DEPARTMENT OF HEALTH AND MENTAL HYGIENE

BOARD OF HEALTH

NOTICE OF ADOPTION OF AMENDMENTS TO ARTICLE 175 OF THE NEW YORK CITY HEALTH CODE

In compliance with §1043(b) of the New York City Charter (the "Charter") and pursuant to the authority granted to the Board of Health by §558 of said Charter, a notice of intention to amend Article 175 of the New York City Health Code (the "Health Code") was published in the City Record on April 22, 2013 and a public hearing was held on May 24, 2013. No testimony or written comments were received. On its own initiative, the Department modified certain legal citations; however no substantive changes have been made to the resolution. At its meeting on June 28, 2013, the Board of Health adopted the following resolution.

Statutory Authority

These amendments to the New York City Health Code are proposed pursuant to Sections 556, 558 and 1043 of the Charter and applicable state and federal law.

- Section 556 of the Charter grants the New York City Department of Health and Mental Hygiene ("Department") jurisdiction to regulate matters affecting health in New York City. Specifically, Section 556 (c)(11) of the Charter authorizes the Department to supervise and regulate public health aspects of ionizing radiation within the five boroughs of New York City.
- Sections 558 (b) and (c) of the Charter empower the Board of Health to amend the Health Code and to include in the Health Code all matters to which the Department's authority extends.
- Section 1043 of the Charter grants rule-making powers to the Department.

The New York State Sanitary Code, in 10 NYCRR §16.1(b)(3), states that localities that have a population of more than 2,000,000 may establish their own radiation licensure requirements in place of State regulations, provided that the local requirements are consistent with Sanitary Code requirements. Section 274 of the federal Atomic Energy Act of 1954 (codified at 42 USC §2021, "Atomic Energy Act") authorizes "Agreement States" to regulate byproduct material, source material and special nuclear material in quantities not sufficient to form a critical mass. New York State is an "Agreement State" within the meaning of the Atomic Energy Act, and the New York City Department of Health and Mental Hygiene program is a component of the relevant Agreement.

Statement of Basis and Purpose

New York State is an Agreement State, meaning that New York State and the United States Nuclear Regulatory Commission (NRC) have entered into an agreement under the Atomic Energy Act through which the NRC has delegated authority to the State to regulate radioactive material at non-reactor sites within its jurisdiction.[1] The New York State Agreement is comprised of the regulatory programs of three agencies:

1. the New York State Department of Health,
2. the New York State Department of Environmental Conservation, and
3. the New York City Department of Health and Mental Hygiene.

[1] New York State's agreement with NRC is available online at, http://nrc-stp.ornl.gov/special/regs/nyagreements.pdf.

Under the Agreement and section 16.1 of the State Sanitary Code, the New York City Department of Health and Mental Hygiene, through the Office of Radiological Health (ORH), regulates radioactive material for medical, research and academic purposes within the five boroughs of New York City.

ORH regulations for radioactive material are contained in Article 175 of the Health Code. ORH licenses and inspects radioactive materials facilities for compliance with Article 175 for the protection of the health and safety of patients, radiation program employees and the general public. There are about 375 licensed sites in New York City possessing radioactive material for medical, academic and research purposes. ORH inspects these facilities once every 1, 2 or 3 years depending on the type of use.

Each Agreement State program is required to maintain compatibility with the NRC regulatory program. NRC Compatibility Categories A and B require that the wording of proposed State program regulatory changes should be "essentially identical", and Category C should reflect the "essential objectives" of relevant NRC regulations. The majority of the rule changes proposed here are under NRC compatibility category B.

In 2007, the NRC promulgated changes to Title 10 of the CFR as the result of an expanded definition of byproduct material. Byproduct material was initially considered material produced by nuclear reactors, and waste product created through the process of producing material for use in reactors. Through an amendment to the Atomic Energy Act, the definition of byproduct material was subsequently widened to include materials produced through a significantly different process - accelerator-produced material - and to include discrete sources of radium-226 (a naturally occurring material).

I. Amendments for Expanded Definitions of Byproduct Material

NRC has significantly broadened its definition of byproduct material to include a wider range of radioactive materials. Byproduct material used to be defined as:

- Material made radioactive through use of nuclear fuel in a utilization facility (most often a nuclear reactor, or a strategic military device), or
- Waste products remaining after source material (e.g., refined uranium ore) is enriched[2] to make it suitable for use as nuclear fuel in a reactor or as strategic military material.

The broadened definition of byproduct material in Title 10 of the CFR now includes, in addition to the above described materials, the following:

- Any discrete sources of radium-226,
- Any material which the NRC determines to pose a threat comparable to that posed by a discrete source of radium-226, or
- Material made radioactive by a particle accelerator.

Incorporating this expanded definition of byproduct material requires a number of amendments to Article 175, in particular, the following:

- §175.02 (*Definitions*) A number of definitions must be changed or added as a result of the new definition of byproduct material.
- §175.03 (*Standards for protection against radiation*) Several radioactive materials must be added to lists in appendices defining environmental release limits of radioactive material. Certain headings in these lists are to be changed.
- §175.101 (*General requirements for radioactive materials licenses*)

[2] Enrichment is a process which increases the concentration in natural uranium of the isotope U-235, which is material most suitable for fuel in a utilization facility.

- Exemptions are proposed to cover licensing of certain items containing small quantities of radioactive material.
- Requirements are proposed to the descriptive information of material sources which an applicant for a license must provide.
- Requirements are proposed stating that an application for a license to use certain accelerator-produced material must include a request to produce those materials or provide evidence of an existing license held by its supplier of those accelerator-produced materials.
- Applicants who apply to use their own accelerator-produced radioactive drugs must provide evidence of their ability to produce those drugs.

- §175.102 (*Requirements for specific types of radioactive materials licenses*) New requirements are proposed for generally-licensed[3] materials regarding:
  - Labeling of products,
  - Leak testing of articles containing specified isotopes,
  - Limitations on transfer of devices, and
  - Records retention following transfer of disposal of devices.
- §175.104 (*Waste disposal*) New requirements are proposed for byproduct material regarding:
  - ultimate disposal of byproduct material at waste disposal facilities.
  - manifesting of byproduct material intended for transfer to waste disposal facilities.

II. Exemptions from Licensing, General Licenses and Distribution of Byproduct Material: Licensing and Reporting Requirements

NRC's expanded definition of byproduct material has affected provisions in Article 175 regarding licensing, distribution and reporting with respect to certain classes of radioactive material or articles containing such radioactive materials. In particular, changes are proposed with respect to:

- §175.101 (*General requirements for radioactive materials licenses*)
  - Exempt quantities may not be aggregated to the extent that combined quantities exceed the limits for exempt amounts set forth in Schedule B of this section, except for byproduct material combined within a device placed in use before May 3, 1999, or as otherwise permitted by regulation.
  - Exemptions to licensing are proposed for certain specified items.
- §175.102 (*Requirements for specific types of radioactive materials licenses*)
  - New reporting requirements are proposed with respect to persons transferring radioactive material to a licensee or shipping radioactive material for export.

In response to the 2007 NRC changes to Title 10 of the CFR concerning the changed definition of byproduct material, New York City must make matching changes to Article 175 of the Health Code to remain compatible with applicable federal regulations.

The amendments are as follows:

Matter in brackets [ ] is deleted.
Matter <u>underlined</u> is new.

[3] A general license is a license granted to manufacturers to produce and distribute common articles which a user may possess without themselves requiring a radioactive materials license. Materials which are generally licensed include smoke detectors, EXIT signs, and watches with luminous dials.

RESOLVED, that subdivision (c) of Section 175.01 of Article 175 of the New York City Health Code, as set forth in Title 24 of the Rules of the City of New York, as last amended by resolution on June 30, 1999, be and the same hereby is amended to update the appropriate Department mailing address, to be printed together with explanatory notes to read as follows:

§175.01 Applicability and inapplicability, communications.

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

[Bureau] Office of Radiological Health

[2 Lafayette Street, 11th Floor] 42-09 28th Street, 14th Floor

[New York] Long Island City, New York [10007] 10011

Notes: The Board of Health amended §175.01(c) of the Health Code on June 28, 2013 to update the appropriate Department mailing address for the Office of Radiological Health.

RESOLVED, that subdivision (a) of Section 175.02 of Article 175 of the New York City Health Code, as set forth in Title 24 of the Rules of the City of New York, as last amended by resolution on March 13, 2012, be and the same hereby is amended to add new definitions and update various other definitions to ensure compatibility with applicable federal regulations, and the paragraphs contained therein be accordingly renumbered, to be printed together with explanatory notes to read as follows:

- Paragraphs 6 through 55 are renumbered as paragraphs 7 through 56;
- Paragraphs 56 through 61 are renumbered as paragraphs 58 through 63;
- Paragraphs 62 through 76 are renumbered as paragraphs 65 through 79;
- Paragraphs 77 through 134 are renumbered as paragraphs 81 through 138;
- Paragraphs 135 through 172 are renumbered as paragraphs 140 through 177;
- Paragraphs 173 through 294 are renumbered as paragraphs 179 through 300;

§175.02 Definitions.

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

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(6) "Act" means the Atomic Energy Act of 1954 (42 U.S.C. 2011 et seq.), as amended.

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[(33)] (34) "Byproduct material" means:
(i) Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or [utilizing] using special nuclear material; and
(ii) The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium or thorium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition.

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

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(64) “Cyclotron” means a particle accelerator in which the charged particles travel in an outward spiral or circular path. A cyclotron accelerates charged particles at energies usually in excess of 10 megaelectron volts and is commonly used for production of short half-life radionuclides for medical use.

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

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[(161)] (165) “Particle accelerator” [(See “Accelerator”).] means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 megaelectron volt. For the purposes of this definition, "accelerator" is an equivalent term.

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(177) “Positron emission tomography (PET) radionuclide production facility” means a facility operating a cyclotron or accelerator for the purpose of producing PET radionuclides.

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[(278)] (283) "Waste" means those low-level radioactive wastes containing source, special nuclear, or byproduct material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level radioactive waste [has the same meaning as in the Low-Level Radioactive Waste Policy Act, P.L. 96-573, as amended by P.L. 99-240, effective January 15, 1986; that is,] means radioactive waste [(a)] not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in [Section lle.(2) of the Atomic Energy Act (uranium or thorium tailings and waste) and (b) classified as low-level radioactive waste consistent with existing law and in accordance with (a) by the U.S. Nuclear Regulatory Commission] subparagraphs (ii), (iii) and (iv) of the definition of “Byproduct material” set forth in this section.

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Notes: The Board of Health amended §175.02(a) of the Health Code on June 28, 2013 to add certain new definitions and update various other definitions to ensure compatibility with applicable federal regulations, particularly 10 CFR §§20.1003 and 30.4.

RESOLVED, that the names of the tables in the Note in the Introduction, the list of elements in the first chart, and the names of the tables in the second chart in Appendix B of Section 175.03 of Article 175 of the New York City Health Code, as set forth in Title 24 of the Rules of the City of New York, as last amended by resolution on March 16, 2005, be and the same hereby is amended to update the name of Table 1 and Table 3 and add new elements to the list of elements to ensure compatibility with applicable federal regulations, to be printed together with explanatory notes to read as follows:

§175.03 Standards for protection against radiation.

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APPENDIX B

ANNUAL LIMITS ON INTAKE (ALI) AND
DERIVED AIR CONCENTRATIONS (DAC) OF
RADIONUCLIDES FOR OCCUPATIONAL EXPOSURE;
EFFLUENT CONCENTRATIONS; CONCENTRATIONS FOR
RELEASE TO SANITARY SEWERAGE

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Table 1 "Occupational [*Values*] *Exposures"*

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Table 3 "Concentration for Releases to Sewerage"

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LIST OF ELEMENTS												
Atomic						**Atomic**						
	Name		**Symbol**		**Number**		**Name**		**Symbol**		**Number**	
***												
	Arsenic		As		33		Niobium		Nb		41	
	_____		__		__		Nitrogen		N		7	
	Astatine		At		85		Osmium		Os		76	
	_____		__		__		Oxygen		O		8	
	Barium		Ba		56		Palladium		Pd		46	

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Table 1	**Table 2**	**Table 3**
Occupational [Values] Exposures	**Effluent Concentrations**	**Concentration for Releases to [Sewers] Sewerage**

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Notes: The Board of Health amended §175.03 of the Health Code on June 28, 2013 to update certain radioactive material release limits and sections headings in Appendix B to ensure compatibility with applicable federal regulations, particularly 10 CFR Part 20 Appendix B.

RESOLVED, that Section 175.101 of Article 175 of the New York City Health Code, as set forth in Title 24 of the Rules of the City of New York, as last amended by resolution on September 25, 2008, be and the same hereby is amended to ensure compatibility with applicable federal regulations relating to certain exempt quantities of byproduct material, to be printed together with explanatory notes, such that

- Subdivisions (a), (c), (f), (j), (m), and (n) are amended;
- Appendixes A through C are renamed Schedules A through C, respectively, and amended;
- Appendixes D and E are renamed Appendix A and C, respectively; and
- A new Appendix B is added

to read as follows:

§175.101 General requirements for radioactive materials licenses.

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

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

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

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

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

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

(3) *Exempt items*. Except for persons who apply radioactive material to, or persons who incorporate radioactive material into the following products, or persons who initially transfer such products for sale or distribution, any person is exempt from the provisions of this Code to the extent that such person receives, possesses, uses, transfers, owns or acquires the following products:
(i) Timepieces or timepiece hands or dials containing radium which were manufactured under a specific license issued by the Department or an agreement state and which meet the following or equivalent conditions:
(A) The timepiece or timepiece hands or dials contain no more than the following specified quantities of radium:

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(e) 1.48 kBq (0.04 µCi) per clock hand; [or]
(f) 4.44 kBq (0.12 µCi) per clock dial; or
(g) 37 kBq (1 µCi) of radium-226 per timepiece in intact timepieces manufactured prior to November 30, 2007.

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

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(H) 37 kBq (1 µCi) of radium-226 per timepiece in timepieces [acquired prior to September 1, 1984] manufactured prior to November 30, 2007.

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[(vii) Thermostat dials and pointers containing not more than 925 MBq (25 millicuries) of hydrogen-3 per thermostat.]

vii. Reserved.

viii. Reserved.

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(x) Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, one or more sources of radioactive material, provided that:
(A) each source contains no more than one exempt quantity set forth in [Appendix] Schedule B of this section, and
(B) each instrument contains no more than 10 exempt quantities. For purposes of this requirement, an instrument's source(s) may contain either one or different types of radioactive materials and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in [Appendix] Schedule B of this section, provided that the sum of such fractions shall not exceed unity; and
(C) for the purposes of §175.101(c)(3)(x), 1.85 kBq (0.05 µCi) of americium-241 shall be considered one exempt quantity.

[(xi) Spark gap irradiators containing not more than 37 kBq (1 µCi) of cobalt-60 per spark gap irradiator for use in electrically ignited fuel oil burners having a firing rate of at least 3 gallons (11.4 liter) per hour.]

xi. Reserved.

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(6) [Any person, except those who manufacture, process, or produce gas and aerosol detectors containing radioactive material, is exempt from the provisions of this Code to the extent that such person receives, possesses, uses, transfers, owns or acquires radioactive material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards provided that detectors containing radioactive material shall have been manufactured, imported, or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR §32.26, or by an agreement state pursuant to equivalent regulations.

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

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

(f) *Applications for specific licenses.*

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(3) [For those applicants or licensees who are required to establish and maintain a radiation safety committee pursuant to this Code, each application or supplementary statement shall be transmitted with a letter signed by the chairman of the radiation safety committee indicating the committee's approval of the requested licensing action.] An application for a specific license to use byproduct material in the form of a sealed source or in a device that contains the sealed source must:

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

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

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

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

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

(4) [At any time subsequent to the filing of an application for a license, including amendments, and before

the termination of a license issued in response thereto, the Department may require the applicant to submit one or more supplementary statements containing additional information to enable the Department to determine whether such application should be approved or denied, or whether a previously issued license should be amended, suspended or revoked.] An application from a medical facility, educational institution, or federal facility to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to licensees in its consortium authorized for medical use under 10 CFR Part 35 or equivalent agreement state requirements, shall include:
(i) A request for authorization for the production of PET radionuclides or evidence of an existing license issued under 10 CFR Part 30 or agreement state requirements for a PET radionuclide production facility within its consortium from which it receives PET radionuclides;
(ii) Evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in 10 CFR § 32.72(a)(2);
(iii) Identification of any individual authorized to prepare the PET radioactive drugs if the applicant is a pharmacy, and documentation that any such individual meets the requirements of an authorized nuclear pharmacist as specified in 10 CFR § 32.72(b)(2); and
(iv) Information identified in 10 CFR § 32.72(a)(3) on the PET drugs to be noncommercially transferred to members of its consortium.

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

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

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

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

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

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

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

(*a*) Satisfy the labeling requirements in 10 CFR § 32.72(a)(4) for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium; and
(*b*) Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in 10 CFR § 32.72(c).
(C) A licensee that is a pharmacy authorized under 10 CFR § 30.32(j) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radioactive drugs : (*a*) an authorized nuclear pharmacist who meets the requirements in 10 CFR § 32.72(b)(2); or (*b*) an individual under the supervision of an authorized nuclear pharmacist as specified in 10 CFR § 35.27.
(D) A pharmacy, authorized under 10 CFR § 30.32(j) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirements of 10 CFR § 32.72(b)(5). All reports and notifications required by 10 CFR § 32.72(b)(5) shall be provided to the Department.

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

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(m) *Reciprocity*.

(1) The holder of a license issued by the New York State Department of Labor, the New York State Department of Health, the U.S. Nuclear Regulatory Commission or any agreement state, may bring, possess or use radioactive material covered by such license within the Department's jurisdiction for a period not in excess of [180] 30 days in any twelve consecutive months without obtaining a license from the Department, provided that:

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

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

[(1)](b) Each holder of, or applicant for, any specific license authorizing the possession and use of sealed sources or plated foils of half-life greater than 120 days and in quantities exceeding 10 times the applicable quantities set forth in Appendix B to this section shall submit a decommissioning funding plan as described in §175.101(n)(5). The decommissioning funding plan must also be submitted when a combination of isotopes is involved if R, as defined in §175.101(n)(1)(a), divided by 1012 is greater than one (1) (unity rule). The decommissioning funding plan must be submitted to the Department within 2 years of the effective date of this provision.

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

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

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[(1)](e) Each applicant for a specific license authorizing the possession and use of unsealed special nuclear material in quantities exceeding 10^5 times the applicable quantities set forth in Appendix B to this section shall submit a decommissioning funding plan as described in §175.101(n)(5). A decommissioning funding plan must also be submitted when a combination of isotopes is involved if R, as defined in §175.101(n)(1)(a), divided by 105 is greater than one (1) (unity rule).

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[APPENDIX] SCHEDULE A

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$$\frac{\text{Concentration of Isotope A in Product 1}}{\text{Exempt concentration of Isotope A}} + \frac{\text{Concentration of Isotope B in Product 1}}{\text{Exempt concentration of Isotope B}} \quad \# 1$$

Source: 10 CFR 30.70 Schedule A-Exempt concentrations.

[APPENDIX B

EXEMPT QUANTITIES

Radioactive material	Microcuries[1]
Americium 241	.01
Antimony 122 (Sb 122)	100
Antimony 124 (Sb 124)	10
Antimony 125 (Sb 125)	10
Arsenic 73 (As 73)	100
Arsenic 74 (As 74)	10
Arsenic 76 (As 76)	10
Arsenic 77 (As 77)	100
Barium 131 (Ba 131)	10
Barium 133 (Ba 133)	10
Barium 140 (Ba 140)	10
Beryllium 7 (Be 7)	100
Bismuth 210 (Bi 210)	1
Bromine 82 (Br 82)	10
Cadmium 109 (Cd 109)	10
Cadmium 115m (Cd 115m)	10

Cadmium 115 (Cd 115)	100
Calcium 45 (Ca 45)	10
Calcium 47 (Ca 47)	10
Carbon 14 (C14)	100
Cerium 141 (Ce 141)	100
Cerium 143 (Ce 143)	100
Cerium 144 (Ce 144)	1
Cesium 131 (Cs 131)	1,000
Cesium 134m (Cs 134m)	100
Cesium 134 (Cs 134)	1
Cesium 135 (Cs 135)	10
Cesium 136 (Cs 136)	10
Cesium 137 (Cs 137)	10
Chlorine 36 (Cl 36)	10
Chlorine 38 (Cl 38)	10
Chromium 51 (Cr 51)	1,000
Cobalt 58m (Co 58m)	10
Cobalt 58 (Co 58)	10
Cobalt 60 (Co 60)	1
Copper 64 (Cu 64)	100
Dysprosium 165 (Dy 165)	10
Dysprosium 166 (Dy 166)	100
Erbium 169 (Er 169)	100
Erbium 171 (Er 171)	100
Europium 152 9.2h (Eu 152 9.2h)	100
Europium 152 13 yr (Eu 152 13yr)	1
Europium 154 (Eu 154)	1
Europium 155 (Eu 155)	10
Fluorine 18 (F 18)	1,000
Gadolinium 153 (Gd 153)	10
Gadolinium 159 (Gd 159)	100
Gallium 72 (Ga 72)	10
Germanium 71 (Ga 71)	100
Gold 198 (Au 198)	100
Gold 199 (Au 199)	100
Hafnium 181 (Hf 181)	10
Holmium 166 (Ho 166)	100
Hydrogen 3 (H3)	1,000
Indium 113m (In 113m)	100
Indium 114m (In 114m)	10
Indium 114 (In 114)	1
Indium 115m (In 115m)	100
Indium 115 (In 115)	10
Iodine 125 (I 125)	1
Iodine 126 (I 126)	1
Iodine 129 (I 129)	0.1
Iodine 131 (I 131)	1
Iodine 132 (I 132)	10
Iodine 133 (I 133)	1

Iodine 134 (I 134)	10
Iodine 135 (I 135)	10
Iridium 192 (Ir 192)	10
Iridium 194 (Ir 194)	100
Iron 55 (Fe 55)	100
Iron 59 (Fe 59)	10
Krypton 85 (Kr 85)	100
Krypton 87 (Kr 87)	10
Lanthanum 140 (La 140)	10
Lutetium 177 (Lu 177)	100
Manganese 52 (Mn 52)	10
Manganese 54 (Mn 54)	10
Manganese 56 (Mn 56)	10
Mercury 197m (Hg 197m)	100
Mercury 197 (Hg 197)	100
Mercury 203 (Hg 203)	10
Molybdenum 99 (Mo 99)	100
Neodymium 147 (Nd 147)	100
Neodymium 149 (Nd 149)	100
Nickel 59 (Ni 59)	100
Nickel 63 (Ni 63)	10
Nickel 65 (ni 65)	100
Niobium 93m (Nb 93m)	10
Niobium 95 (Nb 95)	10
Niobium 97 (Nb 97)	10
Osmium 185 (Os 185)	10
Osmium 191m (Os 191m)	100
Osmium 191 (Os 191)	100
Osmium 193 (Os 193)	100
Palladium 103 (Pd 103)	100
Palladium 109 (Pd 109)	100
Phosphorous 32 (P 32)	10
Platinum 191 (Pt 191)	100
Platinum 193m (Pt 193m)	100
Platinum 193 (Pt 193)	100
Platinum 197m (Pt 197m)	100
Platinum 197 (Pt 197)	100
Plutonium 239	.01
Polonium 210 (Po 210)	0.1
Potassium 42 (K 42)	10
Praseodymium 142 (Pr 142)	100
Praseodymium 143 (Pr 143)	100
Promethium 147 (Pm 147)	10
Promethium 149 (Pm 149)	10
Radium 226 (Ra 226)	0.1
Rhenium 186 (Re 186)	100
Rhenium 188 (Re 188)	100
Rhodium 103m (Rh 103m)	100
Rhodium 105 (Rh 105)	100

Rubidium 86 (Rb 86)	10
Rubidium 87 (Rb 87)	10
Ruthenium 97 (Ru 97)	100
Ruthenium 103 (Ru 103)	10
Ruthenium 105 (Ru 105)	10
Ruthenium 106 (Ru 106)	1
Samarium 151 (Sm 151)	10
Samarium 153 (Sm 153)	100
Scandium 46 (Sc 46)	10
Scandium 47 (Sc 47)	100
Scandium 48 (Sc 48)	10
Selenium 75 (Sc 75)	10
Silicon 31 (Si 31)	100
Silver 105 (Ag 105)	10
Silver 110m (Ag 110m)	1
Silver 111 (Ag 111)	100
Sodium 22 (Na 22)	10
Sodium 24 (Na 24)	10
Strontium 85 (Sr 85)	10
Strontium 89 (Sr 89)	1
Strontium 90 (Sr 90)	0.1
Strontium 91 (Sr 91)	10
Strontium 92 (Sr 92)	10
Sulfur 35 (S 35)	100
Tantalum 182 (Ta 182)	10
Technetium 96 (Tc 96)	10
Technetium 97m (Tc 97m)	100
Technetium 97 (Tc 97)	100
Technetium 99m (Tc 99m)	100
Technetium 99 (Tc 99)	10
Tellurium 125m (Te 125m)	10
Tellurium 127m (Te 127m)	10
Tellurium 127 (Tel 127)	100
Tellurium 129m (Te 129m)	10
Tellurium 129 (Te 129)	100
Tellurium 131m (Te 131m)	10
Tellurium 132 (Te 132)	10
Terbium 160 (Tb 160)	10
Thallium 200 (Tl 200)	100
Thallium 201 (Tl 201)	100
Thallium 202 (Tl 202)	100
Thallium 204 (Tl 204)	10
Thulium 170 (Tm 170)	10
Thulium 171 (Tm 171)	10
Tin 113 (Sn 113)	10
Tin 125 (Sn 125)	10
Tungsten 181 (W 181)	10
Tungsten 185 (W 185)	10
Tungsten 187 (W 187)	100

Vanadium 48 (V 48)	10
Xenon 131m (Xe 131m)	1,000
Xenon 133 (Xe 133)	100
Xenon 135 (Xe 135)	100
Ytterbium 175 (Yb 175)	100
Yttrium 90 (Y 90)	10
Yttrium 91 (Y 91)	10
Yttrium 92 (Y 92)	100
Yttrium 93 (Y 93)	100
Zinc 65 (Zn 65)	10
Zinc 69m (Zn 69m)	100
Zinc 69 (Zn 69)	1,000
Zirconium 93 (Zr 93)	10
Zirconium 95 (Zr 95)	10
Zirconium 97 (Zr 97)	10
Any radioactive material not listed above other than alpha emitting radioactive material	0.1
Any alpha radionuclide not listed above or mixtures of alphaemitters of unknown composition	0.1

[1]To convert microcuries (mCi) to kilobecquerels (kBq), multiply microcuries by 37.]

SCHEDULE B	
EXEMPT QUANTITIES	
Byproduct material	**Microcuries[1]**
Antimony 122 (Sb 122)	100
Antimony 124 (Sb 124)	10
Antimony 125 (Sb 125)	10
Arsenic 73 (As 73)	100
Arsenic 74 (As 74)	10
Arsenic 76 (As 76)	10
Arsenic 77 (as 77)	100
Barium 131 (Ba 131)	10
Barium 133 (Ba 133)	10
Barium 140 (Ba 140)	10
Bismuth 210 (Bi 210)	1
Bromine 82 (Br 82)	10
Cadmium 109 (Cd 109)	10
Cadmium 115m (Cd 115m)	10
Cadmium 115 (Cd 115)	100

Calcium 45 (Ca 45)	10
Calcium 47 (Ca 47)	10
Carbon 14 (C 14)	100
Cerium 141 (Ce 141)	100
Cerium 143 (Ce 143)	100
Cerium 144 (Ce 144)	1
Cesium 129 (Cs 129)	100
Cesium 131 (Cs 131)	1,000
Cesium 134m (Cs 134m)	100
Cesium 134 (Cs 134)	1
Cesium 135 (Cs 135)	10
Cesium 136 (Cs 136)	10
Cesium 137 (Cs 137)	10
Chlorine 36 (Cl 36)	10
Chlorine 38 (Cl 38)	10
Chromium 51 (Cr 51)	1,000
Cobalt 57 (Co 57)	100
Cobalt 58m (Co 58m)	10
Cobalt 58 (Co 58)	10
Cobalt 60 (Co 60)	1
Copper 64 (Cu 64)	100
Dysprosium 165 (Dy 165)	10
Dysprosium 166 (Dy 166)	100
Erbium 169 (Er 169)	100
Erbium 171 (Er 171)	100
Europium 152 9.2 h (Eu 152 9.2 h)	100
Europium 152 13 yr (Eu 152 13 yr)	1
Europium 154 (Eu 154)	1
Europium 155 (Eu 155)	10
Fluorine 18 (F 18)	1,000
Gadolinium 153 (Gd 153)	10
Gadolinium 159 (Gd 159)	100
Gallium 67 (Ga 67)	100
Gallium 72 (Ga 72)	10

Germanium 68 (Ge 68)	10
Germanium 71 (Ge 71)	100
Gold 195 (Au 195)	10
Gold 198 (Au 198)	100
Gold 199 (Au 199)	100
Hafnium 181 (Hf 181)	10
Holmium 166 (Ho 166)	100
Hydrogen 3 (H3)	1,000
Indium 111 (In 111)	100
Indium 113m (In 113m)	100
Indium 114m (In 114m)	10
Indium 115m (In 115m)	100
Indium 115 (In 115)	10
Iodine 123 (I 123)	100
Iodine 125 (I 125)	1
Iodine 126 (I 126)	1
Iodine 129 (I 129)	0.1
Iodine 131 (I 131)	1
Iodine 132 (I 132)	10
Iodine 133 (I 133)	1
Iodine 134 (I 134)	10
Iodine 135 (I 135)	10
Iridium 192 (Ir 192)	10
Iridium 194 (Ir 194)	100
Iron 52 (Fe 52)	10
Iron 55 (Fe 55)	100
Iron 59 (Fe 59)	10
Krypton 85 (Kr 85)	100
Krypton 87 (Kr 87)	10
Lanthanum 140 (La 140)	10
Lutetium 177 (Lu 177)	100
Manganese 52 (Mn 52)	10
Manganese 54 (Mn 54)	10
Manganese 56 (Mn 56)	10

Mercury 197m (Hg 197m)	100
Mercury 197 (Hg 197)	100
Mercury 203 (Hg 203)	10
Molybdenum 99 (Mo 99)	100
Neodymium 147 (Nd 147)	100
Neodymium 149 (Nd 149)	100
Nickel 59 (Ni 59)	100
Nickel 63 (Ni 63)	10
Nickel 65 (Ni 65)	100
Niobium 93m (Nb 93m)	10
Niobium 95 (Nb 95)`	10
Niobium 97 (Nb 97)	10
Osmium 185 (Os 185)	10
Osmium 191m (Os 191)	100
Osmium 191 (Os 191)	100
Osmium 193 (Os 193)	100
Palladium 103 (Pd 103)	100
Palladium 109 (Pd 109)	100
Phosphorus 32 (P 32)	10
Platinum 191 (Pt 191)	100
Platinum 193m (Pt 193m)	100
Platinum 193 (Pt 193)	100
Platinum 197m (Pt 197m)	100
Platinum 197 (Pt 197)	100
Polonium 210 (Po 210)	0.1
Potassium 42 (K 42)	10
Potassium 43 (K 43)	10
Praseodymium 142 (Pr 142)	100
Praseodymium 143 (Pr 143)	100
Promethium 147 (Pm 147)	10
Promethium 149 (Pm 149)	10
Rhenium 186 (Re 186)	100
Rhenium 188 (Re 188)	100
Rhodium 103m (Rh 103m)	100

Rhodium 105 (Rh 105)	100
Rubidium 81 (Rb 81)	10
Rubidium 86 (Rb 86)	10
Rubidium 87 (Rb 87)	10
Ruthenium 97 (Ru 97)	100
Ruthenium 103 (Ru 103)	10
Ruthenium 105 (Ru 105)	10
Ruthenium 106 (Ru 106)	1
Samarium 151 (Sm 151)	10
Samarium 153 (Sm 153)	100
Scandium 46 (Sc 46)	10
Scandium 47 (Sc 47)	100
Scandium 48 (Sc 48)	10
Selenium 75 (Se 75)	10
Silicon 31 (Si 31)	100
Silver 105 (Ag 105)	10
Silver 110m (Ag 110m)	1
Silver 111 (Ag 111)	100
Sodium 22 (Na 22)	10
Sodium 24 (Na 24)	10
Strontium 85 (Sr 85)	10
Strontium 89 (Sr 89)	1
Strontium 90 (Sr 90)	0.1
Strontium 91 (Sr 91)	10
Strontium 92 (Sr 92)	10
Sulphur 35 (S 35)	100
Tantalum 182 (Ta 182)	10
Technetium 96 (Tc 96)	10
Technetium 97m (Tc 97m)	100
Technetium 97 (Tc 97)	100
Technetium 99m (Tc 99m)	100
Technetium 99 (Tc 99)	10
Tellurium 125 m (Te 125 m)	10
Tellurium 127m (Te 127m)	10

Tellurium 127 (Te 127)	100
Tellurium 129m (Te 129m)	10
Tellurium 129 (Te 129)	100
Tellurium 131m (Te 131m)	10
Tellurium 132 (Te 132)	10
Terbium 160 (Tb 160)	10
Thallium 200 (Tl 200)	100
Thallium 201 (Tl 201)	100
Thallium 202 (Tl 202)	100
Thallium 204 (Tl 204)	10
Thulium 170 (Tm 170)	10
Thulium 171 (Tm 171)	10
Tin 113 (Sn 113)	10
Tin 125 (Sn 125)	10
Tungsten 181 (W 181)	10
Tungsten 185 (W 185)	10
Tungsten 187 (W 187)	100
Vanadium 48 (V 48)	10
Xenon 131m (Xe 131m)	1,000
Xenon 133 (Xe 133)	100
Xenon 135 (Xe 135)	100
Ytterbium 175 (Yb 175)	100
Yttrium 87 (Y 87)	10
Yttrium 88 (Y 88)	10
Yttrium 90 (Y 90)	10
Yttrium 91 (Y91)	10
Yttrium 92 (Y92)	100
Yttrium 93 (Y93)	100
Zinc 65 (Zn 65)	10
Zinc 69m (Zn 69m)	100
Zinc 69 (Zn 69)	1,000
Zirconium 93 (Zr 93)	10
Zirconium 95 (Zr 95)	10
Zirconium 97 (Zr 97)	10

Any byproduct material not listed above other than alpha emitting byproduct materials	0.1

[1] To convert microcuries (µCi) to kilobecquerels (kBq), multiply microcuries by 37.

Source: 10 CFR 30.71 Schedule B

[APPENDIX] SCHEDULE C

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

Radioactive material[1]	Release fraction	Quantity (curies)[2]
***		
Promethium-147	0.01	4000
Radium-226	0.001	100
***		

FOOTNOTES:

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

Source: 10 CFR Part 30.72 Schedule C

APPENDIX [D] A

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APPENDIX B

QUANTITIES OF LICENSED MATERIAL REQUIRING LABELING

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

Arsenic-74	10
Arsenic-76	10
Arsenic-77	100
Barium-131	10
Barium-133	10
Barium-140	10
Bismuth-210	1
Bromine-82	10
Cadmium-109	10
Cadmium-115m	10
Cadmium-115	100
Calcium-45	10
Calcium-47	10
Carbon-14	100
Cerium-141	100
Cerium-143	100
Cerium-144	1
Cesium-131	1,000
Cesium-134m	100
Cesium-134	1
Cesium-135	10
Cesium-136	10
Cesium-137	10
Chlorine-36	10
Chlorine-38	10
Chromium-51	1,000
Cobalt-58m	10
Cobalt-58	10
Cobalt-60	1
Copper-64	100
Dysprosium-165	10
Dysprosium-166	100
Erbium-169	100
Erbium-171	100

Europium-152 9.2h	100
Europium-152 13 yr	1
Europium-154	1
Europium-155	10
Fluorine-18	1,000
Gadolinium-153	10
Gadolinium-159	100
Gallium-72	10
Germanium-71	100
Gold-198	100
Gold-199	100
Hafnium-181	10
Holmium-166	100
Hydrogen-3	1,000
Indium-113m	100
Indium-114m	10
Indium-115m	100
Indium-115	10
Iodine-125	1
Iodine-126	1
Iodine-129	0.1
Iodine-131	1
Iodine-132	10
Iodine-133	1
Iodine-134	10
Iodine-135	10
Iridium-192	10
Iridium-194	100
Iron-55	100
Iron-59	10
Krypton-85	100
Krpton-87	10
Lanthanum-140	10
Lutetium-177	100

Manganese-52	10
Manganese-54	10
Manganese-56	10
Mercury-197m	100
Mercury-197	100
Mercury-203	10
Molbdenum-99	100
Neodymium-147	100
Neodymium-149	100
Nickel-59	100
Nickel-63	10
Nickel-65	100
Niobium-93m	10
Niobium-95	10
Niobium-97	10
Osmium-185	10
Osmium-191m	100
Osmium-191	100
Osmium-193	100
Palladium-103	100
Palladium-109	100
Phosphorus-32	10
Platinum-191	100
Platinum-193m	100
Platinum-193	100
Platinum-197m	100
Platinum-197	100
Plutonium-239	.01
Polonium-210	0.1
Potassium-42	10
Praseodymium-142	100
Praseodymium-143	100
Promethium-147	10
Promethium-149	10

Radium-226	.01
Rhenium-186	100
Rhenium-188	100
Rhodium-103m	100
Rhodium-105	100
Rubidium-86	10
Rubidium-87	10
Ruthenium-97	100
Ruthenium-103	10
Ruthenium-105	10
Ruthenium-106	1
Samarium-151	10
Samarium-153	100
Scandium-46	10
Scandium-47	100
Scandium-48	10
Seleium-75	10
Silicon-31	100
Silver-105	10
Silver-110m	1
Silver-111	100
Sodium-24	10
Strontium-85	10
Strontium-89	1
Strontium-90	0.10
Strontium-91	10
Strontium-92	10
Sulphur-35	100
Tantalum-182	10
Technetium-96	10
Technetium-97m	100
Technetium-97	100
Technetium-99m	100
Technetium-99	10

Tellurium-125m	10
Tellurium127m	10
Tellurium-127	100
Tellurium129m	10
Tellurium-129	100
Tellurium-131m	10
Tellurium-132	10
Terbium-160	10
Thallium-200	100
Thallium-201	100
Thallium-202	100
Thallium-204	10
Thorium (natural)[1]	100
Thulium-170	10
Thulium-171	10
Tin-113	10
Tin-125	10
Tungsten-181	10
Tungsten-185	10
Tungsten-187	100
Uranium (natural)[2]	100
Uranium-233	.01
Uranium-234--Uranium-235	.01
Vandium-48	10
Xenon-131m	1,000
Xenon-133	100
Xenon-135	100
Ytterbium-175	100
Yttrium-90	10
Yttrium-91	10
Yttrium-92	100
Yttrium-93	100
Zinc-65	10
Zinc-69m	100

Zinc-69	1,000
Zirconium-93	10
Zirconium-95	10
Zirconium-97	10
Any alpha emitting radionuclide not listed above or mixtures of alpha emitters of unknown composition	.01
Any radionuclide other than alpha emitting radio-nuclides, not listed above or mixtures of beta emitters of unknown composition	.1

[1]Based on alpha disintegration rate of Th-232, Th-230 and their daughter products.
[2]Based on alpha disintegration rate of U-238, U-234, and U-235.

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

APPENDIX [E] C

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***

Notes: The Board of Health amended §175.101 of the Health Code and its Appendices and Schedules on June 28, 2013 to ensure compatibility with applicable federal regulations, particularly relating to certain exempt quantities of byproduct material and 10 CFR Part 30 and its Appendices.

RESOLVED, that subdivision (g) of Section 175.102 of Article 175 of the New York City Health Code, as set forth in Title 24 of the Rules of the City of New York, as last amended by resolution on June 27, 1994, be and the same hereby is amended to update requirements for certain radioactive materials licenses to ensure compatibility with applicable federal regulations, to be printed together with explanatory notes to read as follows:

(g) *General licenses*.

***

[(4) *Certain measuring, gauging or controlling devices*. (i) A general license is hereby issued to receive, possess or use radioactive material when contained in devices used at a fixed location and designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere, when such devices are manufactured or imported in accordance with the specifications contained in a specific license issued to the supplier by the Department, the U.S. Nuclear Regulatory Commission or an agreement state, and authorizing distribution under this general license or its equivalent, provided that:
(A) such devices are labeled in accordance with the provisions of the specific license which authorizes the distribution of the devices
(B) such devices bear a label containing the following or a substantially similar statement which contain the information called for in the following statement:
The transfer, receipt, possession or use of this device, Model[2]*_____ , Serial number*[2] *_____ , are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or of a State with which the Nuclear Regulatory Commission has*

entered into an agreement for the exercise of regulatory authority. Removal of this label is prohibited.
CAUTION-RADIOACTIVE MATERIAL

_____
(Name of supplier[2])

---

[1] Regulations under the Federal Food, Drug and Cosmetic Act authorizing the use of radioactive control devices in food production require certain additional labeling thereon which is found in §121.3001 of 21 CFR Part 121.
[2] The model, serial number, and name of supplier may be omitted from this label provided they are elsewhere specified in the labeling affixed to the device.]

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

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

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

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

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

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

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

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

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

(B) Shall assure that the device is tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at no longer than six month intervals or as frequently as is specified in the label; however:

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

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

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

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

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

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

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

transferred or disposed of.
(b) Each record of a test of the on-off mechanism and indicator required by clause (iii)(B) of this paragraph must be retained for three years after the next required test of the on-off mechanism and indicator is performed or until the sealed source is transferred or disposed of.
(c) Each record that is required by clause (iii)(C) of this paragraph must be retained for three years from the date of the recorded event or until the device is transferred or disposed of.
(E) Shall immediately suspend operation of the device if there is a failure of, or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 185 bequerel (0.005 microcurie) or more removable radioactive material. The device may not be operated until it has been repaired by the manufacturer or other person holding a specific license to repair such devices that was issued under parts 30 and 32 or by an agreement state. The device and any radioactive material from the device may only be disposed of by transfer to a person authorized by a specific license to receive the byproduct material in the device or as otherwise approved by the U.S. Nuclear Regulatory Commission. A report containing a brief description of the event and the remedial action taken; and, in the case of detection of 0.005 microcurie or more removable radioactive material, or failure of or damage to a source likely to result in contamination of the premises or the environs, a plan for ensuring that the premises and environs are acceptable for unrestricted use, must be furnished to the Department by the licensee within 5 days as required by §175.03(l)(7). Upon such a failure, damage, or possible indication of failure or damage, the Department may determine to apply the criteria set out in 10 CFR § 20.1402;
(F) Shall not abandon the device containing byproduct material;
(G) Shall not export the device containing byproduct material except in accordance with 10 CFR Part 110;
(H)*(a)* Shall transfer or dispose of the device containing byproduct material only by: export as provided by clause (iii)(G) of this paragraph; transfer to another general licensee as authorized in clause (iii)(I) of this paragraph; transfer to a person authorized to receive the device by a specific license issued under Parts 30 and 32 of 10 CFR; transfer to a person authorized to collect waste under Part 30 of 10 CFR or the equivalent regulation of an agreement state; or transfer as otherwise approved under item (iii)(H)(*c*) of this paragraph.
(b) Shall, within 30 days after the transfer of a device to a specific licensee or export, furnish a report to the Department. The report must contain: (I) The identification of the device by the manufacturer's (or initial transferor's) name, model number, and serial number;
(II) The name, address, and license number of the person receiving the device (license number not applicable if exported); and
(III) The date of the transfer.
(c) Shall obtain written Department approval before transferring the device to any licensee not specifically identified in item (iii)(H)(*a*) of this paragraph; however, a holder of a specific license may transfer a device for possession and use under its own specific license without prior approval, if, the holder:
(I) Verifies that the specific license authorizes the possession and use, or applies for and obtains an amendment to the license authorizing the possession and use;
(II) Removes, alters, covers, or clearly and unambiguously augments the existing label (otherwise required by clause (iii)(A) of this paragraph) so that the device is labeled in compliance with 10 CFR § 20.1904; however the manufacturer, model number, and serial number must be retained;
(III) Obtains the manufacturer's or initial transferor's information concerning maintenance that would be applicable under the specific license (such as leak testing procedures); and
(IV) Reports the transfer under item (iii)(H)(b) of this paragraph.
(I) Shall transfer the device to another general licensee only if:
(a) The device remains in use at a particular location. In this case, the transferor must give the transferee a copy of this section (§175.102), copies of 10 CFR §§ 20.2201, 20.2202, 30.51, 31.2, and 31.5 and any safety documents identified in the label of the device. Within 30 days of such a transfer, the transferor

shall report to the Department:
(I) The manufacturer's (or initial transferor's) name;
(II) The model number and the serial number of the device transferred;
(III) The transferee's name and mailing address for the location of use; and
(IV) The name, title, and phone number of the responsible individual identified by the transferee in accordance with clause (iii)(L) of this paragraph to have knowledge of and authority to take actions to ensure compliance with the appropriate regulations and requirements; or
(*b*) The device is held in storage in the original shipping container by an intermediate person at its intended location of use prior to initial use by a general licensee.
(J) Shall comply with the provisions of 10 CFR §§ 20.2201 and 20.2202 for reporting radiation incidents, theft or loss of licensed material, but pursuant to 10 CFR § 31.5(c)(10), is exempt from the other requirements of 10 CFR Parts 19, 20, and 21.
(K) Shall respond to written requests from the Department or U.S. Nuclear Regulatory Commission to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it must, within that same time period, request more time to supply the information by providing a written justification for the request to the Department.
(L) Shall appoint an individual responsible for having knowledge of the appropriate regulations and requirements and the authority for taking required actions to comply with appropriate regulations and requirements. The general licensee, through this individual, must ensure the day-to-day compliance with appropriate regulations and requirements. This appointment does not relieve the general licensee of any of its responsibility in this regard.
(M)*(a)* Except as provided in item (iii)(M)(*d*) of this paragraph, shall register, in accordance with items (iii)(M)(*b*) and (*c*) of this paragraph, devices containing at least 370 megabecquerels (10 millicuries) of cesium-137, 3.7 megabecquerels (0.1 millicurie) of strontium-90, 37 megabecquerels (1 millicurie) of cobalt-60, 3.7 megabecquerels (0.1 millicurie) of radium-226, or 37 megabecquerels (1 millicurie) of americium-241 or any other transuranic (i.e., element with atomic number greater than uranium (92)), based on the activity indicated on the label. Each address for a location of use, as described under subitems (iii)(M)(*c*)(IV) of this paragraph, represents a separate general licensee and requires a separate registration and fee as specified in this Code.
(b) If in possession of a device meeting the criteria of item (iii)(M)(*a*) of this paragraph, must register these devices annually with the Department and must pay the fee required by §5.07 of this Code. Registration must be done by verifying, correcting, and/or adding to the information provided in a request for registration received from the Department. The registration information must be submitted to the Department within 30 days of the date of the request for registration or as otherwise indicated in the request. In addition, a general licensee holding devices meeting the criteria of item (iii)(M)(*a*) of this paragraph is subject to the bankruptcy notification requirement in 10 CFR § 30.34(h) and §175.101(k)(1)(vi).
(c) In registering any device meeting the criteria listed in item (iii)(M)(*a*) of this paragraph, the general licensee must furnish the following information and any other information specifically requested by the Department:(I) Name and mailing address of the general licensee.
(II) Information about each device: the manufacturer (or initial transferor), model number, serial number, the radioisotope and activity (as indicated on the label).
(III) Name, title, and telephone number of the responsible person designated as a representative of the general licensee under clause (i)(L) of this paragraph.
(IV) Address or location at which each device is used or stored. For portable devices, the address of the primary place of storage.
(V) Certification by the responsible representative of the general licensee that the information concerning each device has been verified through a physical inventory and checking of label information.
(VI) Certification by the responsible representative of the general licensee that they are aware of the requirements of the general license.

(d) A person generally licensed by an agreement state with respect to any device meeting the criteria in item (iii)(M)(*a*) of this paragraph are not subject to the registration requirements of this clause if the device is used in an area subject to NRC jurisdiction for less than 180 days in any calendar year. The Department will not request registration information from such a licensee.
(N) Shall report any change to the mailing address for the location of use (including change in name of general licensee) to the Department within 30 days of the effective date of the change. For a portable device, a report of address change is only required for a change in the device's primary place of storage.
(O) May not hold any device that is not in use for longer than 2 years. When any device with shutters is not being used, the shutter must be locked in the closed position. The testing required by clause (iii)(B) of this paragraph need not be performed during a period of storage only. However, when a device is put back into service or transferred to another person, and has not been tested within the required test interval, it must be tested for leakage before use or transfer, and the shutter tested before use. Any devices kept in standby for future use is excluded from the two-year time limit in this clause if the general licensee performs quarterly physical inventories of any such device while it is in standby.
(iv) The general license in subparagraph (i) of this paragraph does not authorize the manufacture or import of devices containing byproduct material.

(5) *Labeling of devices*
(i) (A) Each person licensed under 10 CFR § 32.57 shall affix to each source, or storage container for the source, a label which contains sufficient information relative to safe use and storage of the source and includes the following statement, or a substantially similar statement which contains the information called for in the following statement:
(B) "The receipt, possession, use, and transfer of this source, Model _____, Serial No. ,are subject to a general license and the regulations of the United States Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.
CAUTION - RADIOACTIVE MATERIAL – THIS SOURCE CONTAINS AMERICIUM-241 (or RADIUM-226). DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____
(*Name of manufacturer or initial transferor*)"
(C) such devices shall be installed on the premises of the general licensee by a person authorized to install such devices under a specific license issued to the installer by the Department, the U.S. Nuclear Regulatory Commission or an agreement state, if a label affixed to the device at the time of receipt states that installation by a specific licensee is required. This requirement does not apply while devices are held in storage in the original shipping container pending installation by a specific licensee.
(ii) Persons who receive, possess or use a device pursuant to the general license [of §175.102(g)(3)(i)] issued under this subdivision:

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(D) shall have the device tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at the time of installation of the device or replacement of the radioactive material on the premises of the general licensee and thereafter at least every six (6) months or at such longer intervals not to exceed three (3) years as are specified in the label required by [§175.102(g)(3)(i)(A)] §175.102(g)(5)(i)(A) provided, that devices containing only krypton-85 need not be tested for leakage, and devices containing only hydrogen-3 need not be tested for any purpose;
(E) shall have all the tests required by [§175.102(g)(3)(ii)(D)] §175.102(g)(5)(i)(D) and all other services involving the radioactive material, its shielding and containment, performed by the supplier or other person duly authorized by a specific license issued by the Department, the U.S. Nuclear Regulatory Commission or an agreement state, to manufacture, install or service such devices;

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[(4)] *(6) Luminous safety devices for aircraft.*

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[(5)] *(7) Calibration and reference sources.*

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[(6)] *(8) Ice detection devices.*

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

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

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

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

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

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

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

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

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

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

(B) Shall not abandon or dispose of products containing radium-226 (as required by 10 CFR § 31.12(c)(2)). The product, and any radioactive material from the product, may only be disposed of according to 10 CFR § 20.2008 or by transfer to a person authorized by a specific license to receive the radium-226 in the product or as otherwise approved by the Department.

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

(D) Shall dispose of products containing radium-226 at a disposal facility authorized to dispose of radioactive material in accordance with any federal, state or City solid or hazardous waste law, including the federal Solid Waste Disposal Act, by transfer to a person authorized to receive radium-226 by a specific license issued under §175.101 of this Code, or equivalent regulations of U.S. Nuclear Regulatory Commission or of an agreement state, or as otherwise approved by the U.S. Nuclear Regulatory Commission.

(E) Shall respond to written requests from the Department or the U.S. Nuclear Regulatory Commission to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by providing the Department or the U.S. Nuclear Regulatory Commission a written justification for the request.
(iv) The general license in subparagraph (i) of this paragraph does not authorize the manufacture, assembly, disassembly, repair, or import of products containing radium-226, except that timepieces may be disassembled and repaired.

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Notes: The Board of Health amended §175.102 of the Health Code on June 28, 2013 to ensure compatibility with applicable federal regulations, particularly relating to specific types of licenses and certain exempt quantities of byproduct material and 10 CFR Part 31.

RESOLVED, that subdivision (d) of Section 175.103 of Article 175 of the New York City Health Code, as set forth in Title 24 of the Rules of the City of New York, as last amended by resolution on March 23, 2011, be and the same hereby is amended to update internal cross-references for medical use of certain radioactive materials to ensure compatibility with applicable federal regulations, to be printed together with explanatory notes to read as follows:

(d) *Unsealed Byproduct Material--Written Directive Not Required.*
(1) *Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required.* Except for quantities that require a written directive under §175.103[(e)] (b)(6) of this Code, a licensee may use any unsealed byproduct material prepared for medical use for uptake, dilution, or excretion studies that is—

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(2) *Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.* Except for quantities that require a written directive under §175.103[(e)] (b)(6) of this Code, a licensee may use any unsealed byproduct material prepared for medical use for imaging and localization studies that is—

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Notes: The Board of Health amended §175.103 of the Health Code on June 28, 2013 to update internal cross-references for medical use of certain radioactive materials to ensure internal accuracy and compatibility with applicable federal regulations.

RESOLVED, that subdivisions (a) and (f) Section 175.104 of Article 175 of the New York City Health Code, as set forth in Title 24 of the Rules of the City of New York, be and the same hereby is amended to ensure compatibility with applicable federal regulations relating to waste disposal of byproduct material, to be printed together with explanatory notes to read as follows:

(a) *General requirements.* (1) A licensee shall dispose of licensed material only:

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(iv) as authorized [pursuant to §175.104(b), (c), (d) or (e)] under 10 CFR §§ 20.2002, 20.2003, 20.2004, 20.2005, or 20.2008.

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

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(v) [storage until transferred to a storage or disposal facility authorized to receive the waste] disposal at a geologic repository under 10 CFR Parts 60 or 63.

(3)(i) The licensed material that is described in subparagraphs (iii) and (iv) of the definition of byproduct material set forth in paragraph (34) of §175.02, may be disposed of in accordance with 10 CFR Part 61 or the equivalent regulations of an agreement state, even though it is not defined as low-level radioactive waste. Therefore, any licensed byproduct material being disposed of at a facility, or transferred for ultimate disposal at a facility licensed under 10 CFR Part 61 must meet the requirements of 10 CFR § 20.2006.

(ii) A licensee may dispose of byproduct material described in subparagraphs (iii) and (iv) of the definition of byproduct material set forth in paragraph (34) of §175.02, at a disposal facility authorized to dispose of such material in accordance with any federal, state or City solid or hazardous waste law, including the federal Solid Waste Disposal Act, as authorized under the federal Energy Policy Act of 2005.

[(3)] (4) A licensee or applicant for a license shall obtain any permits required by the New York State Department of Environmental Conservation pursuant to 6 NYCRR Part 380, or any successor law or regulation.

[(4)] (5) A licensee or applicant for a license shall develop, document and implement a discharge minimization program required by the New York State Department of Environmental Conservation pursuant to 6 NYCRR Section 380-7, or any successor law or regulation.

(f) *Transfer for disposal and manifests.*

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(5) Any licensee shipping byproduct material described in the definition of byproduct material set forth in subparagraphs (iii) and (iv) of paragraph (34) of §175.02, intended for ultimate disposal at a land disposal facility licensed under 10 CFR Part 61 must document the information required on the NRC's Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with 10 CFR Part 20, Appendix G.

(6) The licensee or applicant for a license shall comply with the requirements of the New York State Department of Environmental Conservation as codified in 6 NYCRR Part 381, or any successor law or regulation.

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Notes: The Board of Health amended §175.104 of the Health Code on June 28, 2013 to ensure compatibility with applicable federal regulations, particularly relating to waste disposal of byproduct material.

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