

## NOTICE OF INTENTION

**Subject:** Proposed amendment of Article 175 of the New York City Health Code.

### Proposed Rule

The Department of Health and Mental Hygiene is proposing that the Board of Health amend Article 175 of the Health Code to make certain technical corrections in order to ensure compatibility with applicable federal regulations. Accordingly, the Department does not believe that a public hearing is needed on this proposal as it would not serve a public purpose.

### Instructions

You may submit written comments about the proposed amendment by mail to:

New York City Department of Health and Mental Hygiene  
Board of Health  
Attention: Rena Bryant, Secretary to the Board  
42-09 28<sup>th</sup> Street, WS 14-55  
Queens, NY 11101

or, electronically through NYC RULES at [www.nyc.gov/nycrules](http://www.nyc.gov/nycrules)  
or, by email to [resolutioncomments@health.nyc.gov](mailto:resolutioncomments@health.nyc.gov)  
or, online (without attachments) at <http://www.nyc.gov/html/doh/html/notice/notice.shtml> on or before 5:00 P.M., on January 31, 2012.

### Comments

Within a reasonable time after receipt, electronic copies of written comments will be available online at the Department's website and paper copies will be available between the hours of 9 A.M. and 5 P.M. at:

New York City Department of Health and Mental Hygiene  
Board of Health  
Office of the Secretary to the Board  
Attention: Rena Bryant  
2 Gotham Center, 14<sup>th</sup> Floor, Room 14-05, CN 30  
Long Island City, NY 11101-4132

### **Statutory Authority**

These amendments to the New York City Health Code (“Health Code”) are proposed pursuant to Sections 556, 558 and 1043 of the New York City Charter (“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 regulate all 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) 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 and a party to the relevant Agreement.

### **Statement of Basis and Purpose**

New York State is an Agreement State, meaning that this 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 New York State to regulate radioactive material at non-reactor sites within its jurisdiction. The New York State Agreement is comprised of three regulatory programs – 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. Under this “Agreement State structure”, 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 at frequencies of 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. The NRC ensures an adequate level of compatibility through its Integrated Materials Performance Evaluation Program and its review of proposed Agreement State regulatory changes based on compatibility with NRC regulations contained in Title 10 of the Code of Federal Regulations (CFR). NRC Compatibility Categories “A” and “B” require that the wording of proposed State program regulatory changes should be “essentially identical,” to NRC regulations, and Category “C” requires that State changes should reflect the “essential objectives” of relevant NRC regulations.

In response to the Article 175 amendments adopted by the Board of Health on March 23, 2011, the NRC had 3 comments requesting minor, technical changes to certain provisions of Article 175 in order to maintain compatibility with applicable federal regulations. Also, § 175.03(1)(8) was inadvertently removed from the Health Code in the March 23, 2011 amendments; the Department seeks to re-instate this provision.

Therefore, the Department is requesting that the following technical corrections be made to §§ 175.02, 175.103 and 175.03 of Article 175:

1. In order to meet the NRC Compatibility Category “A” designation assigned to the definition of “public dose” in 10 CFR § 20.1003, language will be added to §175.02(a) to expand the covered sources of exposure.
2. In order to meet the NRC Compatibility Category “B” designation assigned to 10 CFR §§ 35.190 and 35.390, the term “NRC” must be added to §§ 175.103(j)(4)(iii)(A)(b); 175.103(j)(4)(iii)(B); 175.103(j)(6)(ii)(B) and §175.103(j)(8)(i) concerning training requirements for authorized users.
3. In order to meet the NRC Compatibility Category “B” designation assigned to 10 CFR §35.394, §175.103(j)(8)(i) requires a revision of an internal cross-reference.
4. Health Code § 175.03(l)(8), concerning radiological event reporting requirements, was inadvertently removed from Article 175 during the editing process prior to the last adoption of Board of Health amendments to Article 175 in March 23, 2011 and will be re-instated so that the Department can maintain the NRC Compatibility Category “C” requirements of 10 CFR § 30.50.

#### **Statements Pursuant to Charter §§ 1042 and 1043**

The proposed amendment of §175.103 was not included in the Department’s Regulatory Agenda because it resulted from a recent analysis by the Department. The proposed amendment is exempt from an analysis pursuant to section 1043(d) of the New York City Charter because it meets the exemption in 1043(d)(4) as a rule that implements particular mandates or standards set forth in newly enacted federal laws and regulations with only minor, if any, exercise of agency discretion in interpreting such mandates or standards.

The proposal is as follows:

Matter in brackets [ ] is deleted.

Matter underlined is new.

**RESOLVED**, that paragraph (183) of 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 23, 2011, be and the same hereby is amended to revise the definition of “public dose,” to be printed together with explanatory notes to read as follows:

#### **§175.02            Definitions**

(183) “Public dose” means the dose received by a member of the public from exposure to sources of radiation or to radioactive material released by a licensee or to any other source of radiation under the control of the licensee. Public dose does not include occupational dose, dose received from background radiation, exposure to individuals administered radioactive material and released under §175.103(c)(9), dose received as a patient from medical practices, or dose from voluntary participation in medical research programs.

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Notes: The Department proposes that the Board of Health amend subdivision (a) of §175.02 of Article 175 of the Health Code to revise the definition of “public dose” to ensure compatibility with applicable federal regulations.

**RESOLVED**, that subdivision (j) 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 add a reference to the “NRC” and to revise an internal cross-reference, to be printed together with explanatory notes to read as follows:

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

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**(j) Training and experience requirements.**

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**(4) Training for uptake, dilution, or excretion studies.**

Except as provided in §175.103(j)(14) of this Code, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under §175.103(d)(1) of this Code to be a physician who -

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(iii)(A) Has completed 60 hours of training and experience, including a minimum of 8 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies. The training and experience shall include-

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(b) Work experience, under the supervision of an authorized user who meets the requirements in §§ 175.103(j)(14), 175.103(j)(4), 175.103(j)(5), 175.103(j)(6) of this Code, or equivalent NRC or Agreement State requirements, involving--

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(B) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 175.103(j)(14), 175.103(j)(4), 175.103(j)(5), or 175.103(j)(6) of this Code, or equivalent NRC or Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (a)(1) or (c)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 175.103(d)(1) of this Code.

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**(6) Training for use of unsealed byproduct material for which a written directive is required.**

Except as provided in § 175.103(j)(14) of this Code, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under § 175.103(e)(1) of this Code to be a physician who—

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(ii)(A) Has completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material requiring a written directive. The training and experience shall include—

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(B) Has obtained written attestation that the individual has satisfactorily completed the requirements in clause (A) of subparagraph (i) and number (VII) of item (b) of clause (A) of subparagraph (ii) or clause (A) of subparagraph (ii) of this paragraph, and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 175.103(e)(1) of this Code. The written attestation shall be signed by a preceptor authorized user who meets the requirements in §§ 175.103(j)(14), 175.103(j)(6) of this Code, or equivalent NRC or Agreement State requirements. The preceptor authorized user, who meets the requirements in § 175.103(j)(6)(ii) of this Code shall have experience in administering dosages in the same dosage category or categories (i.e., §175.103(j)(6)(ii)(a)(VII) of this Code) as the individual requesting authorized user status.

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(8) *Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries).*

Except as provided in 175.103(j)(14) of this Code, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries), to be a physician who—

(i) Is certified by a medical specialty board whose certification process includes all of the requirements in clauses (A) and (B) of subparagraph (iii) of this paragraph , and whose certification has been recognized by the [Commission] NRC or an Agreement State, and who meets the requirements in [paragraph (c)(3) of this section] clause (C) in subparagraph (iii) of this paragraph. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC website.); or

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Notes: The Department proposes that the Board of Health amend subdivision (j) of §175.103 of Article 175 of the Health Code to add a reference to the “NRC” in §§ 175.103.(j)(4)(iii)(A)(b); 175.103(j)(4)(iii)(B); 175.103(j)(6)(ii)(B) and 175.103(j)(8)(i) concerning training requirements for authorized users, and to revise an internal cross-reference, in order to ensure compatibility with applicable federal regulations.

**RESOLVED**, that subdivision (l) 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 23, 2011, be and the same hereby is amended by adding a paragraph (8) to re-instate previously-existing requirements for radiological event reporting and to re-number existing paragraphs (8) and (9) to become paragraphs (9) and (10) respectively, to be printed together with explanatory notes to read as follows:

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

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*(l) Reports.*

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(8) Event reporting. (i) Immediate report. Each licensee or registrant shall notify the Department as soon as possible, but not later than four (4) hours, after the discovery of an event that prevents immediate preventive actions necessary to avoid exposures to radiation or radioactive material that could exceed

regulatory limits or releases of licensed material that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, etc.).

(ii) *Twenty-four hour report.* Each licensee or registrant shall notify the Department within twenty-four (24) hours after the discovery of any of the following events involving regulated sources of radiation:

(A) An unplanned contamination event that:

(a) requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area;

(b) involves a quantity of material greater than five (5) times the lowest annual limit on intake specified in Appendix B of this section for the material; and

(c) has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination.

(B) An event in which equipment is disabled or fails to function as designed when:

(a) the equipment is required by regulation or license condition to prevent releases exceeding regulatory limits, or to mitigate the consequences of an accident;

(b) the equipment is required to be available and operable when it is disabled or fails to function; and

(c) no redundant equipment is available and operable to perform the required safety function.

(C) An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body.

(D) An unplanned fire or explosion damaging any regulated radiation source or any device, container or equipment containing licensed material when:

(a) the quantity of material involved is greater than five (5) times the lowest annual limit on intake specified in Appendix B of this section for the material; and

(b) the damage affects the integrity of the licensed material or its container.

(iii) *Preparation and submission of reports.* Reports made by licensees in response to the requirements of subparagraphs (i) and (ii) of this paragraph must be made as follows:

(A) *Licensees shall make reports required by subparagraphs (i) and (ii) of this paragraph by telephone to the Department.* To the extent that the information is available at the time of notification, the information provided in these reports must include:

(a) the caller's name and call back telephone number;

(b) a description of the event, including date and time;

(c) the exact location of the event;

(d) the isotopes, quantities, and chemical and physical form of the licensed material involved; and

(e) any personnel radiation exposure data available.

(B) *Written report.* Each licensee or registrant who makes a report required by subparagraphs (i) or (ii) of this paragraph shall submit a written follow-up report to the Department within thirty (30) days of the initial report. The reports must include the following:

(a) a description of the event, including the probable cause and the manufacturer and model number, if applicable, of any equipment that failed or malfunctioned;

(b) the isotopes, quantities and chemical and physical form of the licensed material involved;

(c) corrective actions taken or planned and the results of any evaluations or assessments; and

(d) the extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

[8] (9) *Report and notification of a medical event.*

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

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Notes: The Department proposes that the Board of Health amend subdivision (l) of §175.03 of Article 175 of the Health Code to re-instate radiological event reporting requirements that had been recently inadvertently removed in order to ensure compatibility with applicable federal regulations, and to re-number subsequent subparagraphs of subdivision (l).