owns articles containing less than 0.1 microcurie (3.7 kBq) of radium-226 which were acquired prior to March 11, 1994.

(3) Gas and Aerosol Detectors Containing Radioactive Material.

(a) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution gas and aerosol detectors containing byproduct material, any person is exempt from the requirement of a license set forth in 105 CMR 120.100 to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material in gas and aerosol detectors designed to protect health, safety, or property provided that detectors containing byproduct material shall have been manufactured, processed, produced, or initially transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR Part 32, § 32.26, which license authorizes the initial transfer of the product for use under 105 CMR 120.104(C)(3). 105 CMR 120.104(C)(3) 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.

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(b) Any person who desires to manufacture, process, or produce gas and aerosol detectors containing byproduct material, or to initially transfer such products for use pursuant 105 CMR 120.104(C)(3)(a), should apply to the NRC for a license pursuant to 10 CFR 32.26 and for a certificate of registration in accordance with 105 CMR 120.128(N).

(4) Radioactive Drug: Capsules Containing Carbon-14 Urea for *In Vivo* Diagnostic Use for Humans.

(a) Except as provided in 105 CMR 120.104(C)(4)(b) and (c), any person is exempt from the requirements for a license set forth in M.G.L. c. 111, § 5P and from 105 CMR 120.100 and 120.500 provided that such person receives, possesses, uses, transfers, owns, or acquires capsules containing 37 kBq (1μ Ci) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each, for *in vivo* diagnostic use for humans.

(b) Any persons who desires to use the capsules for research involving human subjects shall apply for and receive a specific license pursuant to 105 CMR 120.500.

(c) Any person who desires to manufacture, prepare, process, produce, package, or transfer for commercial distribution such capsules shall apply, to NRC, for and receive a specific license pursuant to 10 CFR 32.21.

(d) Nothing in 105 CMR 120.104(C)(4) relieves persons from complying with applicable FDA, other Federal, and State requirements governing receipt, administration, and use of drugs.

(5) Certain Industrial Devices.

(a) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing byproduct material 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 an ionized atmosphere, any person is exempt from the requirement of a license set forth in 105 CMR 120.100 to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material, in these certain detecting, measuring, gauging, or controlling devices and certain devices for producing an ionized atmosphere, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued by the NRC under 10 CFR 32.30, which license authorizes the initial transfer of the device for use under 105 CMR 120.104(C)(5). This exemption does not cover sources not incorporated into a device, such as calibration and reference sources.

(b) Any person who desires to manufacture, process, or produce, or initially transfer for sale or distribution industrial devices containing byproduct material for use pursuant 105 CMR 120.104(C)(5), should apply to the NRC for a license under 10 CFR 32.30 and for a certificate of registration in accordance with 105 CMR 120.128(N).

120.120: Types of Licenses

Licenses for radioactive materials are of two types: general and specific.

(A) The Agency issues a specific license to a named person who has filed an application for the license under the provisions of 105 CMR 120.124.

(B) A general license is provided by regulation, grants authority to a person for certain activities involving radioactive material, and is effective without the filing of an application with the Agency or the issuance of a licensing document to a particular person. However, registration with the Agency may be required by the particular general license.

120.121: General Licenses - Source Material

(A) A general license is hereby issued authorizing commercial and industrial firms; research, educational, and medical institutions; and state and local government agencies to receive, possess, use, and transfer uranium and thorium, in their natural isotopic concentrations and in the form of depleted uranium, for research, development, educational, commercial, or operational purposes in the following forms and quantities:

120.121: continued

(1) No more than 1.5 kg (3.3 lb) of uranium and thorium in dispersible forms (*e.g.*, gaseous, liquid, powder, *etc.*) at any one time. Any material processed by the general licensee that alters the chemical or physical form of the material containing source material must be accounted for as a dispersible form. A person authorized to possess, use, and transfer source material under 105 CMR 120.121(A)(1) may not receive more than a total of 7 kg (15.4 lb) of uranium and thorium in any one calendar year; and

(2) No more than a total of 7 kg (15.4 lb) of uranium and thorium at any one time. A person authorized to possess, use, and transfer source material under 105 CMR 120.121(A)(2) may not receive more than a total of 70 kg (154 lb) of uranium and thorium in any one calendar year. A person may not alter the chemical or physical form of the source material possessed under 105 CMR 120.121(A)(2) unless it is accounted for under the limits of 105 CMR 120.121(A)(1); or

(3) No more than 7 kg (15.4 lb) of uranium, removed during the treatment of drinking water, at any one time. A person may not remove more than 70 kg (154 lb) of uranium from drinking water during a calendar year under 105 CMR 120.121(A)(3); or

(4) No more than 7 kg (15.4 lb) of uranium and thorium at laboratories for the purpose of determining the concentration of uranium and thorium contained within the material being analyzed at any one time. A person authorized to possess, use, and transfer source material under 105 CMR 120.121(A)(4) may not receive more than a total of 70 kg (154 lb) of source material in any one calendar year.

(B) Any person who receives, possesses, uses, or transfers source material pursuant to the general license issued in 105 CMR 120.121(A):

(1) Is prohibited from administering source material, or the radiation therefrom, either externally or internally, to human beings except as may be authorized by the Agency in a specific license.

(2) Shall not abandon such source material. Source material may be disposed of as follows:

(a) A cumulative total of 0.5 kg (1.1 lb) of source material in a solid, non-dispersible form may be transferred each calendar year, by a person authorized to receive, possess, use, and transfer source material under this general license to persons receiving the material for permanent disposal. The recipient of source material transferred under the provisions of 105 CMR 120.121(B)(2)(a) is exempt from the requirements to obtain a license under 105 CMR 120.100 to the extent the source material is permanently disposed. 105 CMR 120.121(B)(2)(a) does not apply to any person who is in possession of source material under a specific license issued under 105 CMR 120.100; or

(b) In accordance with 105 CMR 120.251.

(3) Is subject to the provisions in 105 CMR 120.001 through 120.019, 120.101(A), 120.131(A) through (C), 120.140, 120.142, and 120.150.

(4) Shall respond to written requests from the Agency 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 person cannot provide the requested information within the allotted time, the person shall, within that same time period, request a longer period to supply the information by providing the Agency, using an appropriate method listed in 105 CMR 120.013, a written justification for the request;

(5) Shall not export such source material except in accordance with 10 CFR Part 110.

(C) Any person who receives, possesses, uses, or transfers source material in accordance with 105 CMR 120.121(A) shall conduct activities so as to minimize contamination of the facility and the environment. When activities involving such source material are permanently ceased at any site, if evidence of significant contamination is identified, the general licensee shall notify the Agency by an appropriate method listed in 105 CMR 120.013 about such contamination and may consult with the Agency as to the appropriateness of sampling and restoration activities to ensure that any contamination or residual source material remaining at the site where source material was used under this general license is not likely to result in exposures that exceed the limits in 105 CMR 120.245.

(D) 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 receive, possess, use, or transfer source material.

120.121: continued

(E) Depleted Uranium in Industrial Products and Devices.

(1) A general license is hereby issued to receive, acquire, possess, use, or transfer, in accordance with the provisions of 105 CMR 120.121(E)(2) through (5), depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.

(2) The general license in 105 CMR 120.121(E)(1) applies only to industrial products or devices which have been manufactured either in accordance with a specific license issued to the manufacturer of the products or devices pursuant to 105 CMR 120.128(M) or in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission or an Agreement State which authorizes manufacture of the products or devices for distribution to persons generally licensed by the U.S. Nuclear Regulatory Commission or an Agreement State.

(3) (a) Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license established by 105 CMR 120.121(E)(1) shall file form MRCP 120.100-1 "Certificate - Use of Depleted Uranium Under General License", with the Agency. The form shall be submitted within 30 days after the first receipt or acquisition of such depleted uranium. The general licensee shall furnish on form MRCP 120.100-1 the following information and such other information as may be required by that form:

1. name and address of the general licensee;
2. a statement that the general licensee has developed and will maintain procedures designed to establish physical control over the depleted uranium described in 105 CMR 120.121(E)(1) and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and
3. name and title, address, and telephone number of the individual duly authorized to act for and on behalf of the general licensee in supervising the procedures identified in 105 CMR 120.121(E)(3)(a)2.

(b) The general licensee possessing or using depleted uranium under the general license established by 105 CMR 120.121(E)(1) shall report in writing to the Agency any changes in information furnished by him in form MRCP 120.100-1 "Certificate - Use of Depleted Uranium Under General License". The report shall be submitted within 30 days after the effective date of such change.

(4) A person who receives, acquires, possesses, or uses depleted uranium pursuant to the general license established by 105 CMR 120.121(E)(1):

(a) shall not introduce such depleted uranium, in any form, into a chemical, physical, or metallurgical treatment or process, except a treatment or process for repair or restoration of any plating or other covering of the depleted uranium;

(b) shall not abandon such depleted uranium;

(c) shall transfer or dispose of such depleted uranium only by transfer in accordance with the provisions of 105 CMR 120.140. In the case where the transferee receives the depleted uranium pursuant to the general license established by 105 CMR 120.121(E)(1), the transferor shall furnish the transferee a copy of 105 CMR 120.100 and a copy of form MRCP 120.100-1. In the case where the transferee receives the depleted uranium pursuant to a general license contained in the U.S. Nuclear Regulatory Commission's or Agreement State's regulation equivalent to 105 CMR 120.121(E)(1), the transferor shall furnish the transferee a copy of 105 CMR 120.100 and a copy of form MRCP 120.100-1 accompanied by a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or Agreement State under requirements substantially the same as those in 105 CMR 120.100;

120.121: continued

(d) within 30 days of any transfer, shall report in writing to the Agency the name and address of the person receiving the depleted uranium pursuant to such transfer; and

(e) shall not export such depleted uranium except in accordance with a license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR Part 110.

(5) Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general license established by 105 CMR 120.121(E)(1) is exempt from the requirements of 105 CMR 120.200 and 120.750 with respect to the depleted uranium covered by that general license.

(F) Any person who receives, possesses, uses, or transfers source material in accordance with the general license granted in 105 CMR 120.121(A) is exempt from the provisions of 105 CMR 120.200 and 120.750 to the extent that such receipt, possession, use, and transfer are within the terms of this general license, except that such person shall comply with the provisions of 105 CMR 120.245 and 120.251 to the extent necessary to meet the provisions of 105 CMR 120.121(B)(2) and 120.121(C). However, this exemption does not apply to any person who also holds a specific license issued under 105 CMR 120.100.

(G) No person may initially transfer or distribute source material to persons generally licensed under 105 CMR 120.121(A)(1) or (2), or equivalent regulations of the NRC or an Agreement State, unless authorized by a specific license issued in accordance with 105 CMR 120.128(B) or equivalent provisions of the NRC or an Agreement State. This prohibition does not apply to analytical laboratories returning processed samples to the client who initially provided the sample.

120.122: General Licenses - Radioactive Material Other than Source Material

(A) Requirements for Other General Licenses (Reserved).

(B) Luminous Safety Devices for Aircraft.

(1) A general license is hereby issued to own, receive, acquire, possess, and use tritium or promethium-147 contained in luminous safety devices for use in aircraft, provided:

(a) each device contains not more than 10 curies (370 GBq) of tritium or 300 millicuries (11.1 GBq) 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 or assembled in accordance with the specifications contained in a specific license issued by the Agency or any Agreement State to the manufacturer or assembler of such device pursuant to licensing requirements equivalent to those in 10 CFR Part 32, § 32.53.

(2) Persons who own, receive, acquire, possess, or use luminous safety devices pursuant to the general license in 105 CMR 120.122(B)(1) are exempt from the requirements of 105 CMR 120.200 through 120.299 and 120.750 through 120.760 except that they shall comply with the provisions of 105 CMR 120.281 and 120.282.

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

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

(5) This general license is subject to the provisions of 105 CMR 120.005 through 120.016, 120.131, 120.140, 120.150, and 120.770 through 120.798.

(C) Requirements for Other General Licenses (Reserved).

120.124: continued

(E) In the application, the applicant may incorporate by reference information contained in previous applications, statements, or reports filed with the Agency provided such references are clear and specific.

(F) Applications and documents submitted to the Agency may be made available for public inspection except that the Agency may withhold any document or part thereof from public inspection if disclosure of its content is not required in the public interest and would adversely affect the interest of a person concerned.

(G)(1) Except as provided in 105 CMR 120.124(G)(2), (3), and (4), an application for a specific license to authorize receipt, possession or use of radioactive material in the form of a sealed source or in a device that contains a sealed source shall either:

(a) identify the sealed source or device that contains a sealed source by manufacturer and model number as registered with the Agency under 105 CMR 120.128(N), with the NRC or an Agreement State, or for a source or a device containing radium-226 or accelerator-produced radioactive material with a State under provisions comparable to 105 CMR 120.128(N); or

(b) contain the information identified in 105 CMR 120.128(N)(3).

(2) for sources or devices manufactured prior to October 23, 2012 that are not registered with the Agency under 105 CMR 120.128(N) or with the NRC or an Agreement State, and for which the applicant is unable to provide all categories of information specified in 105 CMR 120.128(N)(3), the applicant must provide:

(a) All available information identified in 105 CMR 120.128(N)(3) 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 radiation safety features, the intended use and associated operating experience, and the results of a recent leak test.

(3) For sealed sources and devices allowed to be distributed without registration of safety information in accordance with 105 CMR 120.128(N)(7)(a), the applicant may supply only the manufacturer, model number, and radionuclide and quantity.

(4) If it is not feasible to identify each sealed source and device individually, the applicant may propose constraints on the number and type of sealed sources and devices to be used and the conditions under which they will be used, in *lieu* of identifying each sealed source and device.

120.125: General Requirements for the Issuance of Specific Licenses

(A) A license application will be approved only if the Agency determines that:

(1) the applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with 105 CMR 120.000 in such a manner as to minimize danger to public health and safety or property;

(2) the applicant's proposed equipment, facilities, and procedures are adequate to minimize danger to public health and safety or property;

(3) the issuance of the license will not be inimical to the health and safety of the public; and,

(4) the applicant satisfies any applicable special requirements in 105 CMR 120.050 through 120.080, 120.126, 120.127, 120.128, 120.300, 120.500, 120.620 120.800, 120.890 and 120.900.

(B) Environmental Report, Commencement of Construction.

(1) In the case of an application for a license to receive and possess radioactive material for commercial waste disposal, or for the conduct of any other activity which the Agency determines will significantly affect the quality of the environment, a license application shall be reviewed and approved by the Agency before commencement of construction of the plant or facility in which the activity will be conducted. Issuance of the license shall be based upon a consideration by the Agency of the environmental, economic, technical and other benefits in comparison with the environmental costs and available alternatives and a determination that the action called for is the issuance of the proposed license, with any appropriate conditions to protect environmental values;

120.125: continued

(2) Commencement of construction prior to such conclusion shall be grounds for denial of a license to receive and possess radioactive material in such plant or facility.

(C) Financial Surety Arrangements and Recordkeeping for Decommissioning.

(1) Unless exempted by 105 CMR 120.125(C)(3), issuance, renewal or amendment of a license shall be dependent upon satisfactory financial surety arrangements to ensure the protection of the public health and safety in the event of abandonment, default or other inability of the licensee to meet the requirements of M.G.L. c. 111H, § 9 and 105 CMR 120.000.

(2) Each applicant for a specific license authorizing the possession and use of unsealed radioactive material with a half-life greater than 120 days and in quantities exceeding 10^5 times the applicable quantities set forth in 105 CMR 120.196: *Appendix B*, Table II shall submit a decommissioning funding plan as described in 105 CMR 120.125(C)(6). The decommissioning funding plan must also be submitted when a combination of isotopes is involved if R divided by 10^5 is greater than 1 (unity rule), where R is defined as the sum of the ratios of the quantity of each isotope to the applicable value in 105 CMR 120.196: *Appendix B*, Table II.

(3) 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 105 CMR 120.125(C)(5) shall either:

(a) submit a decommissioning funding plan as described in 105 CMR 120.125(C)(6); or

(b) submit a certification that financial assurance for decommissioning has been provided in the amount prescribed by 105 CMR 120.125(C)(5) using one of the methods described in 105 120.125(C)(7). 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 prior to the receipt of licensed material. As part of the certification, a copy of the financial instrument obtained to satisfy the requirements of 105 CMR 120.125(C)(7) is to be submitted to the Agency.

(4) (a) Each holder of a specific license issued on or after March 11, 1994, which is of a type described in 105 CMR 120.125(C)(2) or (3), shall provide financial assurance for decommissioning in accordance with the criteria set forth in 105 CMR 120.125(C)(1) through (8).

(b) Each holder of a specific license issued before March 11, 1994, and of a type described in 105 CMR 120.125(C)(2) shall submit, on or before March 11, 1995, a decommissioning funding plan 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 part. If the licensee submits the certification of financial assurance rather than a decommissioning funding plan at this time, the licensee shall include a decommissioning funding plan in any application for license renewal.

(c) Each holder of a specific license issued before March 11, 1994, and of a type described in 105 CMR 120.125(C)(3) shall submit, on or before March 11, 1995, a certification of financial assurance for decommissioning or a decommissioning funding plan in accordance with the criteria set forth in 105 CMR 120.125(C)(1) through (8).

(d) Waste collectors and waste processors, as defined in 10 CFR part 20, Appendix G must establish an Agency-approved decommissioning funding plan to assure the availability of funds for decommissioning activities conducted over the life of the licensed facility. The decommissioning funding plan must include the cost of disposal of the maximum radioactivity (curies) of radioactive material permitted by the license, and the cost of disposal of the maximum quantity, by volume, of radioactive material that could be present at the licensee's facility at any time, in addition to the cost to remediate the licensee's site to meet the license termination criteria of 105 CMR 120.200. The decommissioning funding plan must be submitted by April 6, 2007.

(e) If, in surveys made under 105 CMR 120.225(A), residual radioactivity in the facility and environment, including the subsurface, is detected at levels that would, if left uncorrected, prevent the site from meeting the 105 CMR 120.245 criteria for unrestricted use, the licensee must submit a decommissioning funding plan within one year of when the survey is completed.

120.125: continued

(5) Table of Required Amounts of Financial Assurance for Decommissioning by Quantity of Material:

-1	Greater than 10^4 but less than or equal to 10^5 times the applicable quantities in 105 CMR 120.196: *Appendix B*, Table II in unsealed form. (For a combination of isotopes, if R, as defined in 105 CMR 120.125(C)(2), divided by 10^4 is greater than 1 but R divided by 10^5 is less than or equal to 1.)	$1,125,000
-2a	Greater than 10^3 but less than or equal to 10^4 times the applicable quantities in 105 CMR 120.196: *Appendix B*, Table II in unsealed form. (For a combination of isotopes, if R, as defined in 105 CMR 120.125(C)(2), divided by 10^3 is greater than 1 but R divided by 10^4 is less than or equal to 1.)	$225,000
-2b	Greater than 10 mCi but less than 100 mCi of source material	$225,000
-3	Greater than 10^{10} times the applicable quantities in 105 CMR 120.196: *Appendix B*, Table II in sealed sources or plated foils. (For a combination of isotopes, if R, as defined in 105 CMR 120.125(C)(2), divided by 10^{10} is greater than 1.)	$113,000

(a) Licensees required to submit the $1,125,000 amount must do so by October 6, 2006.
(b) Licensees required to submit the $113,000 or $225,000 amount must do so by April 6, 2007.

(6) (a) Each decommissioning funding plan must be submitted for review and approval and must contain:

1. A detailed cost estimate for decommissioning, in an amount reflecting:
   a. The cost of an independent contractor to perform all decommissioning activities;
   b. The cost of meeting the 105 CMR 120.245 criteria for unrestricted use, provided that, if the applicant or licensee can demonstrate its ability to meet the provisions of 105 CMR 120.246, the cost estimate may be based on meeting the 105 CMR 120.246 criteria;
   c. The volume of onsite subsurface material containing residual radioactivity that will require remediation to meet the criteria for license termination; and
   d. An adequate contingency factor.
2. Identification of and justification for using the key assumptions contained in the cost estimate for decommissioning;
3. A description of the method of assuring funds for decommissioning from 105 CMR 120.125(C)(7), including means for adjusting cost estimates and associated funding levels periodically over the life of the facility;
4. A certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning; and
5. A signed original of the financial instrument obtained to satisfy the requirements of 105 CMR 120.125(C)(7) (unless a previously submitted and accepted financial instrument continues to cover the cost estimate for decommissioning).

(b) At the time of license renewal and at intervals not to exceed three years, the decommissioning funding plan must be resubmitted with adjustments as necessary to account for changes in costs and the extent of contamination. If the amount of financial assurance will be adjusted downward, this cannot be done until the updated decommissioning funding plan is approved. The decommissioning funding plan must update the information submitted with the original or prior approved plan, and must specifically consider the effect of the following events on decommissioning costs:

1. Spills of radioactive material producing additional residual radioactivity in on-site subsurface material;
2. Waste inventory increasing above the amount previously estimated;
3. Waste disposal costs increasing above the amount previously estimated;
4. Facility modifications;

120.125: continued

5. Changes in authorized possession limits;
6. Actual remediation costs that exceed the previous cost estimate;
7. On-site disposal; and
8. Use of a settling pond.

(7) The financial instrument must include the licensee's name, license number, and docket number, and the name, address, and other contact information of the issuer, and, if a trust is used, the trustee. When any of the foregoing information changes, the licensee must, within 30 days, submit financial instruments reflecting such changes. The financial instrument submitted must be a signed original or signed original duplicate, except where a copy of the signed original is specifically permitted. Financial assurance for decommissioning must be provided by one or more of the following methods:

(a) 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 must be made into a trust account, and the trust must be acceptable to the Agency.

(b) A Surety Method, Insurance or Other Guarantee Method. These methods guarantee that decommissioning costs will be paid should the licensee default.

1. A surety method may be in the form of a surety bond, issued by a corporate surety company authorized to transact business in the Commonwealth; or an irrevocable letter of credit.

2. A parent company guarantee of funds for decommissioning costs may be used if the guarantee and test are as contained in 105 CMR 120.198: *Appendix D.* A parent company guarantee may not be used in combination with other financial methods to satisfy the requirements of 105 CMR 120.125(C).

3. For commercial corporations that issue bonds, 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 105 CMR 120.198: *Appendix E.*

4. For commercial companies that do not issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs may be used if the guarantee and test are as contained in 105 CMR 120.198: *Appendix F.*

5. For nonprofit entities, such as colleges, universities, and nonprofit hospitals, a guarantee of funds by the applicant or licensee may be used if the guarantee and test are as contained in 105 CMR 120.198: *Appendix G.*

6. 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 Agency, 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 Agency 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 Agency. An acceptable trustee includes an appropriate state or federal government agency or an entity that 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 Agency has terminated the license.

(c) An External Sinking Fund. 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 must be in the form of a trust. If the other guarantee method is used, no surety or insurance may be combined with the external sinking fund. The surety or insurance provisions must be as stated in 105 CMR 120.125(C)(7)(b).

120.127: continued

(d) add or cause the addition of radioactive material to any food, beverage, cosmetic, drug, or other product designed for ingestion or inhalation by, or application to, a human being.

(2) Each Type A specific license of broad scope issued under 105 CMR 120.127 shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety committee.

(3) Each Type B specific license of broad scope issued under 105 CMR 120.127 shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety officer.

(4) Each Type C specific license of broad scope issued under 105 CMR 120.127 shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals who satisfy the requirements of 105 CMR 120.127(D).

120.128: Special Requirements for a Specific License to Manufacture, Assemble, Repair, or Distribute Commodities, Products, or Devices Which Contain Radioactive Material

(A) Licensing Requirements to Produce for Noncommercial Transfer Positron Emission Tomography (PET) Radioactive Drugs. 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 105 CMR 120.500, or equivalent Nuclear Regulatory Commission, or Agreement State requirements shall include:

(1) A request for authorization for the production of PET radionuclides or evidence of an existing license issued under 105 CMR 120.100 or equivalent Nuclear Regulatory Commission, or Agreement State requirements for a PET radionuclide production facility within its consortium from which it receives PET radionuclides.

(2) Evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in 105 CMR 120.128(J)(1)(b).

(3) Identification of individual(s) authorized to prepare the PET radioactive drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an authorized nuclear pharmacist as specified in 105 CMR 120.128(J)(2)(b).

(4) Information identified in 105 CMR 120.128(J)(1)(c) on the PET drugs to be noncommercially transferred to members of its consortium.

(B) Licensing Requirements to Initially Transfer Source Material to Persons Generally Licensed under 105 CMR 120.121(A).

(1) An application for a specific license to initially transfer source material for use under 105 CMR 120.121(A), or equivalent regulations of the NRC or an Agreement State, will be approved if:

(a) The applicant satisfies the general requirements specified in 105 CMR 120.125; and

(b) The applicant submits adequate information on, and the Agency approves the methods to be used for quality control, labeling, and providing safety instructions to recipients.

(2) Each person licensed under 105 CMR 120.128(B) shall label the immediate container of each quantity of source material with the type of source material and quantity of material and the words, "'radioactive material".

(3) Each person licensed under 105 CMR 120.128(B) shall ensure that the quantities and concentrations of source material are as labeled and indicated in any transfer records.

(4) Each person licensed under 105 CMR 120.128(B) shall provide the information specified in 105 CMR 120.128(B)(4) to each person to whom source material is transferred for use under 105 CMR 120.121(A) or equivalent provisions in the NRC or Agreement State regulations. This information must be transferred before the source material is transferred for the first time in each calendar year to the particular recipient. The required information includes:

(a) A copy of 105 CMR 120.121(A) through (C), (F), and (G) and 105 CMR 120.140, or relevant equivalent regulations of the NRC or Agreement State.

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(b) Appropriate radiation safety precautions and instructions relating to handling, use, storage, and disposal of the material.

(5) Each person licensed under 105 CMR 120.128(B) shall report transfers as follows:

(a) File a report with the Agency by an appropriate method listed in 105 CMR 120.013. The report shall include the following information:

1. The name, address, and license number of the person who transferred the source material;

2. For each general licensee under 105 CMR 120.121(A) or equivalent NRC or Agreement State provisions to whom greater than 50 grams (0.11 lb) of source material has been transferred in a single calendar quarter, the name and address of the general licensee to whom source material is distributed; a responsible agent, by name and/or position and phone number, of the general licensee to whom the material was sent; and the type, physical form, and quantity of source material transferred; and

3. The total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients.

(b) File a report with each responsible NRC or Agreement State agency that identifies all persons, operating under provisions equivalent to 105 CMR 120.121(A), to whom greater than 50 grams (0.11 lb) of source material has been transferred within a single calendar quarter. The report shall include the following information specific to those transfers made to the NRC or Agreement State being reported to:

1. The name, address, and license number of the person who transferred the source material; and

2. The name and address of the general licensee to whom source material was distributed; a responsible agent, by name and/or position and phone number, of the general licensee to whom the material was sent; and the type, physical form, and quantity of source material transferred.

3. The total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients within the NRC's jurisdiction or the Agreement State.

(c) Submit each report by January 31st of each year covering all transfers for the previous calendar year. If no transfers were made to persons generally licensed under 105 CMR 120.121(A) or equivalent NRC or Agreement State provisions during the current period, a report shall be submitted to the Agency indicating so. If no transfers have been made to general licensees within a particular Agreement State during the reporting period, this information shall be reported to the responsible Agreement State agency upon request of that agency. If no transfers have been made to NRC general licensees during the reporting period, this information shall be reported to the NRC.

(6) Each person licensed under 105 CMR 120.128(B) shall maintain all information that supports the reports required by this section concerning each transfer to a general licensee for a period of one year after the event is included in a report to the NRC or to an Agreement State agency.

(C) Requirements for Other Specific Licenses (Reserved).

(D) Licensing Requirements to Manufacture or Initially Transfer Devices Containing Radioactive Material to Persons Generally Licensed under 105 CMR 120.122(D).

(1) An application for a specific license to manufacture or distribute devices containing radioactive material, excluding special nuclear material, to persons generally licensed under 105 CMR 120.122(D) or equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State will be approved if:

(a) the applicant satisfies the general requirements of 105 CMR 120.125;

(b) the applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:

1. the device can be safely operated by persons not having training in radiological protection;

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2. under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in one year a dose in excess of 10% of the annual limits specified in 105 CMR 120.211(A), and

3. under accident conditions such as fire and explosion associated with handling, storage, and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the following organ doses:

a. Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye ..... 15 rems (150 mSv)

b. Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than one square centimeter ..... 200 rems (2 Sv)

c. Other organs ..... 50 rems (500 mSv); and

(c) each device bears a durable, legible, clearly visible label or labels approved by the Agency, which contain in a clearly identified and separate statement:

1. instructions and precautions necessary to assure safe installation, operation, and servicing of the device; documents such as operating and service manuals may be identified in the label and used to provide this information;

2. the requirement, or lack of requirement, for leak testing, or for testing any "on-off" mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by isotope, quantity of radioactivity, and date of determination of the quantity; and

3. the information called for in one of the following statements, as appropriate, in the same or substantially similar form:

The receipt, possession, use, and transfer of this device, Model _____, Serial No. _____, are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or a State with which the U.S. Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited. [The model, serial number, and name of the manufacturer or distributor may be omitted from the label provided the information is elsewhere specified in labeling affixed to the device.]

CAUTION - RADIOACTIVE MATERIAL

_____

Name of Manufacturer or Distributor

[Note: Devices licensed under 10 CFR 32.53 prior to January 19, 1975 may bear labels authorized by the regulations in effect on January 1, 1975.]

(d) each device having a separable source housing that provides the primary shielding for the source also bears, on the source housing, a durable label containing the device model number and serial number, the isotope and quantity, the words, "Caution-Radioactive Material", the radiation symbol described in 105 CMR 120.237, and the name of the manufacturer or initial distributor.

(e) each device meeting the criteria of 105 CMR 120 122(D)(3)(m)1., bears a permanent (*e.g.*, embossed, etched, stamped, or engraved) label affixed to the source housing if separable, or the device if the source housing is not separable, that includes the words, "Caution-Radioactive Material", and, if practicable, the radiation symbol described in 105 CMR 120.237.

(f) the device has been registered in the Sealed Source and Device Registry.

(2) In the event the applicant desires that the device be required to be tested at intervals longer than six months, either for proper operation of the "on-off" mechanism and indicator, if any, or for leakage of radioactive material or for both, the applicant shall include in the application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices and by design features which have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the "on-off" mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the Agency will consider information which includes, but is not limited to:

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a. the identity of each general licensee by name and mailing address for the location of use; if there is no mailing address for the location of use, an alternate address for the general licensee shall be submitted along with information on the actual location of use;

b. the name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;

c. the date of transfer;

d. the type, model number, and serial number of the device transferred; and

e. the quantity and type of byproduct material contained in the device.

2. If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).

3. For devices received from a general licensee, the report must include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

4. If the licensee makes changes to a device possessed by a general licensee, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the changes to information on the device label.

5. The report must cover each calendar quarter, must be filed within 30 days of the end of the calendar quarter, and must clearly indicate the period covered by the report.

6. The report must clearly identify the specific licensee submitting the report and must include the license number of the specific licensee.

7. If no transfers have been made to U.S. Nuclear Regulatory Commission Licensees during the reporting period, this information shall be reported to the U.S. Nuclear Regulatory Commission.

8. If no transfers have been made to general licensees within a particular State during the reporting period, this information shall be reported to the responsible State agency upon request of that agency.

(c) The person shall maintain all information concerning transfers and receipts of devices that supports the reports required by 105 CMR 120.128(D)(5). Records required by 105 CMR 120.128(D)(5)(c) must be maintained for a period of three years following the date of the recorded event.

(E) Special Requirements for the Manufacture, Assembly, or Repair of Luminous Safety Devices for Use in Aircraft. An application for a specific license to manufacture, assemble, or repair luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed under 105 CMR 120.122(B) will be approved if:

(1) the applicant satisfies the general requirements specified in 105 CMR 120.125; and

(2) the applicant satisfies the requirements of 10 CFR Part 32 §§ 32.53 through 32.56.

(F) Special Requirements for License to Manufacture or Initially Transfer Calibration or Reference Sources Containing Americium-241, or Radium-226 for Distribution to Persons Generally Licensed under 105 CMR 120.122(G). An application for a specific license to manufacture or initially transfer calibration or reference sources containing americium-241, or radium-226, for distribution to persons generally licensed under 105 CMR 120.122(G), will be approved if:

(1) the applicant satisfies the general requirement of 105 CMR 120.125; and

(2) The applicant submits sufficient information regarding each type of calibration or reference source pertinent to evaluation of the potential radiation exposure, including:

(a) Chemical and physical form and maximum quantity of americium-241 or radium-226 in the source;

(b) Details of construction and design;

(c) Details of the method of incorporation and binding of the americium-241 or radium-226 in the source;

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(d) Procedures for and results of prototype testing of sources, which are designed to contain more than 0.005 microcurie of americium-241 or radium-226, to demonstrate that the americium-241 or radium-226 contained in each source will not be released or be removed from the source under normal conditions of use;

(e) Details of quality control procedures to be followed in manufacture of the source;

(f) Description of labeling to be affixed to the source or the storage container for the source;

(g) Any additional information, including experimental studies and tests, required by the Commission to facilitate a determination of the safety of the source.

(3) Each source will contain no more than 5 microcuries of americium-241 or radium-226.

(4) The Agency determines, with respect to any type of source containing more than 0.005 microcurie of americium-241 or radium-226, that:

(a) The method of incorporation and binding of the americium-241 or radium-226 in the source is such that the americium-241 will not be released or be removed from the source under normal conditions of use and handling of the source; and

(b) The source has been subjected to and has satisfactorily passed the prototype tests prescribed by 10 CFR 32.57(e).

(5) Each person licensed under 105 CMR 120.128(F) shall affix to each source, or storage container for the source, a label which shall contain sufficient information relative to safe use and storage of the source and shall include the following statement or a substantially similar statement which contains the information called for in the following statement:

The receipt, possession, use, and transfer of this source, Model _____, Serial No. _____, are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or a State with which the U.S. 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 (OR RADIUM-226). DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____

Name of manufacturer or initial transferor

(6) Each person licensed under 105 CMR 120.128(F) shall perform a dry wipe test upon each source containing more than 3.7 kilobecquerels (0.1 microcurie) of americium-241 or radium-226 before transferring the source to a general licensee under 105 CMR 120.122(G) or under equivalent regulations of NRC or an Agreement State. This test shall be performed by wiping the entire radioactive surface of the source with a filter paper with the application of moderate finger pressure. The radioactivity on the filter paper shall be measured using methods capable of detecting 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226. If a source has been shown to be leaking or losing more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226 by the methods described in 105 CMR 120.128(F)(6), the source shall be rejected and shall not be transferred to a general licensee under 105 CMR 120.122(G) or equivalent regulations of NRC or an Agreement State.

(G) Requirements for Other Specific Licenses (Reserved).

(H) Manufacture and Distribution of Radioactive Material for Certain *In Vitro* Clinical or Laboratory Testing Under General License. An application for a specific license to manufacture or distribute radioactive material for use under the general license of 105 CMR 120.122(I) will be approved if:

(1) the applicant satisfies the general requirements specified in 105 CMR 120.125.

(2) the radioactive material is to be prepared for distribution in prepackaged units of:

(a) carbon-14 in units not exceeding ten microcuries (370 kBq) each.

(b) cobalt-57 in units not exceeding ten microcuries (370 kBq) each.

(c) hydrogen-3 (tritium) in units not exceeding 50 microcuries (1.85 MBq) each.

(d) iodine-125 in units not exceeding ten microcuries (370 kBq) each.

(e) Mock Iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each.

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(f) iodine-131 in units not exceeding ten microcuries (370 kBq) each.
(g) iron-59 in units not exceeding 20 microcuries (740 kBq) each.
(h) selenium-75 in units not exceeding ten microcuries (370 kBq) each.

(3) each prepackaged unit bears a durable, clearly visible label:

(a) identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed ten microcuries (370 kBq) of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; 50 microcuries (1.85 MBq) of hydrogen-3 (tritium); 20 microcuries (740 kBq) of iron-59; or Mock Iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each; or cobalt-57 in units not exceeding 0.37 megabecquerel (10 microcuries); and

(b) displaying the radiation caution symbol described in 105 CMR 120.237(A) and the words, "CAUTION, RADIOACTIVE MATERIAL", and "Not for Internal or External Use in Humans or Animals".

(4) the following statement or a substantially similar statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for *in vitro* clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a State with which the U.S. Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority.

_____
Name of Manufacturer

(5) the label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such radioactive material. In the case of the Mock Iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements set out in 105 CMR 120.251.

(I) Licensing the Manufacture and Distribution of Ice Detection Devices. An application for a specific license to manufacture and distribute ice detection devices to persons generally licensed under 105 CMR 120.122(J) will be approved if:

(1) the applicant satisfies the general requirements of 105 CMR 120.125; and
(2) the criteria of 10 CFR Part 32, §§ 32.61 and 32.62 are met.

(J) Manufacture, Preparation, or Transfer for Commercial Distribution of Drugs Containing Radioactive Material for Medical Use under 105 CMR 120.500.

(1) An application for a specific license to manufacture, prepare, or transfer for commercial distribution radioactive drugs containing radioactive material for use by persons authorized pursuant to 105 CMR 120.500 will be approved if:

(a) the applicant satisfies the general requirements specified in 105 CMR 120.125;
(b) the applicant submits evidence that the applicant is at least one of the following:
1. registered or licensed with the U.S. Food and Drug Administration (FDA) as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR 207.20(a);
2. registered or licensed with a State agency as a drug manufacturer;
3. licensed as a pharmacy by a State Board of Pharmacy;
4. operating as a nuclear pharmacy pursuant to 247 CMR 13.00: *Registration Requirements and Minimal Professional Standards for Nuclear Pharmacies*;
5. operating as a nuclear pharmacy within a Federal medical institution; or
6. a Positron Emission Tomography (PET) drug production facility registered with a State agency.

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(a) perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and

(b) check each instrument for constancy and proper operation at the beginning of each day of use.

(4) Nothing in 105 CMR 120.128(J) relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

(K) Manufacture and Distribution of Generators or Reagent Kits for Preparation of Radiopharmaceuticals Containing Radioactive Material[5]. An application for a specific license to manufacture and distribute generators or reagent kits containing radioactive material for preparation of radiopharmaceuticals by persons licensed pursuant to 105 CMR 120.100 for the uses listed in 105 CMR 120.547 will be approved if:

(1) the applicant satisfies the general requirements specified in 105 CMR 120.125;

(2) the applicant submits evidence that:

(a) the generator or reagent kit is to be manufactured, labeled and packaged in accordance with the Federal Food, Drug and Cosmetic Act or the Public Health Service Act, such as a new drug application (NDA) approved by the Food and Drug Administration (FDA), or a "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by the FDA; or

(b) the manufacture and distribution of the generator or reagent kit are not subject to the Federal Food, Drug and Cosmetic Act and the Public Health Service Act.

(3) the applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material contained in the generator or reagent kit;

(4) the label affixed to the generator or reagent kit contains information on the radionuclide, quantity, and date of assay; and

(5) the label affixed to the generator or reagent kit, or the leaflet or brochure which accompanies the generator or reagent kit, contains:

(a) adequate information, from a radiation safety standpoint, on the procedures to be followed and the equipment and shielding to be used in eluting the generator or processing radioactive material with the reagent kit; and

(b) a statement that this generator or reagent kit, as appropriate, is approved for use by persons licensed by the Agency pursuant to 105 CMR 120.547 or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State. The labels, leaflets, or brochures required by 105 CMR 120.128(K) are in addition to the labeling required by the Food and Drug Administration (FDA) and they may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA.

(L) Manufacture and Distribution of Sources or Devices Containing Radioactive Material for Medical Use. An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to 105 CMR 120.500 for use as a calibration, transmission, or reference source or for the uses listed in 105 CMR 120.559, 120.568, 120.570 and 120.589 will be approved if:

(1) the applicant satisfies the general requirements in 105 CMR 120.125;

(2) the applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:

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[5] Although the Agency does not regulate the manufacture and distribution of reagent kits that do not contain radioacitve material, it does regulate the use of such reagent kits for the preparation of radiopharmaceuticals containing radioactive material as part of its licensing and regulation of the users of radioactive material. Any manufacturer of reagent kits that do not contain radioactive material who desires to have his reagent kits approved by the Agency for use by persons licensed pursuant to 105 CMR 120.547 may submit the pertinent information specified in 105 CMR 120.128(K).

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(a) the radioactive material contained, its chemical and physical form, and amount;
(b) details of design and construction of the source or device;
(c) procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents;
(d) for devices containing radioactive material, the radiation profile of a prototype device;
(e) details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests;
(f) procedures and standards for calibrating sources and devices;
(g) legend and methods for labeling sources and devices as to their radioactive content; and
(h) instructions for handling and storing the source or device from the radiation safety standpoint; these instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device; provided, that instructions which are too lengthy for such label may be summarized on the label and printed in detail on a brochure which is referenced on the label.

(3) the label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity, and date of assay, and a statement that the Agency has approved the distribution of the (name of source or device) to persons licensed to use radioactive material identified in 105 CMR 120.535, 120.559, 120.568, and 120.570 or under equivalent licenses of the U.S. Nuclear Regulatory Commission or an Agreement State;
(4) the source or device has been registered in the Sealed Source and Device Registry;
(5) in the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than six months, he or she shall include in his or her application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source; and
(6) in determining the acceptable interval for test of leakage of radioactive material, the Agency will consider information that includes, but is not limited to:
(a) primary containment or source capsule;
(b) protection of primary containment;
(c) method of sealing containment;
(d) containment construction materials;
(e) form of contained radioactive material;
(f) maximum temperature withstood during prototype tests;
(g) maximum pressure withstood during prototype tests;
(h) maximum quantity of contained radioactive material;
(i) radiotoxicity of contained radioactive material; and
(j) operating experience with identical sources or devices or similarly designed and constructed sources or devices.

(M) Requirements for License to Manufacture and Distribute Industrial Products Containing Depleted Uranium for Mass-volume Applications.

(1) An application for a specific license to manufacture industrial products and devices containing depleted uranium for use pursuant to 105 CMR 120.121(E) or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State will be approved if:
(a) the applicant satisfies the general requirements specified in 105 CMR 120.125;
(b) the applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses, and potential hazards of the industrial product or device to provide reasonable assurance that possession, use, or transfer of the depleted uranium in the product or device is not likely to cause any individual to receive a radiation dose in excess of 10% of the annual limits specified in 105 CMR 120.211(A); and

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3. such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the Agency and the general licensee, the type and model number of the device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such product or device is transferred to the generally licensed person;

4. if no transfers have been made to U.S. Nuclear Regulatory Commission licensees during the reporting period, this information shall be reported to the U.S. Nuclear Regulatory Commission; and

5. if no transfers have been made to general licensees within a particular Agreement State during the reporting period, this information shall be reported to the responsible Agreement State agency upon the request of that agency.

(g) keep records showing the name, address, and point of contact for each general licensee to whom he or she transfers depleted uranium in industrial products or devices for use pursuant to the general license provided in 105 CMR 120.121(E) or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State. The records shall be maintained for a period of two years and shall show the date of each transfer, the quantity of depleted uranium in each product or device transferred, and compliance with the report requirements of 105 CMR 120.100.

(N) Sealed Source and Device Registration - Registration of Product Information and Inactivation of Certificates of Registration of Sealed Sources and Devices.

(1) Any manufacturer or initial distributor of a sealed source or device containing a sealed source may submit a request to the Agency for evaluation of radiation safety information about its product and for its registration.

(2) The request for review must be sent to the Agency in duplicate by an appropriate method listed in 105 CMR 120.013.

(3) The request for review of a sealed source or a device must include sufficient information about the design, manufacture, prototype testing, quality control program, labeling, proposed uses and leak testing and, for a device, the request must also include sufficient information about installation, service and maintenance, operating and safety instructions, and its potential hazards, to provide reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property.

(4) The Agency normally evaluates a sealed source or a device using radiation safety criteria in accepted industry standards. If these standards and criteria do not readily apply to a particular case, the Agency formulates reasonable standards and criteria with the help of the manufacturer or distributor. The Agency shall use criteria and standards sufficient to ensure that the radiation safety properties of the device or sealed source are adequate to protect health and minimize danger to life and property.

(5) After completing the evaluation and determining that requirements for registration have been met, the Agency shall issue a certificate of registration to the person making the request. The certificate of registration acknowledges the availability of the submitted information for inclusion in an application for a specific license proposing use of the product, or concerning use under an exemption from licensing or general license as applicable for the category of certificate.

(6) The person submitting the request for evaluation and registration of safety information about the product shall manufacture and distribute the product in accordance with:

(a) The statements and representations, including quality control program, contained in the request; and

(b) The provisions of the registration certificate.

(7) Authority to manufacture or initially distribute a sealed source or device to specific licensees may be provided in the license without the issuance of a certificate of registration in the following cases:

(a) Calibration and reference sources containing no more than:

1. 37 MBq (1 mCi), for beta and/or gamma emitting radionuclides; or
2. 0.37 MBq (10 μCi), for alpha emitting radionuclides; or

120.128: continued

(b) The intended recipients are qualified by training and experience and have sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material in any form in the case of unregistered sources or, for registered sealed sources contained in unregistered devices, are qualified by training and experience and have sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material in unshielded form, as specified in their licenses; and

1. The intended recipients are licensed under 105 CMR 120.127 or comparable provisions of NRC or an Agreement State;
2. The recipients are authorized for research and development; or
3. The sources and devices are to be built to the unique specifications of the particular recipient and contain no more than 740 GBq (20 Ci) of tritium or 7.4 GBq (200 mCi) of any other radionuclide.

(8) After the certificate is issued, the Agency may conduct an additional review as it determines is necessary to ensure compliance with current regulatory standards. In conducting its review, the Agency will complete its evaluation in accordance with criteria specified in 105 CMR 120.128(N). The Agency may request such additional information as it considers necessary to conduct its review and the certificate holder shall provide the information as requested.

(9) A certificate holder who no longer manufactures or initially transfers any of the sealed source(s) or device(s) covered by a particular certificate issued by the Agency shall request inactivation of the registration certificate. Such a request must be made to the Agency by an appropriate method listed in 105 CMR 120.013 and must normally be made no later than two years after initial distribution of all of the source(s) or device(s) covered by the certificate has ceased. However, if the certificate holder determines that an initial transfer was in fact the last initial transfer more than two years after that transfer, the certificate holder shall request inactivation of the certificate within 90 days of this determination and briefly describe the circumstances of the delay.

(10) If a distribution license is to be terminated in accordance with 105 CMR 120.132, the licensee shall request inactivation of its registration certificates associated with that distribution license before the Agency will terminate the license. Such a request for inactivation of certificate(s) must indicate that the license is being terminated and include the associated specific license number.

(11) A specific license to manufacture or initially transfer a source or device covered only by an inactivated certificate no longer authorizes the licensee to initially transfer such sources or devices for use. Servicing of devices must be in accordance with any conditions in the certificate, including in the case of an inactive certificate.

120.130: Issuance of Specific Licenses

(A)(1) Upon a determination that an application meets the requirements of M.G.L. c. 111, §§ 3, 5M through 5P and 105 CMR 120.000 and upon payment of the required fee as specified in 105 CMR 120.130(A)(2), the Agency will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.

(2) Each initial application for a license or a certificate of registration for which a fee is established in 801 CMR 4.00: *Rates* shall be accompanied by a nonrefundable fee, payable to the Commonwealth of Massachusetts, in the amount specified for the corresponding annual fee. Thereafter, the Radiation Control Program will issue an annual fee invoice based on the applicable annual fee specified in 801 CMR 4.00. Fees are payable within 30 days after receipt of a fee invoice.

(B) The Agency may incorporate in any license at the time of issuance, or thereafter by appropriate rule, regulation, or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use, and transfer of radioactive material subject to 105 CMR 120.100 as it deems appropriate or necessary in order to:

(1) minimize danger to public health and safety or property;

(2) require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be appropriate or necessary; and

(3) prevent loss or theft of material subject to 105 CMR 120.100.

120.131: Specific Terms and Conditions of Licenses

(A) Each license issued pursuant to 105 CMR 120.000 shall be subject to all the provisions of M.G.L. c. 111, §§ 3, 5M through 5P, and to all rules, regulations, orders of the Agency and license conditions as provided for in 105 CMR 120.130(B).

(B) (1) No license issued or granted under 105 CMR 120.000 and no right to possess or utilize radioactive material granted by any license issued pursuant to 105 CMR 120.131 shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the Agency shall, after securing full information find that the transfer is in accordance with the provisions of M.G.L. c. 111, §§ 3, 5M through 5P, and to all valid rules, regulations, and orders of the Agency, and shall give its consent in writing.

(2) An application for transfer of license must include:

1. The identity, technical and financial qualifications of the proposed transferee; and
2. Financial assurance for decommissioning information required by 105 CMR 120.125(C), as applicable.

(C) Each person licensed by the Agency pursuant to 105 CMR 120.100 shall confine use and possession of the material licensed to the locations and purposes authorized in the license. Preparation for shipment and transport of byproduct material shall be in accordance with the provisions of 10 CFR Part 71 and 105 CMR 120.770.

(D) Each licensee shall notify the Agency in writing when the licensee decides to permanently discontinue all activities involving materials authorized under the license.

(E) Each licensee shall notify the Agency 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:

(1) the licensee;

(2) an entity (as that term is defined in 11 U.S:C. 101(15)) controlling the licensee or listing the license or licensee as property of the estate; or

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

(F) The notification specified in 105 CMR 120.131(E) shall indicate the bankruptcy court in which the petition for bankruptcy was filed and the date of the filing of the petition.

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

(H) 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 105 CMR 120.548. The licensee shall record the results of each test and retain each record for three years after the record is made.

(I) (1) Authorization under 105 CMR 120.128(A) to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

(2) Each licensee authorized under 105 CMR 120.128(A) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:

1. Satisfy the labeling requirements in 105 CMR 120.128(J)(1)(d) 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.
2. Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in 105 CMR 120.128(J)(3).

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(5) other site-specific factors which the Agency may consider appropriate on a case-by-case basis, such as the regulatory requirements of other government agencies, lawsuits, ground-water treatment activities, monitored natural ground-water restoration, actions that could result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensee.

(J) As the final step in decommissioning, the licensee shall:
(1) Certify the disposition of all licensed material including accumulated wastes, by submitting a completed Agency Form MRCP 120.100-3 or equivalent information; and,
(2) Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey unless the licensee demonstrates that the premises are suitable for release in some other manner. The licensee shall, as appropriate:
(a) Report levels of gamma radiation in units of millisieverts (microroentgen) per hour at one meter from surfaces, and report levels of radioactivity, including alpha and beta, in units of megabecquerels (disintegrations per minute or microcuries) per 100 square centimeters - removable and fixed - for surfaces, megabecquerels (microcuries) per milliliter for water, and becquerels (picocuries) per gram for solids such as soils or concrete; and
(b) Specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.

(K) Specific licenses, including expired licenses, will be terminated by written notice to the licensee when the Agency determines that:
(1) radioactive material has been properly disposed;
(2) reasonable effort has been made to eliminate residual radioactive contamination, if present; and
(3) (a) a radiation survey has been performed which demonstrates that the premises are suitable for release in accordance with Agency requirements; or
(b) other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with Agency requirements.

120.133: Renewal of Licenses

(A) Applications for renewal of specific licenses shall be filed in accordance with 105 CMR 120.124.

(B) In any case in which a licensee, not less than 30 days prior to expiration of his existing license, has filed an application in proper form for renewal or for a new license authorizing the same activities, such existing license shall not expire until final action by the Agency.

120.134: Amendment of Licenses and Registration Certificates at Request of Licensee

(A) Applications for amendment of a license shall be filed in accordance with 105 CMR 120.124 and shall specify the respects in which the licensee desires the license to be amended and the grounds for such amendment. Applications for amendment of sealed source and device registration certificates must be filed in accordance with 105 CMR 120.128(N) and any other applicable provisions and must specify the respects in which the certificate holder desires its certificate to be amended and the grounds for the amendment.

(B) An invoice for an amendment fee will be issued on receipt of a request to amend a license. The amendment will not be issued until after the invoiced amount has been paid.

120.135: Agency Action on Applications to Renew or Amend

In considering an application by a licensee to renew or amend the license or to amend a sealed source or device registration certificate, the Agency will apply the criteria set forth in 105 CMR 120.125, 120.126, 120.127, and 120.128 and in 120.300, 120.500, 120.800 or 120.900, as applicable.

120.198: Appendix D: 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. 105 CMR 120.198: *Appendix D* establishes 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 II.A.1 or II.A.2:

(1) The parent company must have:

(a) 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;

(b) 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);

(c) Tangible net worth of at least $21 million; and

(d) Assets located in the United States amounting to at least 90% 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:

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

(b) Tangible net worth at least six times the current decommissioning cost estimate (or prescribed amount if a certification is used);

(c) Tangible net worth of at least $21 million; and

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

(B) The parent company's independent certified public accountant must have compared the data used by the parent company in the financial test, which is derived from the independently audited, year-end financial statement. In connection with that procedure, the licensee shall inform the Agency within 90 days of any matters coming to the auditor's attention that 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 II.A, the licensee must send notice to the Agency of intent to establish alternate financial assurance as specified in the Agency's regulations. 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.

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III. Parent Company Guarantee. The terms of a parent company guarantee that 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 Agency. 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 Agency, as evidenced by the return receipts.

(B) If the licensee fails to provide alternate financial assurance as specified in the Agency's regulations within 90 days after receipt by the licensee and the Agency 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 Agency has terminated the license.

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

120.198: Appendix E: 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 105 CMR 120.198: *Appendix E*, Section II. The terms of the self-guarantee are in 105 CMR 120.198: *Appendix E*, Section III. 105 CMR 120.198: *Appendix E* 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 following criteria:

(1) Tangible net worth of at least $21 million, and at least ten times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.

(2) Assets located in the United States amounting to at least 90% of total assets or at least ten times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.

(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 Poors (S&P), 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 have compared 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. In connection with that procedure, the licensee shall inform the Agency within 90 days of any matters coming to the attention of the auditor that 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 repeat passage of the test within 90 days after the close of each succeeding fiscal year.

(C) If the licensee no longer meets the requirements of 105 CMR 120.198: *Appendix E*, Section II.(A), the licensee must send immediate notice to the Agency of its intent to establish alternate financial assurance as specified in the Agency'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 Agency. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by the Agency, as evidenced by the return receipts.

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

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

(D) The licensee will promptly forward to the Agency 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) If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poors or Moodys, the licensee will provide notice in writing of such fact to the Agency within 20 days after publication of the change by the rating service. If the licensee's most recent bond issuance ceases to be rated in any category of A or above by both Standard and Poors and Moodys, the licensee no longer meets the requirements of 105 CMR 120 198: *Appendix E*, Section II.(A).

(F) The applicant or licensee must provide to the Agency 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 Agency, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

120.198: Appendix F: Criteria Relating to Use of Financial Tests and Self Guarantees for Providing Reasonable Assurance of Funds for Decommissioning by Commercial Companies That Have No Outstanding Rated Bonds

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 105 CMR 120.198: *Appendix F*, Section II. The terms of the self-guarantee are in 105 CMR 120.198: *Appendix F*, Section III. 105 CMR 120.198: *Appendix F* 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 following criteria:

(1) Tangible net worth greater than $21 million, or at least ten times the total current decommissioning cost estimate (or the current amount required if certification is used) whichever is greater, for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.

(2) Assets located in the United States amounting to at least 90% of total assets or at least ten times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.

(3) A ratio of cash flow divided by total liabilities greater than 0.15 and a ratio of total liabilities divided by net worth less than 1.5.

(B) In addition, to pass the financial test, a company must meet all of the following additional requirements:

(1) The company's independent certified public accountant must have compared the data used by the company in the financial test, which is required to be derived from the independently audited year end financial statement based on United States generally accepted accounting practices for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform the Agency within 90 days of any matters that may 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.

(2) After the initial financial test, the company must repeat passage of the test within 90 days after the close of each succeeding fiscal year.

(3) If the licensee no longer meets the requirements of 105 CMR 120.198: *Appendix F*, Section II.(A), the licensee must send immediate notice to the Agency of its intent to establish alternate financial assurance as specified in 105 CMR 120.125(C). The notice must be sent by certified mail, return receipt requested, within 90 days after the end of the fiscal year for which the year end financial data show that the licensee no longer meets the financial test requirements. The licensee must provide alternative financial assurance within 120 days after the end of such fiscal year.

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

(A) The guarantee shall remain in force unless the licensee sends notice of cancellation by certified mail, return receipt requested, to the Agency. Cancellation may not occur until an alternative financial assurance mechanism is in place.

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

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

(D) The applicant or licensee must provide to the Agency 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 Agency, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

120.198: Appendix G: Criteria Relating to Use of Financial Tests and Self Guarantee for Providing Reasonable Assurance of Funds for Decommissioning by Nonprofit Colleges, Universities, and Hospitals

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 applicant or licensee passes the financial test of 105 CMR 120.198: *Appendix G*, Section II. The terms of the self-guarantee are in 105 CMR 120.198: *Appendix G*, Section III. 105 CMR 120.198: *Appendix G* establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee.

II. Financial Test.

(A) For colleges and universities, to pass the financial test a college or university must meet either the criteria in 105 CMR 120.198: *Appendix G*, Section II.(A)(1) or the criteria in 105 CMR 120.198: *Appendix G*, Section II.(A)(2).

(1) For applicants or licensees that issue bonds, a current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A (including adjustments of + or -) as issued by Standard and Poor's (S&P) or Aaa, Aa, or A (including adjustments of 1, 2, or 3) as issued by Moody's.

(2) For applicants or licensees that do not issue bonds, unrestricted endowment consisting of assets located in the United States of at least $50 million, or at least 30 times the total current decommissioning cost estimate (or the current amount required if certification is used), whichever is greater, for all decommissioning activities for which the college or university is responsible as a self-guaranteeing licensee.

(B) For hospitals, to pass the financial test a hospital must meet either the criteria in 105 CMR 120.198: *Appendix G*, Section II.(B)(1) or the criteria in 105 CMR 120.198: *Appendix G*, Section II.(B)(2):

(1) For applicants or licensees that issue bonds, a current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A (including adjustments of + or -) as issued by Standard and Poor's (S&P) or Aaa, Aa, or A (including adjustments of 1, 2, or 3) as issued by Moody's.

(2) For applicants or licensees that do not issue bonds, all the following tests must be met:

(a) (Total Revenues less total expenditures) divided by total revenues must be equal to or greater than 0.04.

(b) Long term debt divided by net fixed assets must be less than or equal to 0.67.

(c) (Current assets and depreciation fund) divided by current liabilities must be greater than or equal to 2.55.

(d) Operating revenues must be at least 100 times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the hospital is responsible as a self-guaranteeing license.

(C) In addition, to pass the financial test, a licensee must meet the following requirements: (for institutions using 105 CMR 120.198: *Appendix G*: Section II, (A)(2) method of qualifying; for a self-guarantee 105 CMR 120.198: *Appendix G*: Sections II(C)(1) and II(C)(2) will apply.

(1) The licensee's independent certified public accountant must have compared the data used by the licensee in the financial test, which is required to be derived from the independently audited year end financial statements, based on United States generally accepted accounting practices, for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform the Agency within 90 days of any matters coming to the attention of the auditor that cause the auditor to believe that the data specified in the financial test should be adjusted and that the licensee no longer passes the test.

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(2) After the initial financial test, the licensee must repeat passage of the test within 90 days after the close of each succeeding fiscal year.

(3) If the licensee no longer meets the requirements of 105 CMR 120.198: *Appendix G*: Section I, the licensee must send notice to the Agency of its intent to establish alternative financial assurance as specified in Agency regulations. The notice must be sent by certified mail, return receipt requested, within 90 days after the end of the fiscal year for which the year end financial data show that the licensee 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. Self-guarantee. The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

(A) The guarantee shall remain in force unless the licensee sends notice of cancellation by certified mail, and/or return receipt requested, to the Agency. Cancellation may not occur unless an alternative financial assurance mechanism is in place.

(B) The licensee shall provide alternative financial assurance as specified in 105 CMR 120.125(C) within 90 days following receipt by the Agency of a notice of cancellation of the guarantee.

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

(D) The applicant or licensee must provide to the Agency a written guarantee (a written commitment by a corporate officer or officer of the institution) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the Agency, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

(E) If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poor's or Moody's, the licensee shall provide notice in writing of such fact to the Agency within 20 days after publication of the change by the rating service.

(F) If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poor's or Moody's, the licensee will provide notice in writing of such fact to the Agency within 20 days after publication of the change by the rating service. If the licensee's most recent bond issuance ceases to be rated in any category of A or above by both Standard and Poor's and Moody's, the licensee no longer meets the requirements of 105 CMR 120 199: *Appendix E*, Section II.(A).

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

(F) The licensee or registrant shall immediately withdraw a leaking sealed source from use and shall take action to prevent the spread of contamination. The leaking sealed source shall be repaired or disposed of in accordance with this 105 CMR 120.200.

(G) Reports of test results for leaking or contaminated sealed sources shall be made pursuant to 105 CMR 120.288.

SURVEYS AND MONITORING

120.225: General

(A) Each licensee or registrant shall make, or cause to be made, surveys of areas, including the subsurface, that:

(1) are necessary for the licensee or registrant to comply with 105 CMR 120.200; and

(2) are necessary under the circumstances to evaluate:

(a) the magnitude and extent of radiation levels;

(b) concentrations or quantities of radioactive material residual radioactivity; and

(c) the potential radiological hazards of the radiation levels and residual radioactivity detected.

(B) Notwithstanding the provisions in 105 CMR 120.263(A), records from surveys describing the location and amount of subsurface residual radioactivity identified at the site must be kept with records important for decommissioning, and such records must be retained in accordance with 105 CMR 120.125(C)(8), as applicable.

(C) The licensee or registrant shall ensure that instruments and equipment used for quantitative radiation measurements, for example, dose rate and effluent monitoring, are calibrated at intervals not to exceed 12 months for the radiation measured except when a more frequent interval is specified in another applicable section of 105 CMR 120.000 or license condition.

(D) All personnel dosimeters, except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to any extremity, that require processing to determine the radiation dose and that are used by licensees and registrants to comply with 105 CMR 120.211, with other applicable provisions of 105 CMR 120.000, or with conditions specified in a license or certificate of registration, shall be processed and evaluated by a dosimetry processor:

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

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

(E) The licensee or registrant shall ensure that adequate precautions are taken to prevent a deceptive exposure of an individual monitoring device.

120.226: Conditions Requiring Individual Monitoring of External and Internal Occupational Dose

Each licensee or registrant shall monitor exposures from sources of radiation at levels sufficient to demonstrate compliance with the occupational dose limits of 105 CMR 120.200. As a minimum:

(A) Each licensee or registrant shall monitor occupational exposure to radiation from licensed and unlicensed radiation sources under its control and shall supply and require the use of individual monitoring devices by:

(1) adults likely to receive, in one year from sources external to the body, a dose in excess of 10% of the limits in 105 CMR 120.211(A);

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(2) minors likely to receive, in one year from sources external to the body, a deep dose equivalent in excess of one millisievert (0.1 rem) a lens dose equivalent in excess of 1.5 millisievert (0.15 rem), or a shallow dose equivalent to the skin or to the extremities in excess of five millisieverts (0.5 rem);

(3) Declared pregnant women likely to receive during the entire pregnancy, from radiation sources external to the body, a deep dose equivalent in excess of one millisievert (0.1 rem). [Note: All of the occupational doses in 105 CMR 120.211 continue to be applicable to the declared pregnant worker as long as the embryo/fetus dose limit is not exceeded];

(4) individuals entering a high or very high radiation area;

(5) individuals working medical fluoroscopic equipment.

(a) An individual monitoring device used for the dose to an embryo/fetus of a declared pregnant woman, pursuant to 105 CMR 120.218(A), shall be located under the protective apron at the waist.

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

(c) When only one individual monitoring device is used to determine the effective dose equivalent for external radiation pursuant to 105 CMR 120.211(C)(2), it shall be located at the neck (collar) outside the protective apron. When a second individual monitoring device is used, for the same purpose, it shall be located under the protective apron at the waist. The second individual monitoring device is required for a declared pregnant woman.

(B) Each licensee shall monitor, to determine compliance with 105 CMR 120.214, the occupational intake of radioactive material by and assess the committed effective dose equivalent to:

(1) adults likely to receive, in one year, an intake in excess of 10% of the applicable ALI in 105 CMR 120.296: *Appendix B*, Table I, Columns 1 and 2; and

(2) minors likely to receive, in one year, a committed effective dose equivalent in excess of 0.1 millisievert (0.01 rem).

(3) declared pregnant women likely to receive, during the entire pregnancy, a committed effective dose equivalent in excess of 1m Sv (0.1 rem).

(C) Each licensee or registrant shall ensure that individuals who are required to monitor occupational doses in accordance with 105 CMR 120.226(A) wear individual monitoring devices as follows:

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

(2) An individual monitoring device used for monitoring the dose to an embryo/fetus of a declared pregnant woman, pursuant to 105 CMR 120.218(A), shall be located at the waist under any protective apron being worn by the woman.

(3) An individual monitoring device used for monitoring lens dose equivalent, to demonstrate compliance with 105 CMR 120.211(A)(2)(a), shall be located at the neck (collar), outside any protective apron being worn by the monitored individual, or at an unshielded location closer to the eye.

(4) An individual monitoring device used for monitoring the dose to the extremities, to demonstrate compliance with 105 CMR 120.211(A)(2)(b), shall be worn on the extremity most likely to receive the highest exposure. Each individual monitoring device shall be oriented to measure the highest dose to the extremity being monitored.

120.227: Control of Access to High Radiation Areas

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

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

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(F) Licensees or registrants transferring special form sources in vehicles owned or operated by the licensee to and from a work site are exempt from the contamination monitoring requirements of 105 CMR 120.246(B), but are not exempt from the monitoring requirement in 105 CMR 120.246(B) for measuring radiation levels that ensures that the source is still properly lodged in its shield.

120.243: Vacating Premises

Each licensee, registrant, or person possessing non-exempt sources of radiation shall, no less than 30 days before vacating or relinquishing possession or control of premises which may have been contaminated with radioactive material as a result of his activity, notify the Agency, in writing, of the intent to vacate. When deemed necessary by the Agency, the licensee, registrant, or person possessing non-exempt sources of radiation shall decontaminate the premises in such a manner as the Agency may specify.

RADIOLOGICAL CRITERIA FOR LICENSE TERMINATION

120.244: General Provisions and Scope

The criteria in 105 CMR 120.244 apply to the decommissioning of facilities licensed under 105 CMR 120.100,120.300, 120.500, 120.800 and 120.900.

(A) The criteria in 105 CMR 120.244 does not apply to sites, which have been decommissioned prior to October 6, 2006.

(B) After a site has been decommissioned and the license terminated in accordance with the criteria in 105 CMR 120.244, the Agency will require additional cleanup only if, based on new information, it determines that the criteria of 105 CMR 120.244 were not met and residual radioactivity remaining at the site could result in significant threat to public health and safety.

(C) When calculating TEDE to the average member of the critical group the licensee shall determine the peak annual TEDE dose expected within the first 1000 years after decommissioning.

(D) Specific time limits for completion of the decommissioning process are as specified in 105 CMR 120.132(G).

(1) Licensees shall complete decommissioning of the site or separate building or outdoor area as soon as practicable but not later than 24 months following the initiation of decommissioning.

(2) When decommissioning involves the entire site, the licensee shall request license termination as soon as practicable but not later than 24 months following the initiation of decommissioning.

(E) The Agency may approve a request for an alternative schedule for completion of the decommissioning of the site or separate building or outdoor area, and license termination is appropriate, if the Agency determines that the alternative is warranted.

120.245: Radiological Criteria for Unrestricted Use

A site will be considered acceptable for unrestricted use if the residual radioactivity that is distinguishable from background radiation results in a TEDE to an average member of the critical group that shall not exceed 0.10 mSv (10 mrem) per year, including that from groundwater sources of drinking water and the residual radioactivity has been reduced to levels that are as low as reasonably achievable (ALARA). Determination of the levels, which are ALARA, must take into account consideration of any detriments, such as deaths from transportation accidents, expected to potentially result from decontamination and waste disposal.

120.246: Criteria for License Termination Under Restricted Conditions

A site will be considered acceptable for license termination under restricted conditions if:

120.246: continued

(A) The licensee can demonstrate that further reductions in residual radioactivity necessary to comply with the provisions of 105 CMR 120.245 would result in net public or environmental harm or were not being made because the residual levels associated with restricted conditions are ALARA. Determination of the levels, which are ALARA must take into account consideration of any detriments, such as deaths from transportation accidents, expected to potentially result from decontamination and waste disposal;

(B) The licensee has made provisions for legally enforceable institutional controls that provide reasonable assurance that TEDE from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 0.10 mSv (10 mrem) per year;

(C) The licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site. Acceptable financial assurance mechanisms are:

(1) Funds placed into a trust segregated from the licensee's assets and outside the licensee's administrative control, and in which the adequacy of the trust funds is to be assessed based on an assumed annual 1% real rate of return on investment;

(2) A statement of intent in the case of State, or local Government licensees, as described in 105 CMR 120.125(C)(7)(d); or

(3) When a governmental entity is assuming custody and ownership of a site, an arrangement that is deemed acceptable by such governmental entity.

(D) The licensee has submitted a decommissioning plan or License Termination Plan (LTP) to the Agency indicating the licensee's intent to decommission in accordance with 105 CMR 120.132(D), and specifying that the licensee intends to decommission by restricting use of the site. The licensee shall document in the LTP or decommissioning plan how the advice of individuals and institutions in the community who may be affected by the decommissioning has been sought and incorporated, as appropriate, following analysis of that advice.

(1) Licensees proposing to decommission by restricting use of the site shall seek advice from such affected parties regarding the following matters concerning the proposed decommissioning:

(a) Whether provisions for institutional controls proposed by the licensee:

1. Will provide reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 0.10 mSv (10 mrem) TEDE per year;
2. Will be enforceable; and
3. Will not impose undue burdens on the local community or other affected parties.

(b) Whether the licensee has provided sufficient financial assurance to enable a third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site;

(2) In seeking advice on the issues identified in 105 CMR 120.246D(1), the licensee shall provide for:

(a) Participation by representatives of a broad cross section of community interests who may be affected by the decommissioning;

(b) An opportunity for a comprehensive, collective discussion on the issues by the participants represented; and

(c) A publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues.

(E) Residual radioactivity at the site has been reduced so that if the institutional controls were no longer in effect, there is reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group is as low as reasonably achievable and would not exceed either:

(1) 1mSv (100 mrem) per year; or

(2) 5mSv (500 mrem) per year provided the licensee:

(a) Demonstrates that further reductions in residual radioactivity necessary to comply with the one mSv/yr (100 mrem/yr) value of 105 CMR 120.246(E)(1) are not technically achievable, would be prohibitively expensive, or would result in net public or environmental harm;

120.246: continued

(b) Makes provisions for durable institutional controls;
(c) Provides sufficient financial assurance to enable a responsible government entity or independent third party, including a governmental custodian of a site, both to carry out periodic rechecks of the site no less frequently than every three years to assure that the institutional controls remain in place as necessary to meet the criteria of 105 CMR 120.246(B) and to assume and carry out responsibilities for any necessary control and maintenance of those controls. Acceptable financial assurance mechanisms are those in 105 CMR 120.246(C).

120.247: Alternate Criteria for License Termination

(A) The Agency may terminate a license using alternate criteria greater than the dose criterion of 105 CMR 120.245, 120.246(B), and 120.246(D)(1)(a)1., if the licensee:
(1) Provides assurance that public health and safety would continue to be protected, and that it is unlikely that the dose from all man-made sources combined, other than medical, would be more than the one mSv/yr (100 mrem/yr) limit, by submitting an analysis of possible sources of exposure;
(2) Has employed to the extent practical restrictions on the site use according to the provisions of 105 CMR 120.246 in minimizing exposures at the site; and
(3) Reduces doses to ALARA levels, taking into consideration any detriments such as traffic accidents expected to potentially result from decontamination and waste disposal.
(4) Has submitted a decommissioning plan or License Termination Plan (LTP) to the Agency indicating the licensee's intent to decommission in accordance with 105 CMR 120.132(D), and specifying that the licensee proposes to decommission by use of alternate criteria. The licensee shall document in the decommissioning plan or LTP how the advice of individuals and institutions in the community who may be affected by the decommissioning has been sought and addressed, as appropriate, following analysis of that advice. In seeking such advice, the license shall provide for:
(a) Participation by representatives of a broad cross section of community interests who may be affected by the decommissioning;
(b) An opportunity for a comprehensive, collective discussion on the issues by the participants represented; and
(c) A publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues.
(5) Has provided sufficient financial assurance in the form of a trust fund to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site.

(B) The use of alternate criteria to terminate a license requires the approval of the Agency after consideration of the Agency's staff's recommendations that will address any comments by other appropriate agencies and any public comments submitted pursuant to 105 CMR 120.248.

120.248: Public Notification and Public Participation

Upon the receipt of an LTP or decommissioning plan from the licensee, or a proposal by the licensee for release of a site pursuant to 105 CMR 120.246 and 120.247, or whenever the Agency deems such notice to be in the public interest, the Agency shall:

(A) Notify and solicit comments from:
(1) Local governments in the vicinity of the site and any Indian Nation or other indigenous people that have treaty or statutory rights that could be affected by the decommissioning; and
(2) Other appropriate agencies for cases where the licensee proposes to release a site pursuant to 105 CMR 120.247.

(B) Publish a notice in a forum, such as local newspapers, letters to State or local organizations, or other appropriate forum, that is readily accessible to individuals in the vicinity of the site, and solicit comments from affected parties.

120.249: Minimization of Contamination

(A) Applicants for licenses, after July 1, 1999, shall describe in the application how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste.

(B) Licensees shall, to the extent practical, conduct operations to minimize the introduction of residual radioactivity into the site, including the subsurface, in accordance with the existing radiation protection requirements in 105 CMR 120.210 and radiological criteria for license termination in 105 CMR 120.244 through 120.249.

120.251: General Requirements

(A) Unless otherwise exempted, a licensee shall transfer waste containing licensed material for disposal, discharge or decay only:

(1) by transfer to an authorized recipient as provided in 105 CMR 120.256 or in 105 CMR 120.100, or 105 CMR 120.800, or to the U.S. Department of Energy;
(2) by decay in storage;
(3) by release in effluents within the limits in 105 CMR 120.221; or
(4) as authorized pursuant to 105 CMR 120.253 or 120.254.

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

(1) treatment prior to disposal;
(2) treatment by incineration;
(3) decay in storage;
(4) disposal at a land disposal facility licensed pursuant to 105 CMR 120.800; or
(5) storage until transferred to a storage or disposal facility authorized to receive the waste.

120.252: Method for Obtaining Approval of Proposed Disposal Procedures

A licensee or registrant or applicant for a license or registration may apply to the Agency for approval of proposed procedures, not otherwise authorized in 105 CMR 120.000, to dispose of licensed or registered material generated in the licensee's or registrant's operations. Each application shall include:

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

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

(C) The nature and location of other potentially affected facilities; and

(D) Analyses and procedures to ensure that doses are maintained ALARA and within the dose limits in 105 CMR 120.200.

120.253: Discharge by Release into Sanitary Sewerage

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

(1) the material is readily soluble, or is readily dispersible biological material, in water;
(2) the quantity of licensed radioactive material that the licensee releases into the sewer in one month divided by the average monthly volume of water released into the sewer by the licensee does not exceed the concentration listed in 105 CMR 120.296: *Appendix B*, Table III; and
(3) 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 105 CMR 120.296: *Appendix B*, Table III 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 105 CMR 120.296: *Appendix B*, Table III; and